House of Lords
House of Commons
Joint Committee on the
Draft Health Service Safety Investigations Bill

Draft Health Service Safety Investigations Bill: A new capability for investigating patient safety incidents

Report of Session 2017–19

Report, together with formal minutes relating to the report

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The Joint Committee on the Draft Health Service Safety Investigations Bill

The Joint Committee on the Draft Health Service Safety Investigations Bill was appointed by the House of Commons on 17 April 2018 and the House of Lords on 15 May 2018 to examine the Draft Health Service Safety Investigations Bill and to report to both Houses by 24 July 2018. The Committee ceased to exist on its production of this Report.

Membership

House of Lords
Baroness Billingham (Labour)
Baroness Chisholm of Owlpen (Conservative)
Baroness Eaton (Conservative)
Lord Elder (Labour)
Lord Kirkwood of Kirkhope (Liberal Democrat)
Baroness Watkins of Tavistock (Crossbench)

House of Commons
Sir Bernard Jenkin MP (Conservative, Harwich and North Essex) (Chair)
Diana Johnson MP (Labour, Kingston upon Hull North)
Mr David Jones MP (Conservative, Clwyd West)
Andrew Selous MP (Conservative, South West Bedfordshire)
Dr Philippa Whitford MP (Scottish National Party, Central Ayrshire)
Dr Paul Williams MP (Labour, Stockton South)

Powers

The Committee had the power to send for persons, papers and records; to sit notwithstanding any adjournment of the House; to report from time to time; to appoint specialist advisers; and to adjourn from place to place within the United Kingdom.

Publications

The Committee report was published on the Committee’s website and in print by Order of the House. Evidence relating to this report was published on the Committee’s website.

Committee staff

The staff of the Committee were Elizabeth Flood (Commons Clerk), Pippa Patterson (Lords Clerk), Stephen Aldhouse (Committee Specialist), Howard Daley and Claire Morley (Legal Specialists), Ian Hook (Senior Executive Officer), Debbie Courtney (Committee Assistant) and Samantha Colebrook (Committee Support Assistant).

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Summary

Since the Mid Staffordshire NHS Foundation Trust public inquiry under Sir Robert Francis QC reported in 2013, there has continued to be a number of high-profile reviews into incidents where patients have suffered serious harm. There is no doubt that avoidable risks to patient safety in UK health care are commonplace and widespread. In 2015, the House of Commons Public Administration Select Committee (PASC) reported that there are 12,000 avoidable hospital deaths every year. More than 24,000 serious incidents are reported to NHS England, out of a total of 1.4 million mostly low-harm or no-harm incidents annually. In order to improve patient safety, the Government accepted PASC’s central recommendation to establish a new body to conduct patient safety investigations into a small number of incidents, so that the system can learn from common failures, whether in procedures, or the training or management of staff, or in technology or policy. A shadow form of this body, the Healthcare Safety Investigation Branch (‘the present HSIB’), was established in April 2017. It is under the control of NHS Improvement, and lacks the necessary powers and independence to make it fully effective. However, it is intended to lead to the creation of a wholly new capability, separate from the rest of the healthcare system, for conducting investigations into patient safety incidents.

We have been given the task of examining the draft legislation to establish the Health Service Safety Investigations Body (HSSIB). Its independence and powers will be underpinned by statute, like the safety investigation bodies in other safety critical industries, so it can obtain the necessary information to make wide-ranging ‘system safety’ recommendations, including in such areas as staffing levels. HSSIB investigations will not seek to apportion blame, but will prioritise the consideration of ‘human factors’ as causes of the failures it identifies in the provision of healthcare.

At present, there are many pressures which can deter healthcare professionals from alerting the authorities to potential safety problems, or being frank about failings in patient care. These include: a lack of confidence in their own judgement; a culture of deference to senior staff or management; a bullying atmosphere; fear of the damage that may be done to their career if they admit failings; or, a perception that their concerns will be ignored. A common feeling is that it is not safe or prudent to speak out, despite existing obligations to be open, such as the duty of candour.

