22 June 2018

Sir Bernard Jenkin MP
Chair, Draft Health Service Safety Investigation Bill (Joint Committee)
House of Commons
London
SW1A 0AA

Dear Sir Bernard

NHS Providers strongly supports the role of independent systemic safety investigations across healthcare, and I was pleased to provide evidence to your committee last week. You requested that I write with further detail of our concerns relating to the lack of clarity for trusts about the implications of HSIB/HSSIB replacing their local investigations into serious incidents in maternity and neonatal care (with potential for expansion into other clinical services in future).

I would firstly like to take the opportunity to set out the basis of NHS Providers' perspective. We exist to represent NHS foundation trusts and trusts, who in turn exist to provide care for patients and service users through hospital, ambulance, community and mental health services. When we speak for trusts, we are doing so to best enable them to serve those in their care. Trusts are required to work within a set of regulations, policies and frameworks which are intended to ensure properly governed organisations with appropriate measures and standards in place to deliver sustainable, consistent high-quality care. In highlighting those existing requirements placed on trusts, we are seeking to ensure that patients will still enjoy the protection they provide, as well as benefit from the HSSIB's investigations.

NHS Providers recognises that the HSIB's carriage of maternity investigations is intended to bring a greater level and quality of technical investigative capability to drive rapid learning at a system level, in an area of NHS services where serious incidents have devastating and costly consequences for patients and the NHS. We recognise that many trusts do not consistently undertake the quality of investigation that they should do. To that end, we strongly support the system-level learning opportunity that the HSIB offers. However, changes to improve the safety of healthcare services, no matter how well intentioned, should not be made without sufficient clarity of how these changes will affect the trusts and staff who deliver those services.

Our concern is that the current proposals, in seeking – rightly – to introduce greater learning and safety into our healthcare system, have the potential to preclude and cut across, rather than improve, existing mechanisms which are equally important to patients and their families.

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The HSIB's current investigation remit

The HSIB is currently working under two sets of ministerial directions (see Annex 1 for further detail). Its 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 has latterly been required by the 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 and without safe space provisions applying.

Responsibilities and processes undertaken following an incident

Following an incident, trusts have multiple responsibilities to discharge, and a number of parallel processes will be undertaken. 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. To give a brief overview of the main processes that may be undertaken:

<table>
<tr><th colspan="5">Instigated by patients, families, staff; undertaken by or involving the trust</th></tr>
<tr><td colspan="2">Complaints – raised by patients or those representing their interests, which trusts must resolve within six months</td><td colspan="2">Concerns raised by staff – investigated by the line manager or freedom to speak up guardian</td><td>Legal action – taken by patients or their representing their interests representatives against a trust, which will be represented by the NHS Litigation authority and bound by various requirements and orders, including disclosure requirements, and where compensation may be due</td></tr>
<tr><th colspan="5">Processes undertaken by the trust</th></tr>
<tr><td colspan="3">Trust investigation – complying with the Serious Incident Framework (see next section), and completing investigations within 60 days</td><td colspan="2">Liaison with other statutory bodies – potentially including the coroner's office, Health and Safety Executive and the police, as well as NHS commissioners, agencies and professional and organisational regulators</td></tr>
<tr><th colspan="5">Trust responsibilities to those involved</th></tr>
<tr><td colspan="3">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)</td><td colspan="2">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</td></tr>
<tr><th colspan="5">Trust corporate governance responsibilities and legal duties</th></tr>
<tr><td colspan="2">Organisational risk assessment and liability management</td><td colspan="2">Fulfilment of legal obligations such as duty of candour and provision of a safe service</td><td>Moral obligations to patients, families and staff to act fairly and transparently</td></tr>
<tr><th colspan="5">Processes undertaken by external bodies</th></tr>
<tr><td>Criminal investigations of individuals or the trust</td><td>Potential independent investigation – to be completed within six months, according to the Serious Incident Framework (see next section)</td><td>Professional regulatory action to assess competency and fitness to practice</td><td>Organisational regulatory action to assess safety and compliance with legal duties</td><td>Case reviews by the Parliamentary and Health Service Ombudsman as referred to them by patients or their representatives</td></tr>
</table>

The HSIB's national investigations are being added into this complex web. They are differentiated by their independence, their safe space provisions, and their systemic perspective. As such, they will fill a clear gap in how the English healthcare system learns from its mistakes and improves patient safety.

