Witness Name:
Dr Rosie Benneyworth
Statement No.:
Exhibits: 21
Dated: 5 February 2024

THIRLWALL INQUIRY

WITNESS STATEMENT OF DR ROSIE BENNEYWORTH
INTERIM CHIEF INVESTIGATOR
HEALTH SERVICES SAFETY INVESTIGATIONS BODY (HSSIB)

I, Dr Rosie Benneyworth will say as follows: -

Background

1. The Health Services Safety Investigations Body (HSSIB) was established by the Health and Care Act 2022 (the Act) **(RB/1)** [**INQ0010440**] on 1 October 2023, replacing the Healthcare Safety Investigation Branch (HSIB).

2. The HSIB was originally established in April 2017 to undertake independent patient safety investigations into NHS-funded care across England. The HSIB operated with functional independence and shared oversight. It was funded by the Department of Health and Social Care (DHSC) and reported on its performance to both the DHSC and to NHS England (NHSE).

3. The HSIB's formation was initiated by a recommendation from the Public Administration Select Committee **(RB/2)** [**INQ0010441**] to the Secretary of State for Health and Social Care. In 2015, the DHSC established an Expert Advisory Group (EAG) to consider and make proposals for establishing the HSIB. In their report to DHSC **(RB/3)** [**INQ0010442**] the EAG emphasised that the HSIB should be independent in structure and operation, and this must be established in primary legislation.

4. In May 2016, the government laid in Parliament directions to establish the HSIB ('the 2016 Directions') **(RB/4)** [**INQ0010443**]. The 2016 Directions governed HSIB's national investigations.

5. The HSIB's national investigation remit extended to, and not beyond, any healthcare service funded by the NHS in England. This included healthcare delivery within private and independent healthcare settings that had been commissioned or funded by the NHS.

6. The HSIB was a small organisation. It was initially funded to complete up to 30 national investigations a year and had approximately 30-40 members of staff. A HSIB national investigation took between 6-18 months to complete and usually involved extensive fieldwork undertaken in healthcare settings. Recommendations were made at 'system-level' to national healthcare agencies, and other organisations with responsibilities relevant to the healthcare services being investigated.

7. The HSIB's national investigations were conducted by individuals with diverse experience working in safety investigation in healthcare and other safety critical industries such as aviation, rail, and defence. In addition, HSIB investigations were informed by input from specialised clinical and safety science advisors appropriate to the topic of investigation.

8. The HSIB's directions contained reference to the 'safe space' principle, whereby the identity of investigation witnesses and materials was protected from external disclosure unless required by statutory order, or where the HSIB determined there was evidence of an immediate and ongoing risk to patient safety. HSIB investigations proceeded on the basis of this principle, however as this was only set out in the Directions other legal processes could compel the HSIB to provide information under their own legal powers.

9. The 'safe space' principle is based on similar provisions for investigations undertaken internationally in aviation, and in the UK in the transport sectors. This protection was designed to ensure that investigation witnesses could participate with full confidence that the information being gathered for the sole purpose of learning to improve safety, rather than to apportion blame or liability for adverse outcomes.

10. The safe space principle did not impede other regulatory and investigatory bodies, the police, or the courts from exercising their statutory responsibilities to ascertain the circumstances of an incident including to require information from witnesses.

11. On 28 November 2017, the HSIB maternity investigations programme was announced as part of progress against ambitions set in the national maternity safety strategy **(RB/5)** [INQ0010444]. Directions were established to enable HSIB maternity investigations to be undertaken in all NHS maternity services in England **(RB/6)** [INQ0014550]. In response, the size of the HSIB as an organisation rapidly grew to approximately 200-240 staff to meet this new function, with most additional staff forming part of the distinct maternity investigations programme.

12. Key distinctions between the two programmes are set out below:

National investigations programme	Maternity investigations programme
2016 Directions – core purpose of HSIB	**2018** Directions – additional specific programme
Diverse range of healthcare services and safety risks	Explicit focus on NHS maternity services in England
Criteria: we decide • scale of risk and harm • potential for learning to prevent future harm • impact on individuals and public confidence in the healthcare system	**Criteria: set for us** • RCOG Each Baby Counts programme • Direct maternal deaths • Indirect maternal deaths while pregnant or within 42 days of giving birth
Up to **30** investigations a year	Circa **1000** investigations a year
Do not replace local investigations	Replaces the local investigation
Recommendations made to healthcare and beyond	Recommendations made only to the trust
Reports published on HSIB website	Reports belong to the family and the trust

Table 1: Distinction between the HSIB national and maternity investigations

13. As of 30 September 2023, the HSIB maternity investigations programme had completed over 3000 maternity investigations across all trusts providing maternity services across the NHS in England.

14. The abolition of the NHS Trust Development Authority in the Act saw a transfer of the hosting function for HSIB to NHSE **(RB/7)** [INQ0010446] the actual terms of the HSIB's investigative role and remit remained unchanged. Similarly, the legislative basis for the maternity investigations programme's function was updated in April 2022 **(RB/8)** [INQ0010445] with no changes made to the function of the programme.

15. The HSSIB was subsequently enacted by Part 4 of the Act and establishes our independence in statute as a non-departmental public body (NDPB) of the DHSC. After a period of operating in shadow form, the HSIB was replaced by the HSSIB on 1 October 2023.

16. The HSIB's maternity investigations programme did not become part of the HSSIB. Instead, on 9 April 2023 the DHSC announced that HSIB maternity investigation functions would be taken over by the Care Quality Commission (CQC) from 1 October 2023. The Maternity and Newborn Safety Investigations (MNSI) programme is now hosted by the CQC.

17. In the over 3000 investigations conducted by the former HSIB maternity programme I do not believe any matters have been referred to the Police. However, further information and data on the investigations conducted by the HSIB maternity investigation programme is not available to HSSIB. This information now sits with the CQC and the MNSI and they would have additional insight into whether any maternity investigations resulted in referral to the Police.

HSSIBs governance and structure

18. The HSSIB is accountable to the Secretary of State for Health and Social Care as a NDPB. We are a relatively small organisation with only 48 full time equivalent staff. We have an annual operating budget of £5.3 million which is provided as a fixed amount per annum and is not subject to review in line with inflation.

19. The HSSIB is currently led by me as the interim chief investigator and chief executive. This post is currently awaiting confirmation of a permanent appointee by our non-executive directors following the conclusion of a recruitment round which was led by the DHSC.

20. The HSSIB is organised into three directorates to allow it to discharge its duties under the Health and Care Act 2022. These are: Investigations and Insights, Education, and Finance and Performance. Each directorate has an executive lead that, alongside me, make up the senior leadership team.

21. We also have a Chair and five non-executive members appointed by the Secretary of State for Health and Social Care for a term of up to three years. Together with the senior leadership team this makes up the HSSIB board. The HSSIB board meets every two months in public at various locations around the country; typically, being hosted by a local healthcare provider. The HSSIB board has two sub-committees, a remuneration committee and an audit, risk, and assurance committee.

22. The HSSIB is required to exercise its functions effectively, efficiently, and economically. Each year we must prepare annual accounts and provide these to the Secretary of State for Health and Social Care and the Comptroller and Auditor General. They will in turn examine, certify, and report on the annual accounts, and lay copies of them and any report before Parliament.

23. We do not have any permanent office locations and all staff are employed as remote workers. We do have a fixed postal address from which correspondence we receive can be scanned and shared with staff securely via our e-mail system. Our staff meet regularly at organised away days at venues across England.

24. As a new organisation, we are currently developing our own internal policies and procedures in relation to how we would interact with whistleblowers within the HSSIB. In relation to whistleblowing from external staff, whistleblowers

would be signposted to appropriate services to help in supporting and responding to their concerns. Dependant on whether any whistleblowing occurred during HSSIB investigation activity, actions we may be able to take with this information would need to be considered under the HSSIB prohibition of disclosure exemptions (Table 2).

25. The governance requirements for the HSSIB are set out in detail in Schedule 13 of the Act.

HSSIB's place in the patient safety landscape

26. The HSIB took its place as the first national level healthcare safety investigation body for England, and globally, when it began operations in April 2017. We exist, and HSIB existed, within a very complex healthcare landscape with multiple regulatory and quasi regulatory bodies holding different levels of involvement and influence on the patient safety agenda **(RB/9)** [INQ0010447] **(RB/10)** [INQ0010448].

27. Due to our role, we navigate a path between being committed to working in collaboration with partners across the healthcare system to improve patient safety whilst ensuring we retain our impartiality so that we can conduct effective, independent safety investigations.

28. In the course of our work, we engage with a variety of partners across the patient safety landscape in different ways. This can range from planned organisational engagement to make, retain, and enhance professional relationships to bespoke engagement within specific investigations or educational work where we need to interact with distinct organisations, groups, or individuals.

29. It has taken time for the role and function of the HSIB, and now the HSSIB, to become recognised within the healthcare system and there is still further work

for us to do to ensure that healthcare organisations, staff, and the public are aware of our role and scope of our remit in improving patient safety.

30. It is not possible to concisely list the whole range of our interactions. However, I have attempted to highlight key interactions with specific stakeholders and groups, below, to provide an insight into the range of interaction we may have outside of specific investigation work with key partners. Investigation specific type interactions are set out further below.

