October 2019

NHS Providers

Health Service Safety Investigations Bill

Lords second reading

NHS Providers is the membership organisation and trade association for the NHS hospital, mental health, community and ambulance services that treat patients and service users in the NHS. We help those NHS foundation trusts and trusts to deliver high-quality, patient-focused care by enabling them to learn from each other, acting as their public voice and helping shape the system in which they operate. NHS Providers has all trusts in membership, collectively accounting for £84bn of annual expenditure and employing more than one million staff.

The Healthcare Safety Investigations Branch (HSIB) is currently established under ministerial directions as part of the Trust Development Authority and hosted by NHS Improvement. This bill makes provision to establish the Health Service Safety Investigations Body (HSSIB) as an independent entity. It has undergone pre-legislative scrutiny by a Joint Committee, and the government has responded to its report. We contributed extensively to the Joint Committee's work, giving oral and written evidence.

Our briefing below sets out the importance of the HSIB/HSSIB and its contributions to patient safety within the NHS, and our views on a number of key issues raised by the revised version of the bill, in particular relating to the importance of protecting the integrity of safe space. For further information, please contact Ferelith Gaze, head of policy and public affairs (ferelith.gaze@nhsproviders.org).

NHS Providers view

The importance of systemic investigations, safe space, and the design of the investigating body

NHS Providers strongly supports the principle of creating the HSSIB and enabling it to conduct safe space investigations so that the NHS can improve patient care and learn from when things go wrong. This is an approach that has been successfully adopted in a number of other industries (for example, within the airline industry's Air Accidents Investigation Branch [AAIB]) and we support the principle of the HSSIB being established as an independent statutory entity through this bill.

We support the expansion of human factors approaches – where people are encouraged to speak up so they and their organisations can learn when things go wrong, and not punished for speaking honestly – with this being at the heart of the HSIB/HSSIB approach. Organisational cultures that support staff to speak up have higher levels of staff engagement and patient satisfaction, and are associated with reduced errors in care and better safety. As the foreword to the draft bill noted, in the airline industry *"a learning culture*

has led to dramatic improvements in safety".[1] We therefore welcome the creation of the HSSIB as an opportunity to develop a just culture in the NHS and a focus on learning.

For the HSSIB to be able to properly investigate the systemic causes of safety issues, and to harness the knowledge and insight of those involved, a legally protected safe space is essential. There is a wide body of research that evidences the importance of work environments that offer 'psychological safety' for staff to discuss in a confidential setting the circumstances of an incident that has resulted in avoidable harm. It is through a robust application of a safe space that the HSSIB will be able to command the confidence of participants and best understand the safety risks present and make appropriate recommendations.

It is important to note the need for careful design of the HSSIB if it is to properly fulfil its functions. The HSSIB is intended to investigate systemic safety risks and make recommendations to address those risks. It will operate a safe space to encourage those taking part in an investigation to speak freely, and the HSSIB will only disclose information under pre-defined circumstances. The HSSIB does not have a regulatory or operational role. It is expected that the HSSIB will undertake approximately 30 investigations a year. As Carl Macrae and Charles Vincent – who together originally proposed an NHS body equivalent to the AAIB – point out, it is a helpful characteristic of industry investigators that they are relatively small organisations. In describing the design of the investigation branches in the air, maritime and rail industries, they explain that, despite *"important and wide-ranging responsibilities, these agencies are lean organisations that operate with relatively small budgets. They are staffed by relatively small teams of highly skilled investigators who are specialists in incident investigation and safety analysis. To conduct major investigations, these teams co-opt and coordinate the expertise that exists within the industry, working constructively with all organisations and sectors involved in an incident. They lead, coordinate and oversee the work of safety investigation. This collaborative approach not only draws on safety expertise across the industry but actively builds and spreads that expertise too".*[2]

An overview of responsibilities and processes undertaken following an incident within an NHS trust or foundation trust

Following an incident, a number of parallel processes will be undertaken, and trusts have multiple responsibilities to discharge. Some of these will be led by the trust, some will be instigated by those involved in an incident, and some will be carried out by external bodies. These include:

- Actions that may be instigated by patients, families, staff; or undertaken by or involving the trust:
  - Complaints – raised by patients or those representing their interests
  - Concerns raised by staff – investigated by the line manager or freedom to speak up guardian