To obtain the best and most comprehensive information about patient safety incidents, HSSIB’s investigations will be able to operate in a ‘safe space’ for those taking part in them. The vital element of the ‘safe space’ is the confidence it provides that information given to HSSIB will not be unfairly used to expose any individual, but instead will help to produce factual conclusions and recommendations to improve patient safety.

One of the main purposes of the draft Bill is to set up the ‘safe space’: to protect information given to HSSIB. Various organisations were concerned that this will hide information which should otherwise be disclosed. We have listened with particular care to these concerns, since suspicion about HSSIB would undermine its effectiveness. Nonetheless, we are convinced by the evidence that the ‘safe space’ will only protect information held by HSSIB. The ‘safe space’ will have no effect whatsoever on any information or evidence already available, or which can still be acquired and made available by existing
healthcare bodies and non-HSSIB patient safety investigations. HSSIB’s reports will be additional to, not a replacement for, the investigations carried out by trusts, professional regulators, the Care Quality Commission and the Health Service Ombudsman. These assurances address these understandable concerns.

The Government also wants to improve the quality of local investigations, so it proposes that HSSIB accredit some NHS trusts and foundation trusts to undertake ‘safe space’ investigations themselves. They would carry out investigations into other trusts and, eventually, into incidents taking place in their own trust. Many of those who gave evidence to us raised serious concerns about this proposal. We listened carefully to their arguments and we are convinced that this idea is wholly misconceived. It represents too great a conflict of interest for the accredited trusts and would risk damaging confidence in the safe space concept itself. We recommend that this proposal be dropped from the Bill. HSSIB should be funded to help to improve the quality of the many thousands of investigations that are conducted across the health system through advising, assisting and providing training, but not by accrediting others to conduct ‘safe space’ investigations. HSSIB must be a new, independent and separate capability. Making it also a regulator of accredited trusts would confuse its role, and make it part of the system it is investigating.

The new HSSIB’s role has also been confused by the then Secretary of State’s understandable decision to direct the present HSIB to investigate all cases of stillbirth, neonatal death, suspected brain injury or maternal death. These 1,000 or so investigations are taking place outside of the ‘safe space’, and replace the local serious incident investigations conducted by trusts. The Government has suggested that the draft Bill might be amended to allow HSSIB to carry out such non-‘safe space’ investigations more widely. We also reject this idea. Much of the concern about HSSIB arises from a fear that it will undermine the duties of trusts, professional regulators, and the courts to investigate harm and provide accountability. There must be a clear distinction between HSSIB’s role—focussing on learning lessons of general relevance without finding blame—and that of the investigations run by other bodies: providing accountability for individual incidents and, if necessary, finding fault.

HSSIB will need to co-operate closely with trusts, NHS Improvement, the Care Quality Commission, the Health Service Ombudsman and professional regulators, to avoid conflicts over the timing of inquiries and to ease the practical burden on those who may have to give evidence to several different inquiries. However, we recommend that no statutory duty to co-operate should be imposed on HSSIB, as this would cast doubt on its independence from existing structures.

The draft Bill limits HSSIB’s remit to incidents which occur during the provision of NHS services, or at premises where such services are carried out. It also limits HSSIB’s remit to England, as healthcare is a devolved matter. We believe that both of these limitations pose potential problems as they do not recognise the complex interactions of health and social care, private and public healthcare, and the fact that many patients cross borders within the UK to receive aspects of their care under different administrations. We recommend that HSSIB’s remit should be extended to cover all healthcare in England, however funded. We recognise that HSSIB itself cannot be expected to take on responsibility for social care as a whole but suggest that its powers and the protections
of safe space be extended, so that HSSIB investigations can analyse all aspects of
the care pathway. With regard to cross-border care, we are clear that the devolution
settlements must be respected but recommend that the draft Bill should be amended to
enable reciprocal co-operation arrangements between HSSIB and the devolved health
systems, and to give devolved administrations the choice of participating in HSSIB, if
they so wish.