31. NHS organisations have been engaged in all of our investigation work. Each HSIB investigation required an incident or accident to have occurred in NHS funded care to trigger an investigation. This is still the most common route by which a HSSIB investigation may proceed, or if this proceeds via a concern in the independent sector, we would still need to work with NHS care providers to understand the risks to NHS care. We have increased our work to engage with provider organisations more generally, such as NHS Providers and involvement in Integrated Care System quality groups, to help in hearing concerns about safety from across the provider landscape and to raise awareness of HSSIB and our work.

32. Historically, the HSIB had its closest national relationship with NHSE. The HSIB was hosted by NHSE throughout its lifespan and was reliant on NHSE administrative support for a range of functions, whilst retaining operational independence. NHSE is also the main recipient of HSIB and HSSIB safety recommendations and we engage with NHSE to seek updates on progress in relation to this work.

33. It is important for us to retain a positive and constructive working relationship with NHSE as it is a key stakeholder in our work. This includes being the primary recipient of our safety recommendations and being a partner in helping us to deliver educational training and development as part of the NHS patient safety strategy. The HSIB worked closely with NHSE to pilot and develop a recommendation grading process (see paragraph 102) and during our

transition to help ensure we had appropriate corporate support to allow the HSSIB to begin operations.

34. We host regular engagement meetings with the NHSE patient safety team to discuss national patient safety issues and share insights. I attend the NHSE National Quality Board to gain further insights into national discussions about patient safety risks. We also have a memorandum of understanding in place to allow HSSIB to easily access national incident reporting system data in the course of our wider work, whilst retaining the ability to request specific data under the Act if ever required.

35. We host regular engagement meetings with the CQC to share updates on operational work and gain insights into potential areas of investigation work. We have also become a signatory to the emerging concerns protocol and attend the health and social care regulators forum to ensure that we can be aware of patient safety concerns that regulators may begin to identify within the healthcare system. CQC has been a recipient of safety recommendations, and we engage with CQC to seek updates on progress in relation to this work.

36. We host regular engagement meetings with the Parliamentary and Health Service Ombudsman (PHSO) to share updates on operational work and gain insight into potential areas of investigation. We have hosted presentations from PHSO on their work and have reciprocated to share insight into HSIB and HSSIB work.

37. We host regular engagement meetings with the Medicines and Healthcare products Regulatory Agency (MHRA) to share updates on operational work and gain insight into potential areas of investigation. MHRA has been a recipient of safety recommendations, and we engage with MHRA to seek updates on progress in relation to this work.

38. We host regular engagement meetings with the National Institute for Health and Care Excellence (NICE) and ad-hoc meetings as required in our investigation work. We have recently hosted a secondment of a NICE patient safety staff member for 12 days to help it learn more about HSSIB work. We hope to

reciprocate this arrangement to help further our knowledge about how other parts of the system work. NICE has been a recipient of safety recommendations, and we engage with NICE to seek updates on progress in relation to this work.

39. We host regular engagement meetings with a range of professional organisations and colleges representing different healthcare staff groups. This includes engagement with the Academy of Royal Colleges to help in hearing a wider range of feedback and concerns from multiple organisations in a structured way. Where recommendations are made to professional groups or royal colleges, we engage with them to seek updates on progress in relation to this work.

40. We have engaged with the independent sector. This has included working with independent providers to examine surgical care of NHS patients and engaging with the Independent Healthcare Providers Network to understand concerns raised about safety in the independent sector and increase the awareness of HSSIB and our work.

41. We engage with a range of representative groups that support improvements in patient safety and represent the voluntary and charitable sector. We have engaged with organisations such as Healthwatch, Mind, Patient Safety Learning, Patient Voices, and Care Opinion as HSIB and HSSIB to help develop more insight into challenges faced by patients and their families in receiving care. This is an element of engagement that we would like to develop further to ensure that there is an appropriate balance between our engagement with healthcare organisations and patient facing groups when sharing our work and seeking insight into areas for potential investigation.

42. We have worked closely with academic partners to help deliver improvements to our investigation process and to collaborate on our education programme. We have worked alongside Loughborough University on a number of occasions to support our work. This has included internal HSIB work to help us develop taxonomies and systems to identify common issues within safety investigations

and external work as HSSIB to collaborate on preparing and delivering training to the NHS in line with the NHS England patient safety strategy. We have also contributed to research studies from other academic institutions where HSIB and HSSIB knowledge and expertise can add value to their work. We continue to explore possibilities to work in collaboration with other academic partners to help improve safety within the healthcare system.

43. We have worked with companies within specific investigations, typically where we need to learn more or explore a product or service they offer that may be subject to investigation. However, we do not hold regular engagement with specific companies and follow NHS procurement guidance when seeking external support from companies to deliver our work.

44. Of note, where HSSIB is investigating an incident and identifies that another named organisation is also investigating the same incident it is under a duty to co-operate with any other organisation regarding practical arrangements for co-ordinating those investigations. Named organisations are set out in Section 126 of the Act and we would engage with these organisations as required.

HSSIBs education function

Requirements of the Act

45. The HSSIB must comply with any request by a relevant NHS body to provide it with assistance in connection with the carrying out of investigations into incidents occurring during the provision of NHS services or occurring at premises at which NHS services are provided. A relevant NHS body includes: an NHS Foundation trust, an NHS trust, NHS England, and an integrated care board.

46. We must also comply with any request by NHS England to provide any other relevant NHS body with assistance and any request by the Secretary of State to provide a relevant NHS body with such assistance.

47. The assistance offered by the HSSIB may include disseminating information about best practice, developing standards to be adopted, and giving advice, guidance, or training. We can decline to offer advice, guidance, or training where it would be impracticable for us to offer this support.

48. We may also choose to give assistance to a person other than a relevant NHS body if this assistance is requested and to the extent to which that assistance does not significantly interfere with the exercise of the HSSIB's investigation function.

49. We may give assistance to in relation to any matter connected with the carrying out of investigations if we have been requested to provide the assistance by the person to whom assistance it is to be given. The activities we may carry out in giving assistance are not restricted to activities carried out in the United Kingdom and we may impose charges on an appropriate commercial basis. Where we receive money from these charges, we must ensure that any income is used for exercising our functions.

50. The HSSIB's role and function in regard to education is set out in full at Section 127 of the Act.

Operational information

51. Our education function is led by an Education Director and includes nine part time senior investigation educators and two supporting administrative roles. The team has been assembled from multiple disciplines including healthcare, nuclear, occupational psychology, and the police, all with the experience, knowledge and skills in human factors and systems thinking to share with our staff and learners.

52. Our education function currently offers a range of education packages that respond to the needs of staff working in the NHS in England to produce learning that is innovative and practical to share our approaches to investigation and motivate to continue their learning. All our programmes are currently offered free of charge to the NHS in England **(RB/11)** [**INQ0010449**].

53. The majority of our programmes launched in September 2022 and as of the end of December 2023, we have had over 20,000 enrolments across our courses. The vast majority of our learners are enrolled on our on-demand programme, which is 20 hours of CPD learning online, meeting the NHS England Patient Safety Incident Response Framework (PSIRF) training requirement for a systems approach to learning from patient safety incidents.

54. Our other programmes are all delivered live online or in person to small groups of 25 to 30, including the two other elements of PSIRF training; Oversight and Involving those affected in the learning process. We also offer four further courses with more in active development.

55. We are looking to utilise this ability to commercialise some of our unique educational offering and may be able to generate additional revenue for our functions via delivering training to other UK home countries, the independent healthcare sector, international healthcare systems. To this end we are developing links with international teams across government departments and have led on the establishment of the International Patient Safety Organisations Network which currently brings together over 17 national patient safety organisations and representatives from the World Health Organisation.

HSSIB's investigation function

Requirements of the Act

56. The purpose of the HSSIB is defined under Section 109 of the Act as being to investigate incidents that occur in England during the provision of health care services, and which have or may have implications for the safety of patients. Under Section 128 the devolved administrations of Wales and Northern Ireland can also request that HSSIB conduct an investigation within their jurisdiction.

57. Our investigations are intended to identify risks to the safety of patients, and address those risks by facilitating the improvement of systems and practices in the provision of NHS services or other health care services in England. Where

an investigation relates to an incident that did not occur during the provision of NHS services, the HSSIB must consider whether, in relation to any risks identified, the systems and practices in the provision of NHS services could be improved.

58. The purpose of a HSSIB investigation does not include assessing or determining blame, civil or criminal liability, or whether action needs to be taken in respect of an individual by a regulatory body. No individual may be named in a HSSIB investigation report without their consent if they were involved in an incident subject to investigation or have provided information to us for the purposes of an investigation.

59. We may issue interim or final investigation reports that contain a statement of findings of fact made as a result of the investigation and an analysis of those findings. Our reports may also contain recommendations as to the action to be taken by any person as the HSSIB considers appropriate to improve patient safety. Where recommendations are made, we can set a deadline in which to receive a written response; typically, we have provided a response period of three months to recommendation recipients. A person in receipt of a HSSIB recommendation must respond to us in writing setting out the actions they propose to take in pursuance of the recommendations, and we may publish the response.

60. Our investigation reports are not admissible in any civil or criminal proceedings, including employment tribunals or proceedings in front of a regulatory body, unless an order is made by the High Court.

61. We have also taken on additional powers and responsibilities under the Act to enable us to effectively conduct our investigations. These include powers to access premises, access information, protect information, and seek criminal prosecution of persons who may breach provisions of the Act.