[1] Draft Health Service Safety Investigations Bill, Department of Health and Social Care (September 2017) https://www.gov.uk/government/publications/health-service-safety-investigations-bill

[2] Carl Macrae and Charles Vincent, 'Learning from failure: the need for independent safety investigation in healthcare', *Journal of the Royal Society of Medicine* (2014, Vol 107(11)), pp. 439–443. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4224654/

- Legal action – taken by patients or those representing their interests against a trust
- Processes undertaken by the trust:
  - Trust investigation – complying with the Serious Incident Framework, and completing investigations within 60 days
  - Liaison with other statutory bodies – potentially including the coroner's office, Health and Safety Executive and/or the police, as well as NHS commissioners, agencies and professional and organisational regulators
- Trust responsibilities to those involved:
  - Patient and family support – recognising the need to be timely, to keep them informed and involved, and to offer support such as an advocate or counselling and in response to need (eg, transport, language, disability)
  - Employment duties – recognising that those staff involved need pastoral support, and may also need to be assessed for professional competency or involved in legal proceedings
- Trust corporate governance responsibilities and legal duties:
  - Organisational risk assessment and liability management
  - Fulfilment of legal obligations such as duty of candour and provision of a safe service
  - Moral obligations to patients, families and staff to act fairly and transparently
- Processes undertaken by external bodies:
  - Criminal investigations of individuals or the trust
  - Potential independent investigation – to be completed within six months, according to the Serious Incident Framework
  - Professional regulatory action to assess competency and fitness to practice
  - Organisational regulatory action to assess safety and compliance with legal duties
  - Case reviews by the Parliamentary and Health Service Ombudsman as referred to them by patients or their representatives

Local trust investigations are currently undertaken within the requirements of the Serious Incident Framework (the SIF).[3] This sets out the requirements for trusts and commissioners to investigate and learn from serious incidents; involve and support patients, families and carers; and ensure the safety of healthcare delivery, including by working with a number of statutory organisations and procedures to ensure appropriate accountabilities. The *SIF* notes serious incident management as "a critical component of corporate and clinical governance", with trust leaders "ultimately responsible for the quality of care that is provided by that organisation".[4]

The HSIB's national investigations have been added to these responsibilities and processes. They are differentiated by their independence, their safe space provisions, and their systemic perspective. As such,

[3] A new Patient Safety Incident Response Framework (PSIRF) is due to be published in Autumn 2019, with a small number of early adopters working within it, until use is expanded from autumn 2020, and all parts of the NHS in England are expected to use the PSIRF by summer 2021. This will replace the SIF. For more details see: https://improvement.nhs.uk/resources/future-of-patient-safety-investigation/

[4] https://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incidnt-framwrk-upd.pdf

they will fill a gap in how the English healthcare system learns from its mistakes and improves patient safety. This is why NHS Providers has always strongly supported the creation of the HSIB as soon as it was announced and why we support the principle of creating it as an independent statutory organisation through this bill.

Clauses 2 and 3, and 28 – Investigation function; Publication of criteria, principles and processes; Function of giving assistance

The HSIB's original remit was to carry out a small number (around 30 a year) of systemic safety investigations within safe space provisions, which would be carried out in addition to local trust investigations.

It was latterly required by the then Secretary of State to carry out all maternity investigations (in cases of specified outcomes – expected to number around 1000 a year) in the place of local trust investigations in order to facilitate rapid learning and an improvement in the way these investigations were handled. As they will be replacing a trust's investigation, safe space provisions do not apply. It is understood that the maternity investigations will be returned to the NHS in 2021.

We welcome the proposal that those investigations will return to the NHS as there is a risk within these specialist investigation programmes that the role of HSIB could prevent trusts from fulfilling their current responsibilities following the occurrence of a serious incident. For an organisation to be properly governed and to be held accountable, it must have appropriate oversight and control of its operations. It must also have a role in coordinating these multiple processes, for the benefit of patients, their families and staff, as well as to reduce duplication and risk. It is therefore not appropriate for the HSSIB to have a long term role in taking on any such investigations, not least because of the loss of skill within the NHS itself in carrying them out.