We considered the linked issues of the independence, governance and accountability of
HSSIB. Our witnesses emphasised that—to win the confidence of patients, healthcare
practitioners and other bodies with responsibility for patient safety—HSSIB had to
be, and be seen to be, independent of existing healthcare structures, including the
Department of Health and Social Care. We have made several recommendations
intended to increase HSSIB’s independence, including to reinforce its accountability to
Parliament.

We believe that HSSIB will play an important role in improving patient safety, and look
forward to the introduction of this legislation as soon as possible.
1  Introduction

The draft Bill

1. The draft Health Service Safety Investigations Bill ("the draft Bill") will establish the Health Service Safety Investigations Body (or HSSIB), an independent safety investigation body to conduct investigations into patient safety incidents, not for the purposes of finding blame, but to address patient safety risks in NHS-commissioned services in England. The draft Bill proposes to create a 'safe space', to protect information given to HSSIB from disclosure, in the same way as accident investigation bodies in other safety critical activities such as aviation. The draft Bill also provides for HSSIB to accredit NHS trusts to be able to carry out local investigations using 'safe space' (this aspect of the draft Bill is addressed in detail later in this report).\(^1\)

Who this report is for

2. The report by a pre-legislative scrutiny committee is usually written for parliamentarians, a technical and legal readership, and for those who already have close involvement with the issues. We have, however, written this report with a far wider audience in mind: clinicians and nurses, other NHS staff and managers; patients, patient advocates, patients’ families and carers. Parts of this report are inevitably technical, but we also intend it to be useful for readers who want to gain a broad understanding of the issues we address. Readers may find the list of terms and their definitions later in this chapter helpful.

Background

3. The draft Bill has emerged from several major reviews and reports into the handling and investigation of patient safety incidents published in recent years (culminating in the recommendations of a 2015 report by the House of Commons Public Administration Select Committee (PASC), Investigating Clinical Incidents in the NHS).\(^2\) These include the report of the Mid-Staffordshire NHS Foundation Trust Public Inquiry and the Freedom to Speak Up review by Sir Robert Francis QC,\(^3\) the Keogh Mortality Review,\(^4\) the Berwick review into patient safety,\(^5\) and the Report of the Morecambe Bay Investigation by Dr Bill Kirkup

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1 Department of Health, *Draft Health Service Safety Investigations Bill*, Cm 9497, September 2017
   In *Freedom to Speak Up*, Sir Robert Francis recommended the establishment of a national network of Freedom to Speak Up Guardians to support people who come forward with concerns about safety issues; who can ensure that the focus is on the safety issue that has been raised, who can make sure that it is properly investigated and addressed if found to be true; and who can ensure that there are no repercussions for the person who drew attention to it. Following this recommendation, a requirement for trusts and foundation trusts to have a Freedom to Speak Up Guardian has been in place since October 2016.
4 Professor Sir Bruce Keogh KBE, *Review into the quality of care and treatment provided by 14 hospital trusts in England: overview report* (July 2013)
CBE. These reviews highlighted the often poor quality of NHS incident investigations and emphasised the importance of moving away from a culture of individual blame to one of learning, to give healthcare professionals the confidence to be honest and candid when things go wrong.

4. Alongside these large-scale reviews, patients, families, and the organisations which represent them have continued to campaign for better investigations, calling for greater openness and transparency so people can find out what went wrong in their (or their loved one’s) treatment and care, and to enable lessons to be disseminated throughout the health service to ensure similar care failures do not happen again. Championed by Martin Bromiley and the Clinical Human Factors Group, there has also been growing recognition of human factors in patient safety incidents, and the value of investigations that focus on system safety rather than attributing blame to individual professionals.

5. Early in 2014 the Government published its response to the Francis Report, committing to stronger professional responsibility, and openness about mistakes and ‘near misses’, “following the example of the airline industry in building an open culture that learns from errors and corrects them.”

6. Later that year, Dr Carl Macrae and Professor Charles Vincent set out their vision for “a small, permanent independent agency charged with coordinating major inquiries and safety investigations in the NHS”, modelled on the approach of the aviation industry. This agency, they suggested, would provide a national, expert investigative capability in addition to the ‘local’ investigations carried out by individual NHS trusts into safety incidents. It would focus on the wider systemic factors contributing to serious failures of care in order to provide broader safety lessons, and could develop and spread investigative expertise across the NHS.