62. HSSIB investigators have powers to enter, inspect, and seize evidence from any premises in England, other than those used mainly or wholly as private

dwelling. This includes access to premises with a Crown interest on the provision of reasonable notice.

63. HSSIB investigators also have powers to compel individuals to provide information, should they not wish to provide this information voluntarily. This includes by asking that people attend an interview to answer questions, provide specified information by a specified date, or provide documents, equipment, or other items by a specified date. A person may decline to provide information only where to do so would risk the safety of any patient, it might incriminate the person, or any document would be subject of legal professional privilege.

64. Any person that intentionally obstructs an investigator in the performance of their functions, fails without reasonable excuse to comply with a notice to provide information, or provides false or misleading materials to a HSSIB investigation may be liable on summary conviction to a fine.

65. An offence may also be committed by a corporate body. Where a corporate body commits an offence, both the corporate body and a relevant officer may be subject to conviction if:

- the offence was committed with the consent or connivance of an officer of the body corporate, or
- the office is attributable to any neglect on the part of an officer of the body corporate. the body as well as any relevant officer of the body may be subject to criminal proceedings.

A relevant office may include a director, manager, secretary, other similar officer, or any person purporting to act in any such capacity.

66. An offence may also be committed by a partnership and any prosecution brought in the name of the partnership. Where a partnership commits an offence, both the partnership and partner may be subject to conviction if:

- the offence was committed with the consent or connivance of a partner, or

- the offence is attributable to any neglect on the part of a partner.

67. An individual connected with the HSSIB, must not disclose protected material to any person. Protected material includes any information, document, equipment, or other item which:

    - is held by the HSSIB, or an individual connected with the HSSIB, for the purposes of the HSSIB's investigation function,
    - relates to an incident (whether or not investigated by the HSSIB), and
    - has not already been lawfully made available to the public.

    A person connected with the HSSIB includes anyone under contract with the HSSIB, including agency workers or subject matter advisors. This prohibition also applies to someone who obtained protected material because of being connected to the HSSIB, but who is no longer connected to the HSSIB.

68. We consider that materials and information held for the purposes of protected disclosure extend to the physical evidence and artefacts collected or generated via a HSSIB investigation. For example, of HSSB interviewed a patient or staff member we would create a record of this interview. HSSIB would not disclose a record of this interview (expect in line with any exceptions, see paragraph 75). However, this would not inhibit patients, families, or staff in sharing their stories with other organisations if they chose to.

69. The Act contains certain exemptions to the prohibition on disclosure that would allow, or compel, us to disclose protected information. These are:

Health and Care Act 2022	**Details**	**Example**
Section 123	The Secretary of State for Health and Social Care may make additional regulations to require or	Directions are passed requiring HSSIB to disclose protected

	authorise disclosure by the HSSIB.	materials related to a specific investigation.
Schedule 14, Part 1	The HSSIB, or an individual connected to the HSSIB, may disclose protected material to an individual connected with the HSSIB if they reasonably believe that the disclosure is necessary for the purposes of the carrying out of the HSSIB's investigation function.	HSSIB investigators need to share protected information with a contracted subject matter advisor.
Schedule 14, Part 2	The HSSIB, or an individual connected with the HSSIB, may disclose protected material to a person not connected with the HSSIB if the Chief Investigator reasonably believes that the disclosure is necessary for the purposes of the carrying out of the HSSIB's investigation function.	The HSSIB provide a draft report to stakeholders for comment in accordance with section 115.
Schedule 14, Part 3	The HSSIB, or an individual connected with the HSSIB, may disclose protected material to a person if the Chief Investigator reasonably	If the HSSIB sought to prosecute under section 121 (offences relating to investigations) or 124 (unlawful disclosure).

	believes that the disclosure is necessary for the purposes of the prosecution or investigation of an offence	
Schedule 14, Part 4	The HSSIB, or an individual connected with the HSSIB, may disclose protected material to a person where: A) the Chief Investigator reasonably believes that the disclosure of the material is necessary to address a serious and continuing risk to the safety of any patient or to the public, B) the Chief Investigator reasonably believes that the person is in a position to address the risk, and C) the disclosure is only to the extent necessary to enable the person to take steps to address the risk.	The HSSIB could disclose limited information to alert regulators or other authorities to negligent or criminal practice to allow them to begin their own investigations.
Schedule 14, Part 5	A person may apply to the High Court for an order that any protected material be disclosed by the HSSIB to the person for the purposes specified in the application	The High Court may order disclosure of HSSIB protected information.

Table 2: HSSIB prohibition on disclosure exemptions in the Act

70. If a HSSIB investigation revealed suspicions or concerns about the conduct of a member of staff towards a baby or babies in hospital that posed a serious and continuing risk to the safety of any patient or to the public, then we would be able to rely on the exemptions in Schedule 14 part 4 of the Act to allow us to disclose enough information as necessary to allow a person in a position to address that risk to take appropriate action.

71. The HSSIB, a person connected with the HSSIB, or a person who has ceased to be connected to the HSSIB commits an offence if they knowingly or recklessly disclose protected material to another person and know or suspects that the disclosure is prohibited. A person not connected with the HSSIB commits an offence if they receive protected information from the HSSIB (for example, receiving a draft report) and knowingly or recklessly discloses the protected material to another person without reasonable excuse, and knows or suspects that it is protected material.

72. In both instances, a person may be liable to a fine on summary conviction. The offence applies to corporate bodies and partnership as set out at paragraph 26 and 27.

73. The wording of the Act suggests that our protected disclosure provisions take precedence over any other enactment or powers which may otherwise require the disclosure of, or to seize, any information, document, equipment, or other item covered under protected disclosure.

74. The HSSIB's role and functions in relation to investigations are set out in full at Part 4 and Schedule 14 of the Act.

<u>Investigation operations and practise</u>

75. As a new organisation from 1 October 2023, we are currently in a start-up phase that draws on some previous HSIB work and processes whilst seeking to

develop and embed new ways of working for the HSSIB. Certain actions required of HSSIB under the Act are still being progressed and have not yet been launched.

76. Under the Act, we are required to determine and publish:

- the criteria we will use in determining which incidents we investigate,
- the principles which are to govern investigations,
- the processes to be followed in carrying out investigations, and
- the processes for ensuring that patients and their families are involved in investigations.

This must also include the procedures and methods to be used in investigations and the time periods in which we aim to complete investigations. In determining and publishing this information, we must consult with the Secretary of State for Health and Social Care and any other persons we believe are appropriate.

77. We have planned to proceed with this consultation at the point when we also consult on a new strategy for the HSSIB. This is important to ensure we can align our strategic focus with any development in the way we wish to work to increase our ability to identify, investigate, and impact on improvements being made to the most significant areas of patient safety concern across England. We anticipate this will be possible in early 2024.

78. Work ha been ongoing since Spring 2023 to formulate and develop the HSSIB investigation process. This included commissioning work via academic partners to better understand how we could identify areas for investigation and consider how we may begin to demonstrate further impact from our work.

79. Where this work is still in progress we are adopting and further developing old HSIB processes to allow for investigation work to continue until such time formal consultation may take place.

80. We currently have a range of active investigations spanning investigations launched by HSIB under the 2022 Directions and new investigation work launched by HSSIB under the Act. Any investigations begun prior to 1 October 2023 continue under the 2022 Directions and do not attract the increased remit, powers, or statutory prohibition on disclosure. Investigations launched after 1 October 2023 are considered HSSIB investigations for the purpose of the Act.

81. The HSSIB investigation process may be broken down into three distinct phases:

- Insights: Identify and collate information available across the healthcare system in relation to safety risks.

- Investigation: Investigation of the safety risk and any associated incidents at the national level.

- Recommendations: Identifying areas for improvement, which organisations should take ownership of this work, and any other safety learning that we think can help address the risk we have seen.

Insights

82. At the insights phase we are focused on trying to understand what patient safety risks may exist within the healthcare system. To help us do this we aim collect information in a number of ways. These include:

- Direct contact with patients and families: We receive notifications of concerns via the HSSIB website and can also become aware of concerns when speaking with patients and families as part of ongoing investigations.

- Direct contact with NHS and healthcare staff: We receive notifications of concerns via the HSSIB website and can also become aware of concerns when speaking with staff as part of ongoing investigations.

- Access to patient safety incident reporting systems: We have an agreement in place with NHSE to allow us to access national incident reporting systems, such as the outgoing national reporting and learning system (NRLS), the new learning from patient safety events (LFPSE) system, and the strategic executive information system (StEIS).

- Regular contact with national organisations: We have regular conversations with NHSE, national regulators and other organisations with regulatory influence. We also hear from professional bodies, commissioners, and service providers.

- Regular contact with organisations that represent patients: We have regular conversations with organisations who represent patients including Healthwatch, Action against Medical Accidents (AvMA), The Patients Association, PHSO and others.

- Horizon scanning: We collect information about healthcare risks that may be available in academic literature, professional publications, or the media.

83. This information is collated and analysed by our insights team and proposal for areas of investigation are presented at a quarterly meeting. Here a decision is made on what specific areas of risk we should focus more resource on, with the intention of allowing us to make a decision on which areas to investigate.

84. This then triggers a further period in which more targeted interactions take place with partners across the healthcare system. This helps us to further understand specifics about this potential risk and where a HSSIB investigation may be able to focus. In this period, additional contact may be made with several national organisations, patient or family groups, charities, and healthcare providers to gather further insights into this potential area of concern. This will also include additional searches of incident reporting systems, Coroner's prevention of

future death reports, academic articles, and media to provide further information.