We do, however, recognise that, having been directed by the Secretary of State to undertake these investigations for a period, the HSIB does have a valuable role in identifying how NHS providers can sustainably and systematically improve the quality of their maternity investigations and then appropriately support those providers to make the required improvements. There is widespread agreement, evidenced by a range of cases, that the provider sector as a whole needs to significantly improve the quality of these investigations. Nevertheless, there is a big difference between asking the HSSIB to take responsibility for conducting these investigations in perpetuity and asking it to take responsibility for these investigations for a period of time, develop appropriate learning and then support NHS providers to improve accordingly. The latter is much more in alignment with the overall approach the HSSIB will adopt across the rest of its work. Asking the HSSIB to undertake all these investigations in perpetuity risks distorting the organisation's focus, purpose and structure.

However, there is some ambiguity within the bill as to whether and how the maternity investigations would be undertaken . Arguably, they could be brought into the HSSIB's permanent remit by clauses 2 and 3, which are sufficiently broadly drafted to enable the HSSIB to set distinct criteria for various types of investigation – for example, one set for systemic investigations and another for specialist investigations.

This is concerning because it would give the HSSIB latitude to replace substantial portions of local trust investigations, which are vital to trust learning and improvement and to relationships with patients and families, and pursue them under safe space provisions.

In the normal course of events, as a trust undertakes an investigation, concurrent governance processes will also be in effect including:

- liaising with patients and families affected
- board oversight of serious incidents
- clinicians' analyses of lessons or themes arising
- staff will be concerned to find out what happened and why, and will be supported through the multiple processes to establish this
- progress will be reported within the organisation to relevant teams
- scrutiny of processes and findings will be undertaken
- the trust will be acting as a single point of contact for multiple agencies
- public and media interest will be managed, and
- changes to increase safety will be made.

It is not sustainable for the HSSIB to systematically take over such investigations without damaging the trust's ability to remain accountable for the quality of care within their organisation.

While we recognise the motivation for and value of placing the maternity investigations with the HSIB, they should not be part of the HSSIB's permanent core remit. The HSSIB should only sparingly undertake any programme of specialist investigations and where they do, given that they seem likely to replace a trust's own investigation, these investigations should not take place under safe space provisions.

Instead, we would suggest that clause 28 is amended such that specialist investigation programmes are encompassed here outside safe space provisions. Clause 2 could also be helpfully amended to explicitly focus the HSSIB on its c30 national systemic investigations taking place within safe space provisions.

The HSSIB's role should be to bring an independent, expert-led analysis of the contributory factors to mistakes in healthcare and why they recur, by gaining a systemic view and supporting excellence in investigations. That should not come at the expense of local learning and trust's ability to meet their obligations to staff and patients.

Clause 3 – Publication of criteria, principles and processes

In the draft bill, the HSSIB was required to determine and publish the processes for involving a defined list of NHS bodies as well as patients and their families. This subclause (in both the draft bill and current bill, 3(1)(d)), has since been revised to focus on the involvement of patients and their families.

We are content that the range of NHS bodies is not set out on the face of the bill, not least to allow for changing models of care and NHS accountability, as well as the range of potentially relevant organisations. As Macrae and Vincent have argued, *"All the organisations required to improve following an incident need to be involved in the investigative process. The purpose of investigation is not simply to find out what happened but from the very beginning to consider what improvements would be appropriate and to engage with the organisations that might implement them. Learning is a participatory process and begins at the start of an investigation, not at the end of it … Recommendations should be targeted at all relevant organisations across the healthcare system, from device manufacturers to regulators to healthcare providers to educators and professional bodies".*[5]

In this vein, we would welcome confirmation on the floor of the House that part of the intent of clause 3(1)(c) is for the HSSIB to set out those bodies it considers relevant to its investigations. We would also suggest that clause 3(1)(d) could be amended to reference carers as well as patients and their families.

Clause 4 – Representations and requests to investigate

The Joint Committee made clear the importance of the HSSIB's independence of judgement in deciding what investigations it undertakes. Clause 4 should be considered further in this light, especially given the current potential for the Secretary of State to request that the HSSIB undertake a programme of specialist investigations. While it may be practicable to do so, there is equally the risk that, in undertaking such a programme, the HSSIB is distracted from its core remit. It therefore needs to be able to refuse a request from the Secretary of State, where there is reasonable justification. It would be helpful to consider in the House whether this should be made explicit on the face of the bill.

