Witness Name: Dr Rosie Benneyworth
Statement No.: WITN7689001
Exhibits: WITN7689002 - WITN7689011
Dated: 23/06/2023

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR ROSIE BENNEYWORTH ON BEHALF OF THE HEALTHCARE SAFETY INVESTIGATION BRANCH

I provide this statement in response to a request under Rule 9 (1) and (2) of the Inquiry Rules 2006 dated 3 March 2022.

I, Rosie Benneyworth, will say as follows: -

Section 1: Introduction

Please set out your name, address, date of birth and any professional qualifications relevant to the duties you discharge in the Healthcare Safety Investigation Branch.

Name: Dr Rosie Benneyworth,
Address: Healthcare Safety Investigation Branch (HSIB), Premier House, 60 Caversham Road, Reading, RG1 7EB
Date of Birth: GRO-C 1974
Professional Qualifications: BM BS BMedSci MRCGP

Section 2: Response to Evidence

Please provide a brief outline of the role and responsibilities of the Healthcare Safety Investigation Branch.

1. The Healthcare Safety Investigation Branch (HSIB) was established in April 2017 to undertake independent patient safety investigations into NHS-funded care across England. HSIB currently operates with functional independence and shared oversight. It is funded by the Department of Health and Social Care (DHSC) and reports on its performance to both the DHSC and to NHS England.

HSIB's national investigations

2. In May 2016, the government laid in Parliament [Withdrawn] The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016 ('the 2016 Directions') [WITN7689002]. The 2016 Directions govern HSIB's national investigations. They set out the HSIB's composition and required investigatory function to:

    a. investigate incidents or accidents which evidence, or are likely to evidence, risks affecting patient safety.

    b. ascertain the facts relevant to such risks and analyse those facts.

    c. identify improvements or areas for improvement to patient safety.

    d. publish reports about its investigations; and

    e. encourage the development of skills used to investigate local safety incidents in the health service and to learn from them, including suggesting standards which may be adopted in the conduct of local

patient safety investigations.

3. The 2016 Directions also stipulate that, in fulfilling its investigation function, the HSIB must:

    a. take care to ensure it operates independently.

    b. obtain prior patient or family permission to access medical records before it can commence an investigation.

    c. as best feasible, involve the affected patients, families, and healthcare staff in the investigation; and

    d. apply the 'same space' principle as explained in the Directions, whereby the identity of investigation witnesses and materials is protected from external disclosure unless required by statutory order, or where the HSIB determines there's evidence of an immediate and ongoing risk to patient safety.

4. 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 is designed to ensure that investigation witnesses can participate with full confidence that the information is being gathered for the sole purpose of learning to improve safety, rather than to apportion blame or liability for adverse outcomes. The safe space principle does 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.

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

funded by the NHS. HSIB is a small organisation, funded to complete up to 30 national investigations a year. To ensure maximum impact of its work, investigation topics are selected based on criteria that determine whether a patient safety risk entails:

a. evidence of systemic risk – prevalence across the national health system, rather than only isolated incidents in limited healthcare providers or services.

b. significant adverse impact on patients, families and healthcare staff; and

c. learning potential – HSIB's investigation would bring new insight into how the system can address the matter.

6. An HSIB national investigation takes between 6-18 months to complete and usually involves extensive fieldwork undertaken in healthcare settings. Recommendations are made at 'system-level' to national healthcare agencies, and other organisations with responsibilities relevant to the healthcare services being investigated.

7. To 31 March 2023 since April 2017 HSIB has produced:

a. 85 national investigation and national learning reports.

b. Over 200 safety recommendations for the NHS and national healthcare organisations.

8. HSIB's national investigations are 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 are informed by input from specialised clinical and safety science advisors

appropriate to the topic of investigation.