85. The additional insight gathered during this period and a proposal for any planned investigation are then presented for approval. Here a decision is made on whether HSSIB will proceed with an investigation, the specific focus of that investigation, the planned deliverables and timescales, and the investigation and insights team resource committed to that work.

86. Presently, any decisions made in this phase about which investigations we may pursue have been determined with reference to draft investigation selection criteria developed in the latter stages of the HSIB with support from academic partners. These currently subject to consultation with the Secretary of State for Health and Social Care as required under the Act. The interim criteria are used to help use determine where significant risks exist in the system and to help us compare the relative case for an investigation into specific areas, based on the insights we have gained. The criteria are set out below:

Criteria	Low	Medium	High
1. Systemic risk What is the breadth of the systemic risk?	The systemic risk impacts on one health and care environment, and/or geographical area and/or one professional group.	The systemic risk impacts on between two and four health and care environments, and/or geographical areas and/or professional groups.	The systemic risk impacts on five or more health and care environments, and/or geographical areas and/or professional groups.
2. Potential impact What are the impacts of the systemic risk?	The systemic risk leads to low or no harm to patients, minor disruptions to continuity or reliability of care, and/or the use of health and care	The systemic risk leads to moderate harm to patients, moderate disruptions to continuity or reliability of care, and/or has an	The systemic risk leads to serious harm (physical or other), severe disruptions to continuity or reliability of care, and/or has severe

	resources. And/or there are little or no financial impacts for the health and care system (litigation and/or financial pay outs)	impact the use of health and care resources. There are moderate financial impacts for the health and care system (e.g., litigation or financial pay outs, wasted resources)	consequences for the use of health and care resources. And/or it has major financial impacts for the health and care system (litigation, financial pay outs or wasted resources)
3. Added value/unexplored territory Is there potential to add value by carrying out an investigation?	Carrying out an investigation would add little value because other stakeholders have or are carrying out investigation or improvement work in this area.	Carrying out an investigation would add value because HSSIB's involvement could strengthen current or previous investigation and improvement work.	Carrying out an investigation would be highly valuable: HSSIB would be working on a systemic risk that has not been previously investigated by other stakeholders and/or where there is no on-going improvement work.
4. Potential for improvement Would an investigation drive positive change and improve patient safety?	Carrying out an investigation would not drive positive change or improve patient safety.	Carrying out an investigation could possibly drive positive change and improve patient safety.	Carrying out an investigation would definitely drive positive change and improve patient safety.
5. Equality, Diversity, Inclusion, and deprivation Would carrying out an investigation reduce health inequalities?	Carrying out an investigation would not reduce health inequalities in the health and care system.	Carrying out an investigation may possibly reduce health inequalities in the heath and care system.	Carrying out an would definitely reduce health inequalities in the health and care system.

6. Feasibility How easy will it be to carry out an investigation?	It will be straight forward/easy to carry out an investigation on the systemic risk (i.e., we have access to sites, staff, patients, there is buy-in from key stakeholders and internal capacity in the Investigation and Insights team).	There will be some barriers to carrying out an investigation, but these are surmountable.	It will be extremely difficult to carry out an investigation on the systemic risk (for example, lack of access and/or stakeholder buy-in make it unfeasible OR there is no internal capacity in the Investigation and Insights team)

Table 3: Draft HSSIB investigation criteria

These criteria are subject to further refinement and amendment prior to consultation, as we begin to see how these may work in practise. The criteria are intended to provide a decision-making guide to help steer discussion when we are considering where to launch investigations. For example, we may be faced with a decision on which of three potential investigations we proceed with. A selection on which to proceed would consider the scores for each and prompt a discussion. The criteria then help to guide our decision making, to allow for a balanced consideration of factors whilst retaining HSSIB's retains agency in what we choose to investigate.

Investigation

87. At the investigation phase, the HSSIB issues a notification to confirm that an investigation is underway. This is an opportunity for us to notify the wider healthcare system about our work and seek further contact from people and organisations who may be able to assist in our investigation.

88. The timescales in which investigations are delivered varies depending on the investigation topic in question. Typically, a HSSIB investigation should be completed within 12-18 months, but investigations may begin to generate

reports and findings in shorter timescales where we choose to issue interim reports or where more discrete risks are capable of faster investigation.

89. Investigations will typically include a range of approaches to collect, analyse, and report on evidence relating to a specific risk to patient safety at the national level. Evidence collected during our investigations may include:

- Speaking with patient and families: This involve speaking with individual patients or families in relation to a specific incident or incidents, or this may involve speaking with wider groups of patients and families impacted on by this specific risk, for example in focus groups.

- Speaking with NHS and healthcare staff: This involve speaking with individual staff in relation to a specific incident or incidents, or this may involve speaking with wider groups of staff impacted on by this specific risk, for example in focus groups.

- Reviewing relevant medical records, local policies, and incident reports: Medical records may be reviewed to give insight into specific incidents or into the wider useability, accessibility, or function of records in providing care. Local policies may be reviewed to provide insight into 'work as imagine' and 'work as prescribed'; concepts that describe the disconnect between how work may be planned and laid down by organisational leaders and the reality of everyday work.

- Observation visits to understand how healthcare is delivered in practice: Observing staff and patients within the healthcare environment helps to identify 'work as done' and aide in developing an understanding of how care is delivered in context.

- Reviewing academic and professional literature: Additional or emerging academic and professional publications may be identified during the investigation that can help to add to our consideration of the patient safety risks under investigation.

- Speaking with national organisations and reviewing national policies: National organisations provide insight into how national policies, guidance, and responsibilities interact with patient care being provided n healthcare providers. This interaction also helps us to identify which national organisations may be best placed to respond to patient safety risks by taking action.

- Speaking with or working alongside subject matter experts, including healthcare and non-healthcare professionals, and patients or patient groups: Taking insights from these individuals helps to provide specific professional expertise or additional lived experience to help HSSIB investigations better understand and reflect on the issue under investigation. This may include specific clinical expertise from relevant professionals to explore certain medical conditions or practise, professional expertise to explore non-clinical matters related to healthcare such as engineering support or architecture, or people living with specific medical conditions or with experience of interacting with healthcare services in a specific context.

90. We analyse our evidence using a range of methods that adopt a human factors and ergonomics approach (sometimes referred to as 'safety science'). Human factors is an established scientific discipline used in many other safety critical industries, such as aviation, rail transport and nuclear power stations.

91. We use both practical and academic models and tools to help us better understand how patient safety incidents occur. This allows us to adopt a systems perspective that does not find blame or liability with individuals or organisations.

92. Common methods and tools used in our investigations to help develop our findings and safety recommendations include:

    - The Systems Engineering Initiative for Patient Safety (SEIPS).
    - AcciMap.

- ATSB investigation analysis model.
- Functional Resonance Analysis Method.
- Thematic analysis.
- Bow Tie analysis.
- Hierarchical Task Analysis (HTA).
- Systems-Theoretic Accident Mode and Processes/Systems-Theoretic Process Analysis (STAMP/STPA).
- The hierarchy of controls.
- The hierarchy of intervention effectiveness.

Details in relation to all these models and methods are available in a range of professional and academic literature.

93. The findings of our analysis are then reflected in our reports in narrative text and sometimes by also including graphical representations of these models. Our reports also typically include an evidence appendix so that the reader can see how we have approached evidence collection and analysis in any given investigation.

94. The progress of an investigation is monitored via internal governance processes on a bi-monthly basis to allow for regular check and challenge, and escalation of any risks that may impact on the investigation being delivered in a timely and efficient way.

95. There are also meeting with senior staff during the life cycle of an investigation to provide oversight of the investigation process, rigour, and planned outcomes. These meeting allow for check and challenge whilst monitoring progress against agreed timescales, provide a forum to quality review any report, and agrees the recommendations HSSIB will issue on consultation. These meetings are attending by the assigned investigation team, senior investigation, and insights staff, other HSSIB staff members to provide additional challenge, and may also be attended by subject matter experts or experts by lived experience.

96. The Act requires that a draft investigation report is shared with anyone we reasonably believe could be adversely affected by the report or any other person who we believe should be sent a draft. In practice, this typically means that a report is shared on consultation with any patients, families, staff, and local organisations that have assisted with an investigation. We also share a draft report with any professionals and national stakeholders who have assisted with our work or national organisations that may be subject to any safety recommendations.

97. This allows for check and challenge of our evidence and the factual accuracy of our report and its findings. Our consultation process typically lasts for 28 days for reports where we are making safety recommendations and 14 days for reports where we are not making safety recommendations.

98. Responses to comments are collated by the investigation team. and any significant amendments to the investigation report are made and approved at a governance meeting. If a person's comments on a draft report are not taken into account, we provide an explanation to the person why that is.

Recommendations

99. Our investigations produce findings that identify where action can be taken to improve patient safety. Findings of our reports are listed in the executive summary and include relevant information discovered by the HSSIB investigation about the safety risk in question. Examples of findings from our reports can be found below (see paragraph 112 to 120).

100. These findings in turn help to focus and direct where they may need to be safety recommendations, safety observations, safety actions, or other local level learning to help address the risks to patient safety. These different methods are used to help communicate where safety learning may sit in the healthcare system and help to span a range of requested action from national organisations to support that may be offered to 'front line' staff in delivering care.