However, if the HSIB is also carrying out local investigations in place of trusts – as it now is with serious incidents in maternity and neonatal care– there is a risk they 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. The HSIB should not and, in our view, cannot take on that role, but neither can the trust properly do it if it is, at most, an observer (as the trust role is described in the maternity investigations).[1]

Existing requirements for local trust investigations

It is also important to consider the detailed existing requirements around local trust investigations. These are set out in NHS England's *Serious Incident Framework: supporting learning to prevent recurrence* ("the *SIF*").[2] The *SIF* was "developed in collaboration with healthcare providers, commissioners, regulatory and supervisory bodies, patients, patient and victim's families and their representatives, patient safety experts and independent expert advisors for investigation within healthcare". It sets out:

- The fundamental purpose of investigation of serious incidents – such as acts or omissions in care that result in unexpected or avoidable death or injury resulting in serious harm – being "to ensure that lessons can be learnt to prevent similar incidents recurring".
- The primacy of the needs of those affected, with patients and their families / carers to be involved and supported throughout.
- The responsibility of providers for the safety of their patients, visitors and others using their services, and for ensuring "robust systems are in place for recognising, reporting, investigating and responding to Serious Incidents and for arranging and resourcing investigations".
- The responsibilities of other statutory bodies, including:
    - Commissioners, who must assure themselves of the quality of services they have commissioned, in part by evaluating investigations and their outcomes, and coordinating and sharing intelligence with relevant regulatory and partner organisations.
    - The Care Quality Commission and NHS Improvement, who may both use investigations and action plans to monitor "compliance with essential standards of quality and safety", and can take action where they find risks to quality and governance.
- That serious incident investigations should be linked as appropriate with related processes for holding individuals and organisations to account, including "criminal proceedings, disciplinary procedures, employment law and systems of service and professional regulation".

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[1] The maternity investigations are "intended to be the primary and, as far as possible, the only investigation of the individual case … local staff will be involved as observers" (Department of Health's Safer Maternity Care report, p25) and "they will replace the local investigation" (HSIB's piece in National Health Executive magazine).

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

That is, there are requirements in place for trusts and commissioners to investigate and learn from serious incidents, and responsibilities to ensure the safety of healthcare delivery, including by working with a number of statutory organisations and procedures to ensure appropriate accountabilities.

To look at a provider's responsibilities more closely, 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". To that end, requirements include:

- Disclosing serious incidents as soon as possible to the patient, their family and carers.
- Reporting serious incidents to the commissioner without delay, with other regulatory, statutory, advisory and professional bodies informed depending on the nature and circumstances of the incident. A Risk Summit may be held in certain circumstances where local stakeholders come together to collectively share and review information.
- Carrying out a "72 hour review" to identify any necessary immediate action required to ensure safety, assess the incident and propose the appropriate level of investigation (concise, comprehensive or independent – see Annex 2).
- Following prescribed procedures in reporting a serious incident, liaising with regulators and other agencies / partners, having mechanisms to ensure robust investigations and follow up, ensuring meaningful and sensitive engagement with affected patients, their families and carers throughout the process, quality assuring reports and effectively communicating them.
- Having mechanisms to support investigations being led by external agencies such as the police, Health and Safety Executive or local authority, and where required, submitting evidence to contribute towards those investigations.
- Having processes to support collaboration and partnership working where joint investigations are required to avoid duplication of activity or confusion of responsibility.
- Involving and supporting patients, families and carers, and considering needs such as having an independent advocate or counselling, as well as supporting their liaison with other agencies.
- Giving staff involved the opportunity to access advice and support, information about the investigation and their role, and how the investigation is separate to any other legal or disciplinary processes.
- Reporting all serious incidents which meet the definition for a patient safety incident to the National Reporting and Learning Service for national learning.

As the trust undertakes these steps, concurrent governance processes will also be in effect, including board oversight of serious incidents; clinician's 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 unclear how a trust would be able to fulfil these responsibilities if the HSIB/HSSIB undertakes that local investigation in its place. Trusts should not be excluded from any investigatory processes undertaken into matters for which they are accountable and responsible.