Clause 7 – Notices requiring the provision of information etc

Within the draft bill, provision was made (by clause 8) for a person given notice to provide information, documents, equipment or other items to be able to apply to the Chief Investigator for a review of the decision to give the notice. This provision has been removed in the current bill. We would query this, especially as it would now be a criminal offence (rather than a penalty) not to comply with a notice to attend a meeting with the HSSIB or not to provide specified information (as in clause 10). We believe the ability to appeal should be restored in recognition of the increased powers of compulsion the HSSIB has and the introduction of criminal sanctions in the event of non compliance.

Clause 10 – Offences relating to investigations

Clause 10 makes it an offence to intentionally obstruct or unreasonably fail to comply with an HSSIB notice requiring interview attendance or specified information. We understand that this approach is broadly in line with that taken in other sectors.

---

[5] Macrae and Vincent, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4224654/

However, we are concerned that the Bill's new elevation of the sanction for non compliance from a penalty (as in the draft bill) to a criminal offence still needs to be publicly made in relation to the specific context of the health sector and within the HSSIB's work. For example, care needs to be taken in applying fines to the NHS and, at a minimum, expectations need to be set as to reasonableness and impact, and the importance of balancing rights – that is, ensuring a right of review of the HSSIB's giving notice to a person is an essential counterpart to making obstruction or non compliance an offence.

Clause 14 – Exceptions from prohibition: disclosure for purposes of investigation etc

Clause 14 allows the HSSIB to disclose protected materials (ie, information disclosed within safe space provisions) to those who are not part of the HSSIB if the Chief Investigator reasonably believes it necessary for carrying out the HSSIB's functions. The explanatory notes give the example of sharing protected materials with a participant in an investigation.

We are concerned to ensure that the HSSIB's investigations are not made impractical, and it may be that the intent of this clause is to enable full and proper investigation. However, we are equally concerned to ensure that the boundaries of safe space are kept secure. The Joint Committee explored extensively the limits of safe space, finding that:

> The experience in other safety critical industries is that 'safe space' investigations will encourage professionals to be more open with investigators, but only time will tell how effective this will be in the healthcare sector. The 'safe space' approach is based on a better understanding of what people feel when they are under scrutiny. It also supports patients who do not want their information shared more widely. Although initially only introduced on a limited scale, this approach is an innovation for the healthcare sector which presents great possibility for positive evolution of the attitudes and behaviour people have tended to adopt towards patient safety incident investigations…
>
> The question is under what circumstances HSSIB should be allowed or obliged to disclose information and evidence protected by the 'safe space'. We draw a consensus from our evidence. HSSIB should only be expected to disclose such information as is necessary to address a serious and continuing risk to the safety of a patient, or to the public. This is consistent both with the Government's stated aim for the exceptions and with the principle that HSSIB should be about learning not blaming.[6]

In its current drafting, it does not seem to us that clause 14 properly respects safe space . Knowing that information they had given may be passed to a colleague may make a participant wary of disclosing it in the first place. A participant then has to choose between committing an offence if they do not disclose information, and making themselves vulnerable to workplace recriminations if they do and it is shared.

[6] https://publications.parliament.uk/pa/jt201719/jtselect/jthssib/1064/106406.htm#_idTextAnchor024

This is not a healthy choice to be faced with, and goes against the principles and practice of psychological safety that safe space is intended to enable.

We would therefore suggest that if such a clause is necessary, it is far more tightly drawn to preserve a participant's safe space.

Clause 17 – Exceptions from prohibition: High Court order

We note the following:

- The purpose of the HSSIB is to identify safety risks and to address those risks by facilitating the improvement of systems and practices in the provision of NHS services. The integrity of safe space is key to HSSIB's ability to fulfil this purpose.
- The impact assessment notes that, "Litigation in healthcare is a more frequent occurrence than in other areas of accident investigation. It is therefore possible that lawyers representing patients or NHS staff involved in safety incidents that have been investigated by HSSIB, may make applications for disclosure of 'safe space' information hoping to uncover material of benefit to their clients".[7]
- The government's response to the Joint Committee notes on a number of occasions that access to all usual information channels will continue, and the HSSIB's final reports will also be publicly available.[8]

Therefore, we would question whether it is appropriate to simultaneously:

1. Accept that the integrity of safe space is paramount, and
2. Make cooperation with the HSSIB a legal requirement, but
3. Recognise the litigiousness of the NHS, and
4. Acknowledge that disclosable investigatory material will continue to be available, and
5. Make provision for safe space disclosures to be shared outside the investigation and for purposes beyond its original use?