101. Safety recommendations are made to organisations and bodies best placed to take action to address a risk to patient safety at the national level. We do not make safety recommendations to local healthcare organisations. Areas of focus for safety recommendations are typically identified during the course of the investigation. These are then discussed with relevant national stakeholders to best identify which organisation should take ownership of the safety recommendation, the technical wording of how this is presented in the report for maximum impact, and the requirements to respond to the HSSIB safety recommendation once it is made. Typically, organisations are asked to respond within 90 days of the date the investigation and their response is then published on the HSSIB website.

102. We have developed an internal governance process to consider and grade responses to HSSIB recommendations. This helps us to identify if a response is appropriate and addresses the action we have asked an organisation to take or commit to. An escalation process is in place that allows for us to request additional information from recommendees if we do not feel their response addresses our recommendation.

103. Ultimately, where we are unable to obtain a satisfactory response our escalation process dictates that I would then write to the DHSC to confirm that a satisfactory response has not been received and notify them of this. We then clarify this position on our website in relation to any relevant safety recommendation.

104. A safety observation describes important learning that can help to improve safety, and these are highlighted in our reports. A safety observation is usually made where the issue falls outside the key lines of enquiry for the investigation or where there is no national organisation best placed to do this work. We may also make safety observations where we have not been able to find enough evidence to make a safety recommendation. Where this is the case, we can revisit a safety observation once we have more evidence to turn

this into a safety recommendation, for example where a safety observation is made in an interim report and upgraded to a recommendation in a final report.

105. A safety action describes an action a national organisation has completed to address a safety issue we raised during an investigation. Where an organisation completes work before our investigation is published, we credit this action in our reports to reflect the work that has been done. Without this work being completed we would likely have made a safety recommendation.

106. HSSIB investigation reports may identify local level learning for healthcare organisations or staff. This can include prompts or questions to help identify and think about how specific patient safety concerns could be responded to at the local level. HSSIB investigation reports may also identify specific learning for integrated care systems where a more joined up, regional response to a patient safety concern could help to improve care.

HSIB and HSSIB work in relation to neonatal care

107. HSSIB is able to investigate any patient safety incident that would meet the requirements of the Act. This could include incidents relating to babies born in hospital, including those born before 37 weeks of pregnancy and babies born prematurely.

108. For us to launch an investigation into these areas of care any incident would need to go through the above detailed investigation process to help us determine if this was representative of any national patient safety risks that could benefit from a HSSIB investigation. This would be weighed against other investigation priorities and a HSSIB investigation would not replace any existing local investigation or legal processes.

109. This is distinct and different from the approach of the former HSIB maternity investigation programme, which was required to replace local investigations for incidents that met specific qualifying criteria under the

Maternity Directions and that we understand continue now that the programme has moved to the CQC as MNSI.

110. As the HSIB, aggregated learning from maternity investigations was used to prepare and publish national learning reports to help improve maternity and neonatal safety. In addition, specific HSIB investigations have focused on neonatal care in response to specific national safety concerns.

111. Completed national HSIB investigations and learning reports into neonatal care are listed below:

112. National Learning Report: Summary of themes arising from the HSIB maternity programme (March 2020) **(RB/12)** [INQ0010450]

This report summarised eight prominent themes that emerged through analysis of completed maternity investigations. These were:

- *Early recognition of risk*: HSIB maternity investigations highlighted complications in labour or birth which can be traced back to antenatal (pre-birth) care. HSIB investigations found that many mothers, as their pregnancy progressed, experienced events or changes in circumstances which increased their level of risk, but which were not recognised or factored into decision making about their care.
- *Safety of intrapartum care*: HSIB investigations observed variance in the quality and comprehensiveness of advice given to mothers experiencing the initial signs or indications of labour and contacting a maternity unit. In some cases, assumptions were made that the mother was fully aware of her pathway of care and therefore a full assessment of her risk factors was not carried out.
- *Escalation*: HSIB investigations observed maternity units where there were rigid processes for escalation; requests for support move stepwise through a hierarchy of seniority, instead of empowering the clinician to seek the medical support directly. In some cases, this led to a delay in accessing the appropriate expertise. Even when escalation occurred, the response from a more senior clinician was not always supportive or

clear, leaving the staff not knowing what to do next and unclear at what point further escalation was required.

- *Handovers*: HSIB investigations identified occurrences where important information was lost at handovers. Even when trusts had good communication support tools to support handovers, these were sometimes not used effectively to ensure good information transfer.
- *Larger babies*: HSIB investigations found that risks associated with the birth of larger babies were often not discussed with mothers, leaving them unable to make informed choices about the mode of birth for their baby.
- *Neonatal collapse alongside skin-to-skin care*: HSIB investigations observed that midwives can be focused on looking after the mother and carrying out all the documentation required following birth and may get distracted from observing the baby.
- *Group B Streptococcus*: Group B streptococcus (GBS) is a naturally occurring bacterium that mothers can carry in the birth canal without any problem to themselves. Giving antibiotics to the mother during labour reduces the incidence of GBS infection passing on to the baby. HSIB investigations found that mothers are not always provided with all the information in relation to GBS. Investigations found that in some cases this limited their ability to make decisions relating to the use of antibiotics during labour and their timely attendance to the hospital.
- *Cultural considerations*: HSIB investigations found a disproportionate number of misunderstandings and miscommunications between staff and parents from black, Asian, minority and ethnic communities. This can lead to the mother receiving inappropriate care during her pregnancy and influence the choices she makes, sometimes with serious or catastrophic effects on mother and baby.

113. National Learning Report: Severe brain injury, early neonatal death and intrapartum stillbirth associated with group B streptococcus infection (GBS) (July 2020) **(RB/13) [INQ0010451]**

This report summarised findings from 39 HSIB maternity investigation reports to identify common themes emerging around GBS. These were:

- Not all mothers are receiving antenatal information about GBS as recommended in national guidance.
- Mothers who are carrying GBS are not always clear about when they should contact or attend the maternity unit at the onset of labour.
- Mothers with a GBS urine tract infection in the antenatal period are not always being prescribed antibiotic treatment at the time of the positive urine culture, as well as receiving antibiotics during labour.
- Intrapartum antibiotic prophylaxis is delayed or not given to all mothers that require it. Competing demands on the available staff resource was noted to contribute to this.
- Mothers who are known to be colonised with GBS are not always invited into the maternity unit in early labour and this may contribute to delayed intrapartum antibiotic prophylaxis.
- Some local guidelines differed from current national guidance.
- Some local guidelines led to staff confusion regarding the recommended care for mothers in early labour with ruptured membranes.
- GBS culture results were not always known by the clinical team during labour, which led to no intrapartum antibiotic prophylaxis being administered.
- There were earlier opportunities to detect that a newborn baby was unwell. The use of a newborn early warning score chart may have prompted staff to recognise deterioration sooner. There is no universal newborn early warning score chart in use in England.
- Poor neonatal feeding is an important sign that can be related to neonatal infection.
- Delayed neonatal antibiotic administration contributed to some of the poor outcomes.

114. National Learning Report: Neonatal collapse alongside skin-to-skin contact (August 2020) **(RB/14)** [INQ0010452]

This report summarised contributing factors to 12 cases of sudden unexpected postnatal collapse (SUPC). SUPC is a rare but potentially fatal collapse in babies that appear otherwise healthy. Common factors included:

- Sepsis.
- Stroke.
- Persistent pulmonary hypertension.
- Respiratory issues due to opiates given to the mother in the antenatal or intrapartum period.

The report shared learning to help improve care, this included:

- Based on the evidence, a baby who is born apparently well, with good Apgar scores, can be safely laid skin-to-skin with the mother or parent and requires close observation in the first minutes after birth.
- Apgar scores must be attributed using close clinical observation of the baby. This can be achieved with the baby remaining in skin-to-skin contact. There may be a need to interrupt skin-to-skin contact briefly to ensure Apgar scoring is assessed accurately.
- Vigilant observation of the mother and baby should continue, with prompt removal of the baby if the health of either gives concern.
- Mothers should be encouraged to be in a semi-recumbent (half lying, half sitting) position to hold and feed their baby, ensuring the mother can see the baby's face.
- Care should be taken to ensure that the baby's position is such that their airway remains clear and does not become obstructed.
- Staff should have a conversation with the mother and her companion about recognising any changes in the baby's condition.
- Always listen to parents and respond immediately to any concerns raised.

- Medicines given to the mother should be considered when discussing skin-to-skin contact. Pain relief given to mothers can affect their ability to observe and care for their baby.
- Additional risk factors should be considered. The level of risk for SUPC when a baby is in skin-to-skin contact can increase with, for example, increased maternal body mass index, antenatal use of opiate medication, sedation, and staffs' focus on other tasks.