7. Macrae and Vincent’s paper prompted the 2015 PASC inquiry, which endorsed their call for the establishment of a national agency to investigate patient safety incidents in the NHS, not to find blame, but to promote learning and improvement. PASC’s report recommended that such a body should:

investigate the most serious patient safety issues, encourage improvement in the quality of local investigations, better capture and disseminate learning from them and serve as a resource of skills, expertise and experience for the conduct of clinical incident investigations.

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7 Clinical Human Factors Group, ‘Our history’, accessed 10 July 2018


8. After appearing before the PASC inquiry, in March 2015 the then Secretary of State for Health, Jeremy Hunt MP, expressed a belief that “the NHS could benefit from a service similar to the Air Accidents Investigation Branch” (the AAIB) and invited Dr Mike Durkin of NHS England to explore the possibility of establishing such a service.\footnote{HC Deb, 3 March 2015, col 835 [Commons Chamber]}

9. In 2016, the Government established an Expert Advisory Group to provide advice on establishing a Healthcare Safety Investigation Branch (or HSIB). The recommendations of this Group are shown in Box 1. The Government also launched a public consultation on whether introducing the ‘safe space’ principle to healthcare safety investigations—where information provided would be kept confidential unless there was an immediate risk to patient safety, or a High Court order permitting disclosure—would encourage NHS staff to speak up about incidents without the fear of being punished. Following this consultation, the Government determined it would “pursue the option of developing a ‘safe space’ approach for HSIB’s investigations” and—while acknowledging the concerns raised in the consultation—proposed to extend this to local investigations by NHS trusts which met specified conditions.\footnote{Department of Health, \textit{Providing a ‘safe space’ in healthcare safety investigations: Summary of consultation responses and next steps} (April 2017), p 19}

\begin{boxedtext}
\textbf{Box 1: Recommendations of the Expert Advisory Group on the establishment of HSIB}

1. HSIB must be, and must be perceived to be, independent in structure and operation; and must be established in primary legislation with stable institutional arrangements to guarantee this.

2. The objective of safety investigations must be to understand the causes of harm in order to improve systems and prevent future harm, not to apportion blame or liability.

3. Patients, families and staff must be active participants in the process of investigation; and must be engaged with and supported compassionately and respectfully.

4. HSIB must be empowered to investigate safety incidents and their causes anywhere across the entire healthcare system, including NHS organisations, national bodies, local government and commercial providers.

5. Investigations must be led by experts in safety investigation with deep knowledge of human factors, improvement science, healthcare policy and clinical practice appropriate to their role; the assistance and advice of subject matter experts should be co-opted as required. The Branch should provide leadership and expertise on safety investigation matters to the broader system.

6. HSIB must produce detailed reports that explain the causes of safety issues and incidents, and issue recommendations for improving patient safety across the system.

7. HSIB reports must be public documents, and recipients of recommendations must publish their response.
\end{boxedtext}
8. The Branch must promote the creation of a just safety culture, a shared set of values in which healthcare professionals trust the process of safety investigation; and are assured that any actions, omissions or decisions that reflect the conduct of a reasonable person under the same circumstances will not be subject to inappropriate or punitive sanctions.

9. The Branch must provide families and patients with all relevant information relating to their care, reflecting the responsibilities of healthcare providers to uphold the duty of candour. To ensure the continued provision of safety information, and the confidence of healthcare professionals, all other information collected solely for the purposes of safety investigation will be protected, and will not be passed to any other body, or be admissible as part of another body’s proceedings, other than when required on the instruction of a court of law.

10. Safety information must be provided to investigators honestly and openly on the understanding that it will not be used inappropriately. However, hiding or interfering with evidence is unacceptable, and should be made an offence. Similarly, when safety investigations uncover indications of wrongdoing, negligence, unlawful activity or other concerns that constitute an immediate danger to present or future patients, the Branch must inform the relevant responsible body and/or regulator, who may undertake their own inquiry and remedial action.


