Written evidence submitted by The Health Services Safety Investigations Body (PSN0004)

Summary

This submission from the Health Services Safety Investigations Body (HSSIB) provides a background to our organisation and a general response to issues highlighted by the panel in relation to the culture of safety and whistleblowing, training for healthcare staff, and maternity care and leadership. In addition, we have included insights from our work into the wider safety culture in the NHS and its current limitations in understanding and management of patient safety risks, with a focus on how recommendations are made and supported in the system.

Background

1. The Health Services Safety Investigations Body (HSSIB) was established by the Health and Care Act 2022 (the Act) on 1 October 2023 as a new organisation, replacing the Healthcare Safety Investigation Branch (HSIB). HSSIBs role is to undertake independent patient safety investigations across England into NHS care and independent healthcare, where this could also provide learning for NHS care.

2. HSIB was originally established in April 2017 to undertake independent patient safety investigations into NHS-funded care across England. 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. 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.

4. 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 based on this principle, however as this was only set out in the Directions other legal processes could compel HSIB to provide information under their own legal powers.

5. 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.

6. 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 their powers to require information from witnesses.

7. On 28 November 2017, the HSIB maternity investigations programme was announced as part of progress against ambitions set in the national maternity safety strategy. Directions were established to enable the maternity investigations function from 1 April 2017 onwards, to be undertaken in all NHS maternity services in England.

8. The Health Services Safety Investigations Body (HSSIB) was subsequently enacted by Part 4 of the Act and establishes HSSIB’s independence in statute as a non-departmental public body (NDPB) of the DHSC. After a period of operating in shadow form, HSIB transitioned to operating as the HSSIB on 1 October 2023. The ‘safe space’ principle became law under the Act, with only the High Court now having jurisdiction to compel HSSIB to release protected materials outside of HSSIB’s own exemptions.

9. 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.

Culture of safety and whistleblowing

10. Evidence from national inquiries, as well as NHS incident reporting, suggests that the same patient safety problems are often repeated. There has been an ethos in the past, which sometimes assumed that safety events happened because individuals were not trying hard enough and often focused on individual blame. This focus on individuals did not allow appropriate scrutiny and understanding to be generated about the system level factors that influence patient safety events.

11. There has been a significant impact on patient safety from taking this individually focused approach. The Francis Inquiry and many subsequent inquiries have laid bare how staff often feel too afraid to speak up about patient safety concerns and poor culture and this leads to low psychological safety, cultures of defensiveness, blame, denial and the risk of cover-ups and scandals. When staff do speak up, there are numerous examples of where such staff are subject to poor treatment and high-profile employment tribunals damage both individuals and the wider reputation of the NHS as a safe place to work and receive care.

12. HSIB and HSSIB investigations have repeatedly identified common patient safety risks that remain across healthcare despite previous work to help address these concerns from an individual level. This includes numerous NHS never events that continue to occur every year, repeated challenges with IT systems and interoperability, and consistent issues seen in staffing and skill mix when patient safety events occur. We have often heard from staff that these issues are raised within their organisations, and at the national level. However, there is often 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.

13. HSIB and HSSIB investigations have shown healthcare staff greatly value the opportunity to speak with an independent investigation team who combine safety science and human factors knowledge alongside multidisciplinary clinical expertise. 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.

14. Where concerns have already been raised internally with their organisation, there is also hope that speaking with our staff can help to further raise awareness of these issues and help ensure that action is taken in respect of patient safety concerns.

15. On an individual level, 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.

16. Safe space does not hide important information from patients, families, carers, or the public. Other investigations including court processes are not impeded by HSSIB's work and all relevant information HSSIB obtains is published in our report; however, we do not attribute the evidence to individuals who shared it. HSSIB can also rely on exemptions in the Health and Care Act 2022 to ensure that any ongoing safety risks identified in our investigations are quickly addressed, and that we share any necessary information to support such action by other organisations if appropriate.

17. Too often, HSIB and HSSIB investigations have found that we have been the first people to talk to staff, patients, and families about incidents that have occurred and to ask them to share their experience. The culture of learning from patient safety events has not always supported such an approach and has meant that vital information may be missing from safety investigations that can help to shed light on the realities of giving and receiving care in the NHS. Moreover, failing to engage staff, patients, and families impacts on the perception of incident reporting and investigation and may deny the ability for restorative practice to help heal individuals following such events.

18. HSIB and HSSIB 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.

19. Under the Act, HSSIB has gained new powers to ensure our investigators can access premises, secure evidence, and compel people to speak with us if required. We are hopeful that these new powers would mean that, whatever the organisational culture, HSSIB would be able to complete safety investigations that can in turn improve patient safety across the system and help to generate a better understanding of the need for a mature culture around safety in the NHS.