115. Delays to intrapartum intervention once foetal compromise is suspected (November 2020) **(RB/15)** [**INQ0010453**]

This report found that delays to intrapartum intervention once foetal compromise is suspected is a contributing factor to stillbirths, neonatal deaths and babies born with suspected brain injury:

- There has been a national focus on improving safety in maternity care over the last five years. This has resulted in the publication of multiple national reports, with multiple recommendations and multiple programmes of safety improvement work initiated as a result. There are recurring themes in the reports, such as loss of situation awareness (an awareness and understanding by staff of everything that is going on around them and its potential effects) and the importance of teamworking and multidisciplinary training.
- Situation awareness is often characterised in national reports as something that is under an individual's control. As a result, training is often proposed as a means of avoiding loss of situation awareness. However, situation awareness is more appropriately seen as the outcome of the interaction between staff and all the other elements that make up a work system and hence is an organisational issue.
- Without a shared understanding of what is happening across the whole maternity unit it is not possible for staff to effectively monitor performance or anticipate future requirements. The labour ward co-ordinator is expected to be supernumerary to facilitate this understanding. This is often not possible due to work demands. A role divorced from delivering

hands-on care and dedicated to monitoring activity across the maternity unit and anticipating future events provides an organisational means to foster such understanding.

- Regular multidisciplinary ward rounds enable staff to monitor, anticipate and respond in a timely way to emerging problems. They promote a shared knowledge and understanding of the situation (known as a shared mental model). They also provide an opportunity for role-modelling values and standards of practice.
- Shared situation awareness can be promoted by activities such as safety huddles (short multidisciplinary briefings where staff focus on at-risk patients or potential/existing safety problems) and structured information sharing tools.
- The benefits of multidisciplinary training, including in-situ simulation have been highlighted in national reports and other studies. Such training supports three of the abilities necessary for resilient performance – response, anticipation, and learning.
- Learning from experience is an important aspect of organisational resilience that requires time and resource.
- Management of the flow of patients between different parts of the maternity service is critical to resilient performance. Providing senior clinical review at triage assists with flow management by promoting an early and effective response and anticipating future needs.
- Having a second supernumerary labour ward co-ordinator to oversee elective and emergency workload may, in larger units, reduce delays in response to elective cases and so increase the resilience of the unit.
- Although it is difficult to change some aspects of a healthcare setting's physical infrastructure, there are some adjustments that can be made that may increase resilience, such as use of digital enhanced cordless technology (DECT) telephones and locating consultant offices on or near the labour ward.
- National reports have highlighted the negative impact of inadequate staffing and high workload on safe care. The effect may be ameliorated, to a degree, through organisational resilience created by other factors.

- Teamwork and psychological safety form the bedrock of resilient performance. The significance of these factors has long been recognised and there are ongoing national initiatives directed at assessing and improving teamwork and psychological safety.
- The Care Quality Commission is considering how to incorporate the assessment of factors such as teamwork and psychological safety in its regulation of maternity units.

The report asked maternity units to consider the following questions:

- Does your unit have a role, or another means, separate from the labour ward co-ordinator, dedicated to monitoring and anticipation of activity across the maternity service and troubleshooting, such as a roving bleep holder?
- Do you have regular multidisciplinary ward rounds throughout the day?
- Do you have regular safety huddles and multidisciplinary handovers using a structured information tool? Do you hold multidisciplinary in situ simulation and facilitated debriefing that includes both technical and non-technical skills? Are scenarios and incidents encountered in your unit included in the training?
- Do you know what your staff's perceptions of teamwork, psychological safety and communication are within your unit? Are actions taken in response? How are midwifery staff empowered to contact consultants directly if they have concerns?
- Is time and resource dedicated to regular multidisciplinary forums that provide a safe space to openly discuss scenarios where things did not go well? Do these forums also include discussion and reflection on scenarios where things went well despite unexpected events?
- Are senior midwifery staff assigned to triage and assessment areas? Is there adequate medical presence in these areas?
- In larger units, is the workload on the labour ward separated into elective and emergency work? If so, are there separate labour ward co-ordinators for each?

- How does the physical infrastructure support work? For example, use of DECT telephones, availability of equipment, consultant offices on/near the labour ward, proximity of antenatal ward and neonatal unit to the labour ward.
- How are issues with staffing and workload escalated and responded to? Are senior trust personnel aware and involved?

The report made a recommendation to the Care Quality Commission to in include assessment of relational aspects such as multidisciplinary teamwork and psychological safety in its regulation of maternity units. The CQC told us that they had plans for a programme of focused maternity inspections with an emphasis on safety and that the framework for these inspections would closely align with our recommendation.

116. National Learning Report: Severe brain injury, early neonatal death and intrapartum stillbirth associated with larger babies and shoulder dystocia (February 2021) **(RB/16)** [INQ0010454]

This report was based on an analysis of 31 HSIB maternity investigation reports and identified that many of the challenges in providing care lie in how larger than average gestational age babies (LGA) are identified and the subsequent management of care of the mother during pregnancy:

- Risk factor screening for gestational diabetes mellitus (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 symphysis fundal height (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 induction of labour when a LGA baby is suspected on ultrasound scan.

- There was varied information shared with mothers regarding the risks and benefits of having a vaginal birth or caesarean section 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 hypoxic ischaemic encephalopathy (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 head to body interval at birth.

The report made a recommendation to the Royal College of Obstetricians and Gynaecologists to take into consideration the findings of this HSIB review when updating the RCOG Green Top shoulder dystocia guideline (No.42). RCOG responded to confirm that the HSIB findings would be

incorporated into the next iteration of the RCOG guideline for shoulder dystocia.

117. National Learning Report: Intrapartum stillbirth: learning from maternity safety investigations that occurred during the COVID-19 pandemic 1 April to 30 June 2020 (September 2021) **(RB/17)** [**INQ0010455**]

This report was based on an analysis of 37 completed HSIB maternity investigation reports. It found the following six themes, set out in a graphic below:

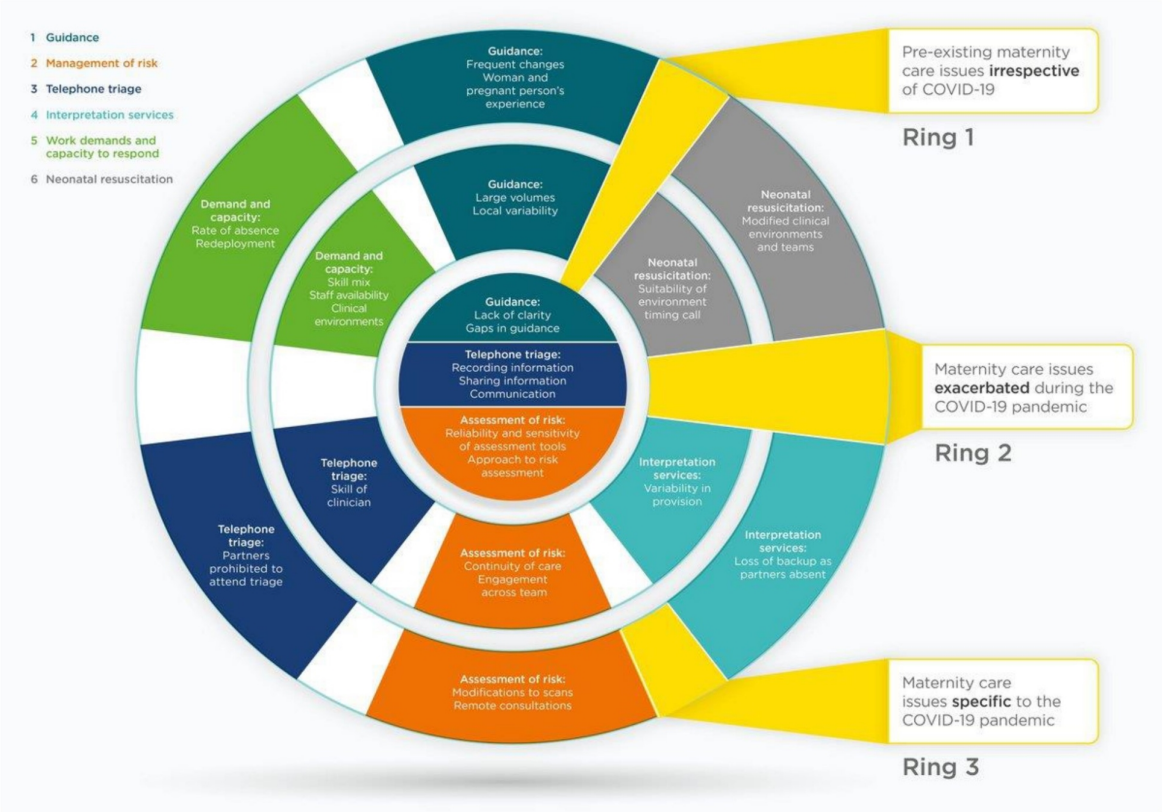

Figure 1: Themes from Intrapartum stillbirth: learning from maternity safety investigations that occurred during the COVID-19 pandemic 1 April to 30 June 2020

The report made a series of recommendations to NHSE. The recommendations and responses are set out below:

- Lead work to develop a process to ensure consistency and clarity across national maternity clinical guidance. NHSE responded to say that the Maternity Transformation Programme (MTP) Insight Oversight Group would develop a 'live' national registry of published recommendations to help ensure consistency across national maternity clinical guidance. NHSE would also use the MTP Insight Oversight group to further help align clinical guidance and improve consistency and clarity.
- Lead work to collate and act on the evidence on the risks and benefits associated with the use of remote consultations at critical points in the maternity care pathway. NHSE responded to say that the MTP Insight Oversight Group would ascertain what evidence/work is underway looking at remote consultations. The MTP Insight Oversight Group would also collate evidence on the risks and benefits of remote consultations and share with the relevant organisations to help inform their future guidance on remote consultations.
- Lead the development of minimum operating standards for pre assessment maternity telephone triage services to support safe and consistent telephone triage to ensure reliable identification of risks. NHSE responded to say that it would review and describe best practice in telephone triage and work with local maternity systems to develop recommended minimum operating standards for pre-assessment maternity telephone triage services.
- Develop minimum operating standards for interpretation services in maternity care which will include a communication risk assessment. NHSE responded to say it would review national guidance for interpretation services for maternity users and work with NHS Shared Business Services to incorporate into the procurement framework a minimum operating standard for interpretation services in maternity care which will include a communication risk assessment.
- Develop a framework to support Trusts to anticipate operational risk in maternity services when delivering neonatal resuscitation. NHSE responded to say its National Maternity Core Competency Framework contained minimum standards in relation to neonatal life support. NHSE

said it would also review the minimum requirements for this module to include the need for trusts to develop their own local framework to identify and mitigate potential risks for maternity and neonatal services when responding to the need for neonatal resuscitation.