10. Following the publication of the Expert Advisory Group’s report, and the outcome of the Government’s ‘safe space’ consultation, HSIB began operating as a branch of the Department of Health (hosted by NHS Improvement) on 1 April 2017, led by Keith Conradi (formerly chief investigator for the AAIB). Mr Conradi’s appointment was subject to a pre-appointment hearing by the House of Commons Public Administration and Constitutional Affairs Committee—PACAC, PASC’s successor committee—in June 2016, and was approved unanimously.

11. Meanwhile, PACAC expressed concerns that key elements of PASC’s recommendations were not being implemented. PACAC recommended that HSIB should be established in primary legislation to secure its independence and to safeguard the principles protecting information from its investigations from disclosure. In response, the Government published the draft Bill in September 2017. It was subsequently decided that a Joint Committee of both Houses would provide for wider scrutiny and engagement with the draft Bill.

12. In November 2017, the then Secretary of State, Jeremy Hunt, instructed HSIB to investigate all cases of “stillbirth, neonatal death, suspected brain injury or maternal death”. This, the Government said, would amount to approximately 1,000 investigations per year.

14 Healthcare Safety Investigation Branch, https://www.hsib.org.uk/
17 Department of Health, Draft Health Service Safety Investigations Bill, Cm 9497, September 2017
and, significantly, they would be undertaken outside of the protections of the ‘safe space’. In order to discharge this responsibility, HSIB was allocated extra funding and began a process of recruiting a large number of additional investigatory staff. The implications of the Government’s decision to impose 1,000 additional maternity investigations on HSIB are assessed in Chapter 5.

Our inquiry

13. The Joint Committee was appointed by the House of Commons on 17 April and the House of Lords on 15 May 2018 to conduct pre-legislative scrutiny of the Government’s draft Bill. Both Houses instructed the Committee to report by 24 July 2018.

14. Within this timescale, we have given a range of stakeholders the opportunity to express their views. We held nine evidence sessions and issued a public call for written evidence which received 52 responses. Our witnesses included representatives of NHS management and trusts, professional associations, regulators, academic and legal experts, healthcare professionals, patient safety organisations, patients and family members and the Chief Investigator of the current HSIB, as well as the Minister of State for Care. A full list of those who gave oral and written evidence is attached to this report.

15. We take this opportunity to express our gratitude to all those who submitted evidence or appeared before us, often at necessarily short notice. We thank our Specialist Adviser, Gillian Stamp, who was also an adviser to PASC in their 2015 inquiry and report. We are also most grateful to the Government’s Bill team for their thorough and prompt assistance throughout this inquiry in responding to our various queries.

16. In making this report, we confirm our support for the Government’s ambition to improve patient safety and the quality of patient safety incident investigations within the NHS in England through the establishment of the proposed independent body. Our inquiry is just the start of parliamentary and public debate on this Bill, but we believe the Bill will be improved—and will be more likely to achieve the Government’s stated objectives—if the recommendations of this report are accepted. It is in this spirit that we commend our report to both Houses of Parliament.

Report structure

17. Chapter 2 sets out our understanding of the role and remit of HSSIB, aiming to address concerns resulting from confusion about the additional capability which HSSIB will provide, the nature of the investigations it will conduct, and its relationship with other regulatory and investigative bodies. Chapter 3 explores the concept of the ‘safe space’, why it is needed, and why evidence and information gathered by HSSIB must be protected from disclosure. Chapter 4 considers proposals for HSSIB to accredit NHS trusts to undertake local ‘safe space’ investigations, why this is not appropriate and, consequently, why we recommend removing this provision from the legislation. Chapters 5 and 6 examine the scope, powers and procedures of HSSIB. Finally, Chapter 7 considers the draft Bill’s provisions relating to HSSIB’s independence and accountability.

18. In Appendix 3 we list a range of technical drafting points which we put to the Government’s Bill team during the inquiry. The Government’s response to those points
is included in Appendix 3, together with our conclusions and recommendations on those issues. The Government should implement the technical recommendations listed in the final column of Appendix 3.