20. 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 (PSIRF) will have a positive effect on the safety culture within NHS organisations. We have supported this work to help provide a better understanding of the system level factors that could lead to patient safety events occurring and to ensure that NHS organisations and staff are equipped with the tools and specialism to help them better explore and learn from things that may go wrong.

21. HSIB and HSSIB 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. However, the existence of such policies and guidance are often pointed to as evidence of a safe culture where a reaction to an adverse event has been accounted for.

22. Without fully understanding why patient safety events occur and how work is done, this approach can create substantial "safety clutter". This often requires staff to develop 'workarounds' and 'adaptations' to maintain performance under pressure whilst balancing patient safety considerations, what Eric Hollnagel refers to as the Efficiency Thoroughness Trade-Off (ETTO). Where this unseen work results in positive outcomes, or helps to maintain capacity, it is often gratefully received by organisations. However, when this leads to things going wrong staff may be individually blamed for not following policies or guidance, even where such policies or guidance may not work in practice.

23. There does still appear to be a gap in how learning and a new approach to safety is shared and embraced in primary care. We note that primary care providers (including dentists and community pharmacy) are not included in the current scope of PSIRF and HSIB investigations have historically encountered challenges when engaging with primary care providers. This has included a lack of incident reporting data to allow insight into safety in these organisations and refusals to engage with HSIB investigations on a few occasions. When this has occurred, it has limited the learning we could take from patient safety events and has reinforced negative perceptions and cultures around safety in primary care.

24. HSSIB would support action to help improve engagement amongst primary care providers to ensure they have the knowledge, skills, and resource to better engage in the developing patient safety landscape. This could include steps to ensure that the advancements in safety culture and incident response being promoted via PSIRF can also be embedded within this sector.

25. HSSIB investigations have also highlighted challenges to patient safety where the lack of a shared culture and responsibility toward risk can lead to patient harm. HSIB investigations into harm caused by delays in transferring patients to the right place of care highlighted an 'air gap' that exists between health and social care, and a gap in organisational responsibility and accountability when considering where risk sits in the patient pathway.

26. We have also seen this extend to differences in understanding safe care and culture surrounding safe care in the interfaces of physical and mental health services. HSSIB investigations are currently considering patient safety events that have occurred when patients with mental health needs are cared for in acute physical healthcare hospitals. Emerging findings from our investigations suggest that safety may be considered differently in these settings, for example by creating safe (but often sterile) environments without ligature risks but without creating therapeutic environments and interactions that can help facilitate safe care and reduce the risk of further mental health problems.

27. 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.

Training of staff in health and social care

28. Part of HSSIBs remit is to provide training and support to NHS staff to help equip them to better investigate patient safety events and understand safety from the systems perspective. 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.

29. HSSIB has worked with NHSE and the Academy of Royal Colleges to help develop new mandatory training for NHS staff. The new NHSE mandatory training in essentials for patient safety and essentials of patient safety for boards and senior leadership teams help to provide a foundation basis to understand safety and some of the concepts required to help make NHS care safer for all.

30. HSSIB has also worked with colleagues in NHSE to develop more advanced training that complies with the requirements of PSIRF and provides specific training in a systems approach to the investigation of patient safety events. This includes courses: a systems approach to investigating and learning from patient safety incidents, involving those affected by patient safety incidents in the learning process, and PSIRF oversight.

31. 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. We have developed our safety investigation for strategic decision makers and senior leaders in healthcare course to help address the need. 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.

32. An ongoing HSSIB investigation into the NHS workforce challenges and patient safety has focused on the role of temporary staff in the NHS. One emerging finding from this investigation is the lack of induction that temporary staff may undergo to help equip them with the practical knowledge they need to work in a care environment (for example, IT log-on details) and the wider values, safety, and cultural expectations of the employing NHS organisation. We are continuing this work and expect to report on our findings in Autumn 2025.

Maternity care and leadership

33. On 28 November 2017, the HSIB maternity investigations programme was announced as part of progress against ambitions set in the national maternity safety strategy:

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.

34. HSIB's maternity investigations programme included a remit to investigate direct or indirect maternal deaths of women while pregnant or within 42 days of the end of pregnancy (excluding women who died by suicide) and perinatal deaths when the baby died within the first week of life (0-6 days) of any cause. HSSIB understands this remit continues with MNSI.

35. 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. The investigation reports were not published; they were produced for the family and the trust. The 'safe space' principle also did not apply to these investigations.