HSIB's maternity investigations

9. On 28 November 2017, the HSIB maternity investigations programme was announced as part of progress against ambitions set in the national maternity safety strategy, Safer Maternity Care: progress and next steps [WITN7689003]:

HSIB will apply its independent, professionalised investigative approach to the investigations of early neonatal deaths, term stillbirths and cases of severe brain injury in babies ('Each Baby Counts' cases), as well as all cases of maternal death. Like HSIB's national-level investigations, these maternity investigations will be about understanding the facts of what went wrong, rather than assigning blame or liability and will focus on the human and system factors that may be contributory causes. However, this group of maternity investigations will differ from HSIB's national investigations in important ways. They will have a dual purpose. To provide the family of the baby or mother who was harmed with a full account of what happened in the individual case; and, by finding out what went wrong, to extract the maximum learning for the individual Trust in question and for the wider healthcare system. This should mean that HSIB maternity investigations will be shorter allowing families to know what happened more quickly and ensure that all relevant information is passed to the family. Each HSIB maternity investigation will take a clinically appropriate approach, working with families, clinicians with neonatal, paediatric and obstetric expertise and with local teams to establish what happened. (p.24)

10. Directions were established to enable the maternity investigations function from 01 April 2017 onwards, to be undertaken in all NHS maternity services in England - NHS_Trust_Development_Authority__HSIB__Directions_2018.pdf [WITN7689004].

11. Since it commenced on 01 April 2018 - 31 March 2023, the HSIB maternity investigations programme has completed over 3000 maternity investigations across all trusts providing maternity services across the NHS in England. The investigation reports are not published – they are produced for the family and the trust.

12. Table 1 provides a summary overview of the differences between the two programmes:

Table 1: Summary of HSIB investigation programmes

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

Legal standing: HSIB and the Health and Care Act 2022

13. The abolition of the NHS Trust Development Authority in the Health and Care Act 2022 saw a transfer of the hosting function for HSIB to NHS England as set in the National directions 2022 (publishing.service.gov.uk) [WITN7689005] – the actual terms of the HSIB's investigative role and remit remain unchanged. Similarly, the legislative basis for the maternity investigations programme's function was updated to in April 2022 to The NHS England (Healthcare Safety

Investigation Branch) directions 2022 - GOV.UK (www.gov.uk) [WITN7689006] with no changes made to the function of the programme.

14. Part 4 of the Health and Care Act 2022 (legislation.gov.uk) [WITN7689007], *The Health Services Safety Investigations Body*, establishes HSIB's independence in statute as a non-departmental public body (NDPB) of the Department of Health and Social Care. After a period of operating in shadow form, HSIB will, on 01 October 2023, commence operating as the Health Services Safety Investigation Body (HSSIB) in accordance with the legislation.

15. As an NDPB, the HSSIB will be accountable to the Secretary of State for Health and Social Care. It will have a board led by a chair appointed by the Secretary of State (the chair-designate is Professor Ted Baker), and non-executives appointed by the chair. The chief executive of HSSIB and executive team will be appointed by the non-executives.

16. The HSSIB will operate with enhanced powers which encompass:

    a. Prohibition of disclosure, which means that HSSIB's investigation materials will not be disclosed outside the organisation unless permission is granted by the High Court or the chief executive of HSSIB determines it to be appropriate for patient safety (see Schedule 14) [WITN7689008]

    b. Powers of entry, seizure and inspection which enable HSSIB investigators to quickly access healthcare premises to commence an investigation, without the prior permission of the organisation, patient or family to access relevant medical records; and

    c. Powers to require information from investigation witnesses and other relevant persons.

17. It is HSSIB's intention that these powers will be a safeguard used only in the most exceptional circumstances – it is our experience that healthcare staff and organisations, and patients and families, share a common purpose in seeking to understand the systemic causes of patient safety harm and, to that end, are willing and voluntary participants in HSIB investigations.

18. A key difference will be that HSIB's maternity investigations programme will not become part of the HSSIB. Instead, on 9 April 2023 the Department of Health and Social Care announced that HSIB maternity investigation functions would be taken over by the Care Quality Commission from 1 October 2023. HSIB and CQC are currently working together to further determine how this transition will be managed.