The report made a recommendation to RCOG to ensure that future iterations of its guidance clarify the management of a reported change in foetal movements during the third trimester of pregnancy with due regard to national policy. RCOG responded to say guidance in question pre-dated the COVID pandemic and that its guidance was currently being updated with any evidence that met its standards for inclusion.

The report made a recommendation to NHSX to develop specifications for electronic patient record (EPR) systems that require adherence to national interconnectivity standards for the exchange of core maternity healthcare information. The specifications should include functionality to enable both women and pregnant people and professionals to add to the record, and also support alerting functionality. NHSX responded to say that it was working with NHSE to accelerate the deployment of EPR systems to support maternity care and also to ensure that these systems communicate with one another and offer a digital window to women, pregnant people and their families.

The report made a recommendation to the Department of Health and Social Care (DHSC) to commission a review to improve the reliability of existing assessment tools for foetal growth and foetal heart rate to minimise the risk for babies. DHSC responded to say that it accepted the recommendation and, subject to the necessary approvals, would look to commission this research in due course.

118. National Investigation: Emergency neonatal blood transfusion at birth following acute blood loss during labour and/or delivery (March 2022) **(RB/18)**

INQ0010456

The investigation found:

- The administration of a blood transfusion as part of resuscitation requires a number of preparatory steps, including collecting the blood and undertaking various checks before using it. Inclusion in resuscitation training of a prompt for clinicians to consider the need for a transfusion, and to prepare for it if appropriate, may help reduce any delay.
- Involving members of neonatal teams (staff who specialise in the care of newborn babies) in multidisciplinary training in maternity units is not routine. Standardising their inclusion in such training would promote a shared understanding of relevant clinical information and ways of working.

The investigation made recommendations to:

- NHS Resolution to amend the maternity incentive scheme guidance for year five to include the neonatal team as one of the professions required to attend multi-professional training. This recommendation was accepted and actioned.
- The Resuscitation Council (UK) to amend the Newborn Life Support training course to highlight that neonatal resuscitation teams should consider foetal blood loss in the event of neonatal resuscitation that includes chest compressions. In addition, this consideration should be included in the guidance to support the newborn life support algorithm. This recommendation was accepted and actioned.

119. National Investigation: Management of preterm labour and birth of twins (March 2022) **(RB/19)** [INQ0010457]

The investigation found:

- There are currently no proven treatments available to reduce the risk of preterm labour for twin pregnancies.
- There are gaps in scientific knowledge and challenges to completing research in the field of preterm labour and birth. This creates a challenge for the development of detailed guidelines to support clinical decision making.

- Guidelines and equipment recommended for managing and monitoring singleton (one baby) and full-term pregnancies are used to assist with clinical decision making about preterm twin pregnancies; some interventions within the guidelines are unproven for use in preterm twin pregnancies.
- Research and national improvement initiatives, such as the British Association of Perinatal Medicine perinatal optimisation care pathway and NHS England and NHS Improvement 'Saving babies' lives care bundle version two' and the Maternity and Neonatal Safety Improvement Programme are improving the standardisation and implementation of evidence-based interventions.
- Intelligence from national data gathered by maternity units can support the learning on preterm labour and birth in twin pregnancies.

The investigation made safety observations to support:

- Further research aimed to generate additional knowledge to predict and prevent preterm labour for twin pregnancies among different groups of women/pregnant people.
- Increased awareness among the public and healthcare professionals of the limitations of interventions for the prevention of preterm labour of multiple births.
- Regular analysis data on multiple births so the interpretation of this data can inform learning and research.

The investigation also noted a safety action from NICE to delete from its guideline for preterm labour and birth the recommendation relating to milking the cord. NICE also agreed to amend a recommendation on clamping of the cord.

120. National Investigation: Detection of jaundice in newborn babies (January 2023) **(RB/20)** [INQ0010458]

The investigation found:

- The assessment of visual signs of jaundice in newborn babies is subjective and more challenging with babies who have black or brown skin.
- Stakeholders have differing opinions about the reliability of visual signs to detect jaundice in newborn babies.
- Some neonatal units have introduced safety measures to mitigate the risk of reliance on visual signs of jaundice.
- National guidance does not recommend routinely measuring bilirubin levels in babies who are not visibly jaundiced.
- National guidance for jaundice in newborn babies maybe more applicable to term babies (those born after 37 weeks of pregnancy) than those born prematurely.
- National guidance does not contain information on how to address the challenges of detecting jaundice in newborn babies with black or brown skin.
- Some universities providing education to NHS students on the detection of jaundice are seeking to ensure that teaching aids and literature represent the diversity of the population.
- Levels of bilirubin can vary according to the gestational age of a baby (how long the baby was in the womb). Laboratory staff do not calculate the gestational age of a baby and therefore whether their bilirubin level is within the expected range.
- Laboratory practice varies in terms of whether they set specific reference ranges for bilirubin in newborn babies; whether they have a defined threshold for communicating results to neonatal units; and whether the telephone alert limit (the level of bilirubin that triggers laboratory staff to report the result to clinical staff by telephone) reflects the thresholds in national guidance.
- Neonatal staff may be unaware that laboratories analyse blood samples to see if they are icteric (indicate jaundice). These staff will not know to look for a comment about this on blood test reports.

The investigation made recommendations to:

- NICE to review the available evidence and updates its guidance if appropriate, regarding the reliability of visual signs to detect jaundice in newborn babies, particularly in babies with black and brown skin and risk factors for jaundice identified by this investigation, including prematurity. The recommendation was accepted and actioned.
- The Royal College of Pathologists to understand current practice and make any appropriate recommendations: to promote the adoption of an icteric threshold at which a bilirubin test may be cascaded or reported, and to set neonatal specific reference ranges for total bilirubin and thresholds for direct communication of these results to clinicians. We are waiting on a response to this recommendation.

The investigation also made safety observations to support:

- Regulators of pathology services to consider the findings of the investigation and amend their guidance if necessary.
- Development of a national standardised Early Warning System track and trigger observation chart for use in neonatal unit settings

121. Going forward, MNSI would be able to provide insights to our work in the same way as other organisations to help inform our decisions on areas to investigate and could report a specific risk to the HSSIB for consideration. Following this, it is also possible that we could choose to consider an incident being investigated by MNSI as part of any wider HSSIB investigation, but this would not replace any MNSI or other local processes.

122. There is currently no overlap between active investigation work being undertaken by the HSSIB and specific work to investigate neonatal related incidents being undertaken by MNSI. No current HSSIB investigation is focused on neonatal related safety risks. However, as set out above, this would not preclude us from investigating in this area in the future in accordance with the process we have outlined above.

HSSIB's position on the current neonatal care landscape

123. The HSIB and the HSSIB have gathered a range of information via our investigations to allow us an insight into the current governance structures and processes within healthcare and to provide comment on how these may be improved. These insights apply across the healthcare sector and not to neonatal services alone. However, we feel that learning from our experiences would help to improve neonatal care, alongside improvements in other areas of the NHS.

124. Evidence from national inquiries and NHS incident reporting systems suggest that the same patient safety problems are often repeated with limited learning taken from incidents to improve patient safety. Often NHS investigation processes have been of variable quality and have focused on individual actions or omissions in providing care. NHS investigation processes have failed to equip staff with the knowledge, skills, and experience to conduct 'systems based' investigations that recognise the complexity of healthcare and that all adverse events have multiple contributing factors, that re often outside an individual's control.

125. The new NHS England patient safety strategy and patient safety incident response framework aims to address these concerns. In support, HSSIB has worked closely with colleagues across the healthcare system, including academic partners, to help ensure that the training available to NHS staff in patient safety can help to better equip them to understand, identify, and address concerns.

126. HSSIB has also found a need to ensure that senior organisational leaders also understand and can support effective systems-based approaches to investigation of patient safety events. Without this, HSSIB heard concerns staff may be trained in providing a systems-based approach to investigation, but that this may not be supported or fully understood by senior organisational

leaders and that a previous more individual focused approach to investigation could persist.

127. In circumstances such as those being considered by the Inquiry, we acknowledge a more individual approach may be required when considering criminal acts. However, even where this is the case the importance exploring the wider system factors that interact to create incidents and/or opportunities for criminal action must be considered if we are to improve patient safety.