36. HSIB produced investigations and several national learning reports where findings and safety learning from the maternity programme was aggregated and shared with the healthcare

system. This included the following reports, which are all available via the HSSIB website (www.hssib.org.uk).

- Summary of themes arising from the HSIB maternity programme (March 2020)
- Severe brain injury, early neonatal death and intrapartum stillbirth associated with group B streptococcus infection (GBS) (July 2020)
- Neonatal collapse alongside skin-to-skin contact (August 2020)
- Delays to intrapartum intervention once foetal compromise is suspected (November 2020)
- Severe brain injury, early neonatal death and intrapartum stillbirth associated with larger babies and shoulder dystocia (February 2021)
- Intrapartum stillbirth: learning from maternity safety investigations that occurred during the COVID-19 pandemic 1 April to 30 June 2020 (September 2021)
- Emergency neonatal blood transfusion at birth following acute blood loss during labour and/or delivery (March 2022)
- Management of preterm labour and birth of twins (March 2022)
- The assessment of venous thromboembolism risks associated with pregnancy and the postnatal period (December 2022)
- Assessment of risk during the maternity pathway (March 2023)

37. The former HSIB maternity investigation programme is now hosted within the CQC as MNSI. We suspect MNSI would be able to provide a more significant response to this question based on its experiences and ability to comment on the maternity system via the scope and volume of its ongoing work.

Comment on wider safety culture and recommendation implementation

38. HSSIB is also tasked with making recommendations to national organisations to help improve patient safety. Due to the complex landscape that exists in the NHS it can be challenging to identify which organisation should take the lead, or 'own' any recommendations for improvement.

39. 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. This is felt particularly where recommendations are made to improve safety across the system.

40. HSIB and HSSIB have encountered numerous occasions where it has been challenging to identify which organisation is responsible for taking specific actions within the healthcare system to improve safety. HSIB investigations have also identified 'gaps' in the system where specific safety risks appear to fall between organisations and where there is no consensus about ownership, for example in the HSIB investigation about hospital transmission of COVID-19 it was unclear if Public Health England or NHSE owned and were required to update national infection, prevention, and control guidance.

41. This is largely due to the complex nature of healthcare with both academic and professional work identifying that there are more than 120 organisations with either regulatory or quasi regulatory responsibilities. This is in comparison to other industries on which the approach taken by HSSIB is based, for example in the transport sector recommendations at the national level are typically made to the Department of Transport to facilitate improvement across the system as opposed to in healthcare where recommendations are often required to be made to numerous specific, individual organisations.

42. HSSIB has been facilitating work commissioned by DHSC, Chairs of arm's length bodies (ALBs), and NHS chief executive officers into safety and risk following a request from the Secretary of State for Health and Social Care for these organisations to look at increased collaboration. This work has focused on recommendations and is now progressing with oversight from the NHSE National Quality Board and includes representation from a wide range of organisations across the healthcare system.

43. This work has identified that there is not a common set of principles used in the formation of recommendations made to healthcare organisations. This has resulted in challenges, particularly where the cost and effectiveness of implementing recommendations is not understood. ALBs are often unaware of work happening in other ALBs and this can lead to duplication of effort, and duplication or conflicting recommendations being made with differing evidential basis. As a result, NHSE has developed a set of principles to help in guiding how recommendations are formulated (CREATED SMART) but these have not been widely accepted or adopted.

44. We have also found that at provider level, organisations are often having to manage large numbers of recommendations at board level, without clarity as to which recommendations are mandatory or optional. This makes prioritisation and action on recommendations difficult.

45. In addition, there is no consistent method of measuring impact across organisations, and many organisations are not collecting data on the impact of recommendations on improving patient care. There was also a lack clarity about accountability for oversight of recommendations at national, regional, and local level.

46. As a result, the group identified four potential workstreams to support the development and implementation of recommendations in healthcare. These were:

- To develop an agreed set of principles for all organisations to use when making a safety or improvement recommendations and explore a system of governance to ensure adherence to these principles.
- To develop a proposal for the formation of a shared repository of work being undertaken by ALBs, including how this could be implemented and the costs involved in its development and maintenance.
- To identify how different ALBs and other organisations are measuring impact of safety recommendations on patient care and explore whether there is an opportunity to collaborate on the assessment of impact.
- To further develop and support the work of NHS Resolution on a tool to support implementation of recommendations in emergency medicine.

47. This work supports the 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 everyone understands their own accountability and responsibilities.

48. 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.

49. We understand that to date there has been very little discussion across health and care about the implementation of a safety management system and how this could assist in more clearly defining the ownership, accountability, and action required to effectively respond to safety recommendations.

50. 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 to help improve the oversight and outcome of safety recommendations made to improve care.

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