Sharing learning from investigations

19. In addition to safety learning from its investigations, HSIB supports patient safety improvement through:

    a. publishing national learning reports, which present a synthesis of learning from HSIB national or maternity investigations according to a particular theme.

    b. investigation education for improved local safety investigations in healthcare in England. To date, we have enrolled nearly 10,000 individuals across England and internationally, in our courses that explore patient safety investigation processes, methodologies and best practice.

You will see that Mr Bragg proposes that there should be a statutory responsibility for all employees in the NHS to make a report when serious

injury or death has occurred which might have been preventable, and that there should be a new, single organisation with responsibility to collect such information, to investigate incidents and to make sure that effective action has been taken. Please set out your response, from the perspective of the Healthcare Safety Investigation Branch, to this proposal. Please provide any further comments regarding Mr. Bragg's proposals that you wish to provide.

20. It is important for all incidents involving serious injury or death in any sector to be reported so the health and care system can identify where improvements in care are needed.

21. Incidents should be reported across all parts of the health and care system and should capture incidents that cross boundaries between providers in the system (e.g. between primary and secondary care such as transfers of care)

22. As well as serious injury or death, it is important that 'near misses' or more minor incidents are reported as these may indicate the potential for more serious events in the future. This would be comparable to other industries - within the maritime environment there exists a Marine Guidance Note (MGN 564) that states it's a legal requirement under the Merchant Shipping (accident reporting and investigation) Regulations 2012, regulation 19 that a ships master / ships skipper or the owner of the vessel must report casualties of fatalities to the Marine Accident Investigation Branch. In the aviation sector, there are also legislative requirements for mandatory safety occurrence reporting at the national level, which informs the European Aviation Safety Strategy. Oversight is provided managed by the UK regulator, the Civil Aviation Authority, the European Safety Agency, EASA, and the ICAO at the international level. More information is available on the single reporting system (European Co-ordination Centre for Accident and Incident Reporting Systems) ECCAIRS Occurrence reporting | Civil Aviation Authority (caa.co.uk) [WITN7689009].

23. Whether or not there is statutory reporting, there needs to be an effective user tested system for reporting that requires minimal training, is simple to use, and from which relevant data can be easily extracted and analysed to help identify where hazards and risks to patient safety are evident across the system. It is important that any aggregate data from incidents or investigations is possible at a provider, ICS and national level to identify patient safety themes.

24. Multiple organisations hold data regarding patient safety including the CQC, NHS England, medical examiners, Coroners, HSIB and other national, regional, and local organisations. It would be helpful to aggregate this data to inform the identification of patient safety priorities across the health and care system. Aggregation of data should start locally at clinical service, provider and ICB level. This can then be aggregated at regional and national levels. It is vital that data is collected in a standardised manner to enable consistent analysis and understanding of patient safety concerns. Data collection and aggregation needs to be considered as part of an integrated safety management system to enable identification of systemic risks and to monitor risks through the system. There would be an opportunity to work with academic partners to understand the most effective mechanism to aggregate data.

25. It is important that providers of health and care ensure that employees have adequate time to complete this reporting, receive appropriate training on systems and process, and that they are aware of their responsibility to do this.

26. It is vital that the provider enables a culture to support safe patient care where people understand the importance of learning from incidents and speaking up when they have concerns. Safety culture in organisations is often problematic, and this can lead to defensiveness, lack of transparency, and a lack of effective learning from safety events.

A. 27. Statutory reporting would require consideration of the following –

a. How it would be monitored and enforced
b. The consequences of non-reporting
c. How 'serious injury' was defined.
d. Whether 'serious injury' or death could ever be identified as preventable prior to an appropriate investigation being completed.

28. Any investigation needs to be good quality, based on established safety science approaches, without apportionment of blame, and extract all learning from the incident in question. HSIB undertakes an investigation education programme with the objective of improving the quality of safety investigations across England.

29. Presently, a range of organisations may conduct investigations into NHS care, including: the local organisation, the Care Quality Commission, the Parliamentary and Health Service Ombudsman, the Coroner, NHS Resolution and more. Consideration would need to be given as to the relative role and remit of these organisations and processes, in comparison with any new single body, to clearly understand and define where a single investigatory framework would fit.