We recognise that the *SIF* is currently under review by NHS Improvement, and that significant changes have been proposed that will likely affect the processes and duties on trusts outlined above. Furthermore, we recognise that these changes have been proposed by NHS Improvement, in consultation with trusts, regulators and commissioners, to address identified challenges and shortcomings with the current approach for the quality and learning from NHS local investigations. However, we cannot see how any changes would alter the fundamental responsibility on trusts to fulfil the duties set out above.

It is worth the Committee noting that the changes to the NHS policy for patient safety investigations will take some time yet to be confirmed and implemented, but the HSIB has already commenced maternity investigations with 11 providers in south east England without sufficient clarity of how the HSIB's work interacts with trust responsibilities.

The HSIB is in effect replacing a trust's investigation as well as the option of a further independent investigation, without itself taking on the relevant responsibilities and without acting according the principles, timescales and requirements of the *SIF*.

For example, we understand that from an early interaction one trust has reported to us, the HSIB's maternity investigations could take up to six months to be completed. If a trust decides that it still needs to carry out its own investigation to ensure a timely response to those involved, it may feel constrained in deciding on the level (ie, concise vs comprehensive) and how it carries out that investigation in order to minimise duplication and avoid added strain on the parents and staff. Trusts are also unsure as to how this would affect what they are able to share with those involved and other agencies, and how it would affect its potential conclusions and next steps.

The draft Bill and local investigations

The present model put forward in the draft Bill and related documents sets out the HSSIB as carrying out around 30 safe space investigations a year, and then accrediting trusts to carry out investigations likewise, whether internally or externally. The HSSIB, in doing so, is accountable to the Secretary of State.

However, the possibility that the HSSIB could lead local investigations in place of the trust fundamentally changes this, creating risk and jeopardy for trusts and the possibility of conflict with other legislation, regulation and guidance. The model of maternity investigations has not been considered in the drafting of the Bill, and a number of clauses need to be interrogated in this light.

1) *The HSSIB's mission, purpose and powers*
    - The HSSIB is intended to be a small organisation carrying out a small number of investigations a year.[3] This gives it an agility and lean approach which should lead to better collaboration and coordination, and builds on the approach taken in the transport accident investigation branches. To undertake 1000+ investigations requires a significantly greater infrastructure and resourcing, which necessarily moves more slowly and becomes a part of the system – reinforced by its answering to the Secretary of State – rather than a separate, objective and independent entity which recommends system-wide changes to facilitate local safety improvement.
    - For the HSSIB to carry out local investigations, it would seem necessary that there is a model of delegation (in contrast to the approach taken by other accident investigation branches), which most likely would take place through accreditation and the extension of safe space provisions to trusts. As we set out in our written

[3] As set out in the factsheets and impact assessment.

evidence, this creates an inherent conflict of interest. The system needs to undertake significant, long-term cultural change, demonstrating that it is open and learns from its mistakes. Safe space accreditation for trusts risks undermining this.

- The maternity investigations do not take place within safe space provisions. The national systemic investigations do. The draft Bill – rightly, given its intended focus on the latter investigations – does not contain provisions for safe space to be switched on and off. But if the HSSIB undertakes local investigations, will these then be undertaken within a safe space? Wouldn't trusts and other system agencies be further stymied in their work to provide an appropriate response if safe space provisions did apply? Conversely, how could trust in the HSSIB be maintained if the provisions only applied for some investigations?
- There seems to be significant potential for scope creep, enabled in part by an absence of detail and consultation around qualifying incident criteria. Rather than only 30 systemic investigations, it should be asked whether the HSSIB could also be undertaking national inquiries, case reviews and local investigations. Each of the latter have specific and necessary purposes, addressing different aspects of learning and redress, and we believe, as we outlined in our oral evidence, that there is a danger they cannot be satisfactorily undertaken by the HSSIB.
- As the impact assessment states, nearly 24,000 serious incidents were reported and investigated in 2016.[4] No single organisation could take these on – and we do not expect that the HSSIB would be tasked as such. However, it has already been tasked with undertaking a significant proportion of those (c1000 maternity investigations), which weakens the serious incident architecture within a trust and the internal expertise and focus a trust has on ensuring a skilled response.