We do acknowledge that there are two tests that the High Court would need to apply in deciding whether to approve an application for protected material disclosure: any adverse impact on investigations arising from deterring participation, and any adverse impact on the ability of the Secretary of State's to secure the improvement of the safety of NHS services.

However, we would note the HSSIB's powers of compulsion, added since this clause was originally drafted, which now seems in conflict with the first test, meaning that the High Court will struggle to argue that future participants will be deterred (even though in practice they will be more nervous to do so). The purpose of and objective for the HSSIB must be to facilitate improvements to patient safety, taking

---

[7] https://publications.parliament.uk/pa/bills/lbill/2019-2020/0004/20004-IA.pdf

[8] https://www.gov.uk/government/publications/government-response-to-health-service-safety-investigations-bill-report

precedence over all other considerations. Protection of safe space is key here. As the Joint Committee concluded:

> To avoid any perceived dilution of the 'safe space', and to put the question beyond doubt, we recommend that the Bill expressly prohibit both the Parliamentary Commissioner for Administration and the Health Service Commissioner for England from having access to the information and material in clause 28 of the draft Bill, regardless of their entitlement under any other legislation. These bodies are well used to conducting their own investigations without access to HSSIB material. In this respect, the introduction of HSSIB has no impact on them whatsoever, except that they will be able to draw upon the reports and other material published by HSSIB.[9]

We would therefore question whether clause 17 is too widely drawn, and whether it has been sufficiently revised in light of wider changes to the bill since first drafted. The tests for an application must be sufficiently strong to ensure that disclosure is only sought in extremis, that there is a clear and unarguable public interest in any disclosure, and that the safety of participants is respected, and that current and future investigations are not jeopardised.

Clause 19 – Disclosure to coroners

It is deeply concerning that coroners may require the disclosure of protected material, and in turn that the coroner may apply to the High Court to disclose that protected material. This clearly has the potential to fundamentally undermine the integrity of the safe space provisions.

Moreover, we would draw attention to the sum of the powers now set down in this bill:

1. The HSSIB now has powers of compulsion, whereby they can require interview attendance and disclose of information, and
2. Obstructing or failing to comply with the HSSIB is an offence punishable by a fine, and
3. Disclosures made to the HSSIB are made within safe space provisions, but
4. Anyone can apply for High Court disclosure of protected materials, subject to two tests and the HSSIB's representations, with one of those tests essentially nullified by the HSSIB's powers of compulsion
5. Coroners can require the HSSIB to disclose protected materials, and
6. Coroners can apply to the High Court to further disclose protected materials, subject to two tests and the HSSIB's representations, with one of those tests essentially nullified by the HSSIB's powers of compulsion

It cannot be right for, on the one hand, someone to be compelled to give information and to do so on the understanding that they act within a safe space and would be committing an offence if they did not, and on the other, to enable that information to be made publicly available.

---

[9] https://publications.parliament.uk/pa/jt201719/jtselect/jthssib/1064/106406.htm#_idTextAnchor024

It is neither the HSSIB's purpose nor duty to act as a branch of the coroner. The coroner has multiple other avenues of information and powers of investigation, and it does not need access to the HSSIB's protected material simply thanks to the convenience of the HSSIB's existence. As the Joint Committee concluded:

> We recommend that the draft Bill be amended to put beyond any possible doubt that the 'safe space' cannot be compromised save in the most exceptional circumstances, and therefore that the prohibition on disclosure applies equally to disclosure to coroners…for the avoidance of any doubt, we recommend that the Government clarify, both in public statements and in the legislation, that the prohibition on disclosure is of application in all circumstances, except as provided for in the Bill itself.[10]

We would urge removal of this clause, or at the very least significant revision of this clause to limit the coroner's powers in respect of the HSSIB's protected materials in order to maintain the integrity of safe space and preserve the intent of the HSSIB to facilitate a learning culture within the NHS.