**Definition of terms**

19. It may be useful to explain what we mean when using certain terms in this Report:

- **'Accredited trust'** an NHS trust or foundation trust approved by HSSIB to conduct certain safety investigations with the benefit of the prohibition on disclosure which creates a ‘safe space’ for participants.

- **'Duty of candour'**
  
  i) a legal duty, imposed on health and social care providers and managers, and enforced by the Care Quality Commission (CQC), to ensure that all providers registered with the CQC are open and transparent with people who use services when something goes wrong.\(^\text{18}\)

  ii) a professional duty to which healthcare professionals are subject by their regulators which ensures that healthcare professionals are open and honest with patients.\(^\text{19}\)

- **'English NHS body'** (with regard to HSSIB’s scope) all bodies delivering NHS services in England, including primary, secondary, and tertiary care services.

- **'Healthcare professional'** a person who is qualified and allowed by regulatory bodies to provide a healthcare service to patients, including members of the medical, dental, pharmacy, nursing, midwifery, and allied health professions.

- **'HSIB'** the Healthcare Safety Investigation Branch, which began operating in April 2017; see also ‘HSSIB’.

- **'HSSIB'** the Health Service Safety Investigations Body which this draft Bill will establish.

  N.B. To reflect the Committee’s conclusions regarding the scope of HSSIB, in Chapter 5 we recommend that the body should be renamed the Healthcare Safety Investigations Body. To avoid confusion with the current HSIB, we continue to refer to the new body as HSSIB throughout this report.

- **'Human factors'** organisational, individual, environmental and job characteristics that influence behaviour in ways that can have an impact on safety.\(^\text{20}\)

- **'Just culture'** embodies a “commitment to learning from mistakes but also allows for people and organisations to be held to account for reckless behaviour that causes harm.”\(^\text{21}\)

- **'Near miss'** an event not causing harm, but that had the potential to cause injury.

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\(^{18}\) Care Quality Commission, ‘[Regulation 20: Duty of candour](https://www.cqc.org.uk/guidance/regulations)', accessed 11 July 2018

\(^{19}\) Nursing & Midwifery Council, ‘[Read the professional duty of candour](https://www.nmc-uk.org/what-we-regulate/role-and-duty/candour)', accessed 11 July 2018

\(^{20}\) Clinical Human Factors Group, ‘[What are clinical human factors](https://www.clinicalhumanfactors.org.uk/what-classification-clinical-human-factors)', accessed 11 July 2018

\(^{21}\) Care Quality Commission ([SIB0040](https://www.cqc.org.uk/about/corporate-service-identity), para 2.7
‘Patient advocates’ are independent of social services and the NHS, and are not part of a patient’s family or one of their friends. An advocate’s role “includes arguing a patient’s case when [needed], and making sure health and social care services follow correct procedures”.\(^{22}\)

‘Patients, families and carers’ the terms ‘patients’, ‘patients and families’, and ‘patients, families and carers’ are used interchangeably in this report.

‘Patient safety incident’ “any unintended or unexpected incident which could have or did, lead to harm for one or more patients receiving healthcare”.\(^{23}\)

‘Safe space’ (in the context of the draft Bill) the protection of information, etc., held by HSSIB in connection with its investigations, by barring HSSIB from disclosing it (except in certain limited circumstances), to encourage people to speak freely to it.

‘Satellite services’ services run by an NHS trust in locations other than their main unit e.g. The Walton Centre NHS Foundation Trust based in Liverpool runs satellite neurology clinics across its catchment population (which includes North Wales) to enable people to access outpatient consultations and some tests closer to their homes.