2) The 2016 and 2018 Directions

As the explanatory notes state, the Bill allows for the "transfer to the HSSIB of any property, rights or liabilities of the NHS Trust Development Authority connected with the discharge of the HSSIB's functions". However, there is no explicit point of termination for those 2016 directions.

There is no mention of the 2018 maternity directions – which themselves refer to the 2016 directions, and the responsibilities of the Trust Development Authority in hosting the HSIB – and their status once the Bill is passed is unclear.

An alternative approach

To summarise the approach created and implied by the ministerial directions and draft Bill:

- In the **current situation,** trusts carry out local investigations, and independent investigations may also be commissioned. Until the creation of the HSIB, there was no body to carry out national systemic investigations.
- The **draft Bill** would establish the HSSIB as a safe space national investigator accountable to the Secretary of State, with accreditation enabling qualifying trusts to undertake investigations within safe space provisions.
- In the context of the **ministerial directions**, the draft Bill also creates the possibility that the HSSIB will replace local trust investigations (within or without safe space provisions). Whether the HSSIB would undertake case reviews and national inquiries is unclear.

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4 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/644839/HSSIB_impact_assessment.pdf

We propose an alternative approach which better achieves the intentions of establishing the HSSIB, and recognises that trust needs to be built throughout the system, through a number of ways, as appropriate to the context and objectives:

- As is current practice:
    - It is for trusts to undertake their own serious incident investigations individually or in co-operation with other entities as deemed appropriate.
    - Trusts may approach the HSIB to suggest a local incident as an opportunity for wider system learning.
    - The HSIB may approach a trust seeking the opportunity to investigate an incident that has been reported and which HSIB considers offers an opportunity for wider system learning.
- To improve current practice in local investigations:
    - The HSSIB could establish standards for educating and training incident investigators to ensure high quality local investigations and to help embed a culture of learning.
    - National and local NHS bodies, and staff from board to ward, need to live their role in enabling and role modelling a just culture.
- As we understood the draft Bill to be drafted:
    - The HSSIB should be explicitly focused on its c30 national systemic investigations taking place within safe space provisions – this will build trust through independence and psychological safety.
- To improve the draft Bill:
    - The types of investigation the HSSIB is expected to carry out should be clarified, with a duty to consult added on defining the qualifying incident criteria.
    - It should be made explicit that local trust investigations will not be replaced by those of the HSSIB.
    - There should be independence from the Secretary of State, with the HSSIB accountable to Parliament.
    - The intended powers of the Secretary of State in clause 4(2), wherein the HSSIB must consider his or her requests to carry out investigations, should be clarified.
    - There should be no capacity for providers to become accredited and take on safe space provisions – trust at a local level is built through transparency.

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.

Proposed next steps

To support the above amendments, we would suggest that the committee calls for an urgent piece of work is carried out to provide a full impact assessment wherein:

- A full consultation is undertaken on the potential for the HSSIB to undertake local investigations in place of trusts, with a particular emphasis on engaging trusts and those involved in the HSIB's maternity investigations.
- The full range of responsibilities a provider and other statutory bodies have to fulfil in the event of an incident are set out, both directly related to the incident and wider corporate governance duties.

- Any barriers to fulfilling those responsibilities in the event of the HSSIB carrying out a local investigation in place of the trust are set out, along with any arising risks, duplication and regulatory implications.
- Any conflicts between the policy objectives for safe space provisions and the HSSIB having the potential to switch off those provisions should be set out.
- Any conflicts between HSSIB applying safe space provisions while carrying out local investigations in the place of the trust should be set out.
- An analysis is provided of how any such conflicts and risks might be mitigated and managed, or whether an alternative approach is required.

Assessing the degree of conflict between the potential responsibilities of HSSIB and the existing responsibilities of a trust

We have been closely following the Committee's evidence sessions and are pleased that it has been exploring the issues we raised around the possible conflict between the potential responsibilities of the HSSIB and the existing responsibilities of a trust. While third parties will have a view on whether such a conflict exists, we would argue that it is vital the Committee gives appropriate weight to the views of trust board-level leaders who have to exercise trust responsibilities on a day-to-day basis. They are uniquely well placed to identify whether a potential conflict exists or not and are, we believe, significantly better qualified to assess the extent of any possible conflict than those who have not had to exercise such responsibilities. We also note that some witnesses to the Committee, when asked about these issues, do not seem to have taken into account the key point that the maternity investigations (as opposed to the 30 national systemic investigations) are designed to replace, not supplement, local trust level investigations.