30. Recommendations need to be based on appropriate systems-based investigations to help avoid unintended consequences in the system. Appropriate recommendations should; allow the owner of the recommendations to be easily identified, be developed in collaboration with appropriate services, be implementable, and have a metric or outcome associated with them by which to measure progress.

31. HSIB does not have any legal powers to enforce recommendations made as a

result of our investigation. However, other national organisations that carry out investigation or regulatory work do have this power, and consideration would need to be given as to whether a power to 'enforce' recommendations was also required of any single oversight body.

32. It would be helpful to aggregate and monitor recommendations made to the system to ensure they were impactful and that improvements were being made to reduce the risk of further harm to patients.

You will see from the statement of Ms Braithwaite that the Professional Standards Authority for Health and Social Care supports the establishment of a single body responsible for overseeing the safety system for health and social care. To the extent not already addressed above, please set out your response, from the perspective of the Healthcare Safety Investigation Branch, to this suggestion.

33. The current patient safety system has developed over time, often piecemeal, in response to individual safety incidents. As a result, it is overcomplicated, and this potentially leads to fragmentation of the management of safety across the health and care system and reducing impact of any learning and the potential for improvement.

34. However, creating a single body for safety may be over simplistic. It is important to understand what is meant by 'oversight'. Is it the assessment of risk, the collection of safety data, the performance management of safety interventions, regulation of safety, inspection, investigation of safety incidents or education? It would be difficult for one organisation to undertake all of these roles. Nevertheless, it is essential that the various bodies undertaking all these functions operate as part of a co-ordinated safety system.

35. There is therefore a need for a much more structured approach to

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. For example, all airlines in the UK (and throughout most of the world) are required, by law, to operate a safety management system. 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.

36. We understand that to date there has been very little discussion across health and care about the implementation of a safety management system. Other industries can help us develop our understanding of how safety management systems may work in health and care and have been supportive in our work for the National Learning Report (referenced in 4). We are holding a series of roundtable discussions in the summer with stakeholders and through our work to date we have seen some examples of good practice in health and care that will be highlighted in the report. We understand that there is also some research that has been commissioned by NHS England to understand what implementing a safety management system would entail.

37. HSIB published an interim report (hsib-interim-bulletin-harm-caused-by-delays in-transferring-patients-to-the-ri_I718NOQ.pdf (hsib-kqcco125-media.s3.amazonaws.com) [WITN7689010] for the 'Harm caused by delays in transferring patients to the right place of care' Investigation in November 2022. In this bulletin we made the following safety observation: It may be beneficial for there to be a whole-system patient safety accountability and responsibility framework that spans health and social care. HSIB is currently undertaking a

National Learning Report on how Safety Management Systems may be used in health and care. Although there are governance systems and patient safety roles in NHS organisations, they do not fully align with the concept of a Safety Management System as used in other safety critical industries. It has been proposed that health and care would benefit from a Safety Management System approach and previous work by HSIB has highlighted how safety could be managed more effectively. The initial findings from this ongoing work are that there is a need for: a tool to assess safety maturity across the health and care system; a multi-level framework that specifies a patient safety accountability and responsibility framework; and the need to promote safety management principles in health and care. If it would help the Inquiry we can share a copy of the National Learning Report when we send it to stakeholders for consultation.

38. HSIB is tasked with making recommendations to national organisations to help improve patient safety. Due to the complex landscape that exists in the NHS (patien1.pdf (hee.nhs.uk) [WITN7689011] it can be challenging to identify which organisation should take the lead, or 'own' any recommendations for improvement. An oversight framework to identify where in the system recommendations should be placed or took responsibility for action and supporting work proceeding in this area, would be beneficial.

39. The healthcare system is very complex, so while it can learn from other industries, it cannot simply copy their safety management systems. While learning from them and from its own previous experience it should develop an approach to safety management integrated across all providers and all levels of the healthcare system.

40. There have been several previous bodies responsible for safety in the NHS in the past. It would be important to understand where these organisations have been impactful and where there were opportunities to work in a different way.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed GRO-C

Dated 22/06/2023