128. Many previous inquiries into NHS care have identified that staff may feel afraid to speak up about patient safety concerns for fear of retribution, with poor culture at certain organisations being linked to a number of reported examples of where such staff are subject to discrimination or poor treatment. This may be compounded by situations where it may be unclear which staff are or should be accountable for care and how they are supported to provide safe care by their organisation and national bodies.

129. From an individual staff perspective, concerns about clear accountability in clinical processes have been presented in non-neonatal focused HSIB investigation reports and this is still an emerging finding in relation to responsibilities in operating theatres in an ongoing HSSIB investigation into 'Retained swabs following invasive procedures'. Considering this from a systems perspective also requires a consideration of whether staff being held accountable have been supported with appropriate organisational resources, training, knowledge, skills, and support to ensure they can be rightly held to account when things may go wrong.

130. Due to concerns about how patient safety concerns being shared by staff may be received, HSIB and HSSIB investigations have shown healthcare staff greatly value the opportunity to speak with an independent and professional investigation team. Speaking openly about what happened after a patient safety event is easier when staff know that the purpose of the conversation is to identify the systemic risks that made delivering healthcare safely more difficult, rather than to pinpoint individuals for blame.

131. Staff have often appeared more willing to speak with HSIB and HSSIB investigations owing to the protections offered by 'safe space'. As set out above, this protection has long been established in other national accident investigation bodies to ensure that staff involved in incidents could speak freely about their own experiences of an incident, and often more importantly, their wider day to day experiences of working within their field or for their employer.

132. At an organisational and national level, the healthcare system is very complex and can pose a challenge in clearly identifying lines of accountability for actions. Our investigations have identified that patient safety policies, their implementation and regulation are highly fragmented. Safety recommendations from separate bodies often overlap and conflict, multiple guidelines exist for similar conditions, and local policies and guidelines are often do not account for or acknowledge the complexity of healthcare work.

133. Due to this, we have seen common patient safety risks across healthcare persist despite interventions from national organisations to help address these concerns. This is impacted on by an absence of resource, understanding, or capability within the system to help address these risks in full. When these risks are not addressed, staff can become unwilling to continue raising these concerns for fear of being labelled as a 'problem' or from frustration at the lack of action.

134. Our investigations have encountered significant variability in the safety culture within a range of NHS organisations and their understanding of concepts such as just culture, freedom to speak up, or whistleblowing. This has ranged from full and transparent engagement from NHS organisations to allow our investigators access to staff, resources, premises, and information that demonstrates a commitment to positive learning and improved safety, to HSIB staff being denied access and engagement from healthcare providers who are reluctant to engage in a safety investigation process. This has been more common in primary care settings.

135. We are hopeful that NHSE's development of the national patient safety strategy and new approaches to understanding and learning from patient safety events, under the patient safety incident response framework will have a positive effect on the safety culture within NHS organisations.

136. A mechanism by which a more joined up approach to safety across all care sectors and organisations could be supported is via Integrated Care Systems (ICSs) and the Integrated Care Boards (ICBs). HSSIB has observed that NHSE's national approach to system transformation has not considered the specific role that ICSs and ICBs can play in organising, promoting, maintaining, and assessing patient safety. Without this clarity there is a risk that the development of safety culture remains organisationally focused with continued variability in the system and a missed opportunity to promote shared values toward safety culture and increased accountability and collaboration across providers. ICSs and ICBs could be required to hold overall responsibility for safety and setting the culture toward safety across the system.

137. There is a need for a much more structured approach to safety and the development of a safety management system across the health and care landscape, comparable to best practice in other industries. In other safety-critical industries, nominated individuals are personally accountable for safety risks and clearly defined frameworks ensure that each individual understands their own accountability and responsibilities.

138. This is a familiar concept in other safety-critical industries and ensures that safety is considered in a systematic and proactive way with goal setting, planning, and assurance, as well as measurement of performance. This requires accountability from the top of an organisation and allows safety to be actively managed in the same way – and with the same priority – as performance and finance.

139. We have published an investigation report on Safety Management Systems: An introduction for healthcare **(RB/21)** [**INQ0010459**]

management systems for healthcare and will be undertaking further investigation work in this area.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: PD

Dated: 5 February 2024

Exhibits

RB/1 – The Health and Care Act 2022 [Online]. Available at: https://www.legislation.gov.uk/ukpga/2022/31/contents/enacted (Accessed: 22 December 2023)

RB/2 - House of Commons Public Administration Select Committee. (2014). Investigating clinical incidents in the NHS [Online]. Available at: https://publications.parliament.uk/pa/cm201415/cmselect/cmpubadm/886/886.pdf (Accessed: 22 December 2023)

RB/3- Report of the Expert Advisory Group. (2016). Healthcare Safety Investigation Branch [Online]. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/522785/hsibreport.pdf (Accessed: 22 December 2023)

RB/4 - The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016 [Withdrawn] [Online]. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1088077/Withdrawn_HSIB_directions.pdf (Accessed; 22 December 2023)

RB/5 - Department of Health. (2017). Safer maternity care [Online]. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/662969/Safer_maternity_care_-_progress_and_next_steps.pdf (Accessed: 22 December 2023)

RB/6 - The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2018 [Withdrawn][Online]. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/662969/Safer_maternity_care_-_progress_and_next_steps.pdf (Accessed: 22 December 2023)

RB/7 - The NHS England (Healthcare Safety Investigation Branch) Directions 2022 [Online]. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1087677/30.6.22_National_directions_.pdf (Accessed: 22 December 2023)

RB/8 - The NHS England (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2022 [Online]. at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1087676/30.6.22_Maternity_directions_final.pdf (Accessed: 22 December 2023)

RB/9 - Oikonomou E, Carthey J, Macrae C, Vincent C. Patient safety regulation in the NHS: mapping the regulatory landscape of healthcare. *BMJ Open*. 2019;9(7):e028663. Published 2019 Jul 9. doi:10.1136/bmjopen-2018-028663

RB/10 – Patient Safety Learning. (2023). The elephant in the room: Patient safety and Integrated Care Systems [Online]. Available at: https://www.patientsafetylearning.org/blog/the-elephant-in-the-room-patient-safety-and-integrated-care-systems (Accessed: 22 December 2023)

RB/11 – Health Services Safety Investigations Body. (2023). NHS Education prospectus 2023 [Online]. Available at: https://hssib-education.turtl.co/story/nhseducation-prospectus/page/1 (Accessed: 22 December 2023)

RB/12 – Health Services Safety Investigations Body. (2020). National Learning Report: Summary of themes arising from the HSIB maternity programme [Online]. Available at: https://www.hssib.org.uk/patient-safety-investigations/summary-of-themes-arising-from-the-hsib-maternity-programme/ (Accessed: 22 December 2023)

RB/13 - Health Services Safety Investigations Body. (2020). National Learning Report: Severe brain injury, early neonatal death and intrapartum stillbirth associated with group B streptococcus infection (GBS) [Online]. Available at: https://www.hssib.org.uk/patient-safety-investigations/severe-brain-injury-early-neonatal-death-and-intrapartum-stillbirth-associated-with-group-b-streptococcus-infection/ (Accessed: 22 December 2023)

RB/14 - Health Services Safety Investigations Body. (2020). National Learning Report: Neonatal collapse alongside skin-to-skin contact [Online]. Available at: https://www.hssib.org.uk/patient-safety-investigations/neonatal-collapse-alongside-skin-to-skin-contact/ (Accessed: 22 December 2023)

RB/15 – Healthcare Safety Investigation Branch. (2020). Delays to intrapartum intervention once foetal compromise is suspected [Online]. Available at: https://www.hssib.org.uk/patient-safety-investigations/delays-to-intrapartum-intervention-once-fetal-compromise-is-suspected/

RB/16 - Healthcare Safety Investigation Branch. (2021). National Learning Report: Severe brain injury, early neonatal death and intrapartum stillbirth associated with larger babies and shoulder dystocia [Online]. Available at: https://www.hssib.org.uk/patient-safety-investigations/delays-to-intrapartum-intervention-once-fetal-compromise-is-suspected/

RB/17 - Healthcare Safety Investigation Branch. (2021). National Learning Report: Intrapartum stillbirth: learning from maternity safety investigations that occurred during the COVID-19 pandemic 1 April to 30 June 2020 [Online]. Available at: https://www.hssib.org.uk/patient-safety-investigations/delays-to-intrapartum-intervention-once-fetal-compromise-is-suspected/

RB/18 - Healthcare Safety Investigation Branch. (2022). National Investigation: Emergency neonatal blood transfusion at birth following acute blood loss during labour and/or delivery [Online]: https://www.hssib.org.uk/patient-safety-investigations/emergency-neonatal-blood-transfusion-at-birth/ (Accessed: 22 December 2023).

RB/19 - Healthcare Safety Investigation Branch. (2022). National Investigation: Management of preterm labour and birth of twins [Online]. Available at: https://www.hssib.org.uk/patient-safety-investigations/management-of-preterm-labour-and-birth/ (Accessed: 22 December 2023)

RB/20 - Healthcare Safety Investigation Branch. (2023). National Investigation: Detection of jaundice in newborn babies [Online]. Available at: https://www.hssib.org.uk/patient-safety-investigations/detection-of-jaundice-in-newborn-babies/ (Accessed: 22 December 2023)

RB/21 - Health Services Safety Investigations Body. (2023). Safety Management Systems: An introduction for healthcare [Online]. Available at: https://www.hssib.org.uk/patient-safety-investigations/safety-management-systems/ (Accessed: 22 December 2023)