We have had further discussions with trust leaders since our evidence session, including drawing on the early experience of the trusts where the HSIB is carrying out its first maternity investigations. That dialogue has served to heighten, not reduce, our concerns. We would be happy to bring together a group of trust leaders for a discussion with the Committee to explore this further.

I hope this is helpful to your consideration of the draft Bill, and would of course be pleased to provide further information or meet to discuss these issues.

Yours sincerely

Chris Hopson
Chief Executive

cc
Caroline Dinenage MP, Minister of State for Care, Department of Health and Social Care
Keith Conradi, Chief Investigator, Healthcare Safety Investigation Branch
Ian Dalton CBE, Chief Executive, NHS Improvement
Dr Kathy McLean, Executive Medical Director and Chief Operating Officer, NHS Improvement
Sir David Behan CBE, Chief Executive, Care Quality Commission
Simon Stevens, Chief Executive, NHS England

Annex 1: The HSIB's ministerial directions

The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016[5]: These establish the HSIB as a hosted organisation with a remit particularly focused on supporting the Secretary of State in discharging his duty to "secur[e] continuous improvement in the quality of services". The HSIB's function is to investigate "incidents or accidents which in the view of the Chief Investigator evidence, or are likely to evidence, risks affecting patient safety" and identify patient safety improvements, as well as "encouraging the development of skills used to investigate local safety incidents in the health service and to learn from them". The HSIB is accountable to the Secretary of State and to Parliament.

Safe space provisions are briefly set out, stating that disclosure of material gathered by the HSIB is to be avoided apart from in cases of "overriding public interest or legal compulsion".

The reports of the HSIB must focus on these aspects, and not "the activities of particular individuals". It is explicitly "not the function of the Investigation Branch in conducting investigations and publishing its findings, analysis and any recommendations, to identify civil or criminal liability in any matter, nor to apportion blame or otherwise support fault-based legal or regulatory or other formal action against persons whose actions come under consideration as part of its investigations".

It is understood that the HSIB/HSSIB is expected to carry out c30 investigations a year.

The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases)Directions 2018[6]: The HSIB is required to investigate all maternity investigations where stillbirth, early neonatal death or severe brain injury has occurred. In doing so, it must seek to establish the facts and sequence of events leading to the outcome, and consider any concerns raised by those involved. The HSIB "must consult and seek evidence or information" from the mother (or someone representing her interests) and her family, anyone involved in the care of the mother and baby, and anyone else considered necessary for the investigation. Safe space provisions do not apply to these investigations.

In concluding its investigation, the HSIB must consider where deficiencies in practice should be rectified at the relevant provider or more widely; disseminate its conclusions; alert NHS England and relevant clinical commissioning groups as appropriate; and inform the mother (so someone representing her interests). Thematic reports must be published annually.

It is understood that there will around 1000 such investigations a year, and that these investigations are "intended to be the primary and, as far as possible, the only investigation of the individual case … local staff will be involved as observers"[7] and "they will replace the local investigation".[8]

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[5] https://www.gov.uk/government/publications/nhs-trust-development-authority-directions-2016

[6] https://www.gov.uk/government/publications/nhs-trust-development-authority-hsib-maternity-investigations-directions-2018

[7] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/662969/Safer_maternity_care_-_progress_and_next_steps.pdf

[8] http://www.nationalhealthexecutive.com/Comment/the-hsib-approach-to-maternity-investigations

Annex 2: *SIF* investigation levels

The *SIF* sets out three levels of investigation[9]:

Level of investigation	Application	Timescale
Concise investigations	Suited to less complex incidents which can be managed by individuals or a small group of individuals at a local level	Should be completed within 60 days
Comprehensive investigations	Suited to complex issues which should be managed by a multidisciplinary team involving experts and / or specialist investigators	
Independent investigations	Suited to incidents where the integrity of the internal investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally due to the size of organisation, or the capacity / capability of the available individuals and / or number of organisations involved.	Should be completed within 6 months of being commissioned

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