Clause 23 – Opportunity to comment on draft report

The draft bill required the HSSIB to send a draft of the report to every person who participated in the investigation. The current bill instead requires a draft to be sent to "any person who the HSSIB reasonably believes could be adversely affected by the report once published", and that the HSSIB may also send a draft to anyone else that it "believes should be provided with a draft". Those who receive a draft report have the opportunity to comment.

We believe this revision has introduced an ambiguity. The government response to the Joint Committee states that it "will review [clause 31 of the draft bill] to consider further whether there should be an express obligation on HSSIB to share the draft report with any person whose reputation could be damaged by it".[11] This has been translated to "adversely affected" within the current bill. We would suggest that the intent behind this phrasing, if it is limited to reputational issues, isn't clear, and if it adverse effect is limited to reputation issues, then this has the potential to be seen as downgrading the interests of all the participants within an investigation. We suggest that the wording of clause 23 is revised to make its intent and meaning clearer.

Further issues of note

Investigating the whole care pathway

The Joint Committee found that, "HSSIB investigations must not exist in an NHS 'silo' and should be able to explore all aspects of a patient journey and the interaction between services. HSSIB, however, should not be tasked or expected to be an investigatory body for social care.", but nonetheless recommended that

---

[10] https://publications.parliament.uk/pa/jt201719/jtselect/jthssib/1064/106406.htm#_idTextAnchor024

[11] https://www.gov.uk/government/publications/government-response-to-health-service-safety-investigations-bill-report

"the powers associated with HSSIB investigations and the protections of the 'safe space' be extended to social care so that investigations can analyse all aspects of the care pathway".[12]

The government responded that, "We agree with the Committee that the new body should not be an investigatory body for social care but that it should be empowered to investigate all aspects of the health care pathway relating to a patient safety investigation, including where there are transitions and other interactions of the pathway with social care provision. We will look at the best way to meet this recommendation in the revised Bill, including how the new body's investigative powers may need to be changed. We will engage with stakeholders to ensure their views are reflected in this process."[13]

However, it is not clear how this agreed recommendation has been taken up and reflected in the bill. We would welcome further debate here and consideration of whether further revisions would be helpful. We believe that the HSSIB should be able to look across the care pathway for two key reasons:

1. NHS care and private healthcare interact in a number of ways. For example, capacity constraints may mean that care paid for by the NHS is delivered by the private sector; or where patients being cared for in the private sector require emergency care, this will be provided by the NHS. In the primary sector, particular dentists and opticians, there is a significant mix of NHS and private care undertaken which would be difficult to distinguish in terms of staffing and procedures. Therefore to exclude the private sector from investigations limits understanding of safety risks. We suggest that the HSSIB's remit extends to all providers registered with the Care Quality Commission (CQC).
2. Changing models of care and NHS structures, and increased system working, also need to be considered. For example, it is intended that NHS care will increasingly be delivered in the community, and consideration needs to be given to nursing and care homes and other forms of long-term care facilities and how they would be encompassed within the bill.

Pre-appointment scrutiny

The Joint Committee recommended that "both the chair of HSSIB's board and HSSIB's Chief Investigator be subject to pre-appointment scrutiny by the Commons Health and Social Care Committee".[14] The government responded that "We agree with the Committee's intention and will engage with the Health and Social Care Select Committee on the best way to achieve this, in line with Government guidelines on pre-appointment scrutiny".[15] However, this pre-scrutiny has not been added to the bill.

The HSSIB will need to be fully independent of political influence, and maintain consistency of purpose through periods of political change which may impact on the regulatory and commissioning environment. It would be helpful to understand why it has been omitted and what potential there is to

---

[12] https://publications.parliament.uk/pa/jt201719/jtselect/jthssib/1064/106402.htm

[13] https://www.gov.uk/government/publications/government-response-to-health-service-safety-investigations-bill-report

[14] https://publications.parliament.uk/pa/jt201719/jtselect/jthssib/1064/106402.htm

[15] https://www.gov.uk/government/publications/government-response-to-health-service-safety-investigations-bill-report

undertake pre-appointment scrutiny, especially as we believe is a helpful balance to the HSSIB's accountability to the Secretary of State.