‘System safety’ / ‘systemic factors’ a focus on all aspects of the healthcare system that affect safety, which may include people, process or procedures, technology, equipment, or policy and regulatory requirements—‘systemic’ issues or failures might include system design, inadequate management systems or poor training which induce errors.\(^{24}\)

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\(^{22}\) NHS Choices, ‘Your guide to care and support’, accessed 24 July 2018

\(^{23}\) NHS Improvement, ‘Report a patient safety incident’, accessed 11 July 2018

\(^{24}\) Clinical Human Factors Group, Human factors in healthcare: commons terms (2015)
2 Purpose of HSSIB

Independent patient safety investigations

An independent capability

20. The Health Service Safety Investigations Body is intended to be an independent organisation with powers to investigate serious patient safety incidents for the purpose of improving patient safety in England. It will be a new capability, utilising the protection of ‘safe space’ to gather information for the single purpose of making healthcare safer. It is significant that HSSIB will not be part of the Department of Health and Social Care (“the Department”) or the NHS. It will be able to make recommendations to anyone (individual or body) but will not be responsible for enforcing its recommendations.

21. The Government told us that establishing HSSIB in statute as a non-departmental public body will underscore its independence from Government and the health service. Nevertheless, the draft Bill provides for the Secretary of State to exercise a number of powers over HSSIB including the right to make representations in relation to investigations (clause 4). This suggests that HSSIB and its investigations will be under the influence of the Secretary of State, which is not what is intended. There should be no inhibition on the Secretary of State or anyone else making their views known about any matter concerning HSSIB, but it is wrong to give the Secretary of State special status in this regard. We make recommendations about this and HSSIB’s wider governance in Chapter 7.

Learning centred investigations

22. The Government said that HSSIB will “focus on those incidents where there is the greatest potential for system learning”. Part 2 of the draft Bill is clear that it is not the purpose of HSSIB to establish blame, civil or criminal liability, or whether action needs to be taken by a regulatory body. Its purpose is solely to investigate the causes of patient safety incidents in order to identify and to address “risks to the safety of patients by facilitating the improvement of systems and practice in the provision of NHS services”. The term ‘systems and practice’ can mean anything that affects what people do, or do not do, in healthcare. This could include their training, their habits and attitudes (‘human factors’), their equipment, the drugs or treatments they use, or the way they are managed or regulated, how their responsibilities are funded, or even the framework of government policy.

23. Chris Hopson, Chief Executive of NHS Providers, described how trusts anticipate that HSSIB will operate. He said that HSSIB’s work will be:

effectively to conduct a small number of systematic reviews that look at serious incidents where there have been failures across a number of trusts. For example, trust A, trust B and trust C might have the same problem, but it might not be apparent to the system unless somebody is looking at that systemic level.
24. We discuss how HSSIB will operate in more detail in Chapter 6, but we must first clarify the role of HSSIB—what it will do and what it will not do—and the relationship between HSSIB’s investigations and the investigations and other actions which other bodies, like NHS trusts, are expected to take when a serious patient safety incident occurs. It will be for HSSIB to determine the criteria for investigation. The Government’s fact sheets relating to the Bill note that HSSIB can consider a request from any patient or family member to launch an investigation. Sir David Behan, Chief Executive of the Care Quality Commission (CQC), characterised HSSIB as filling a gap that currently exists in the inspection and investigative systems related to the NHS:

In the six years I have been doing this role, a number of individuals have come to us wanting their individual circumstances investigated. The CQC does not have the powers to carry out individual investigations of circumstances. […] One thing that is being done is the filling of a gap around individual investigations.

25. It will be for HSSIB to choose how it incorporates specific individual cases into its safety investigations but, as described by Keith Conradi, these will only be “reference events” which “anchor” the wider work. Dr Carl Macrae of the University of Oxford explained how, in practice, HSSIB’s investigations will differ from those undertaken locally:

the core intent of HSSIB is to investigate an area of systemic risk to patient safety. It will use particular incidents to explore that. That is a very different proposition from what local trusts and organisations need to do when they are investigating an incident to understand it for their own organisation and for the family to provide information.

Jennifer Benjamin, Deputy Director, Quality, Patient Safety and Investigations at the Department of Health and Social Care, confirmed that the Government’s interpretation of how HSSIB will function is consistent with that of its Chief Investigator:

the purpose of this body is not to investigate individuals, but to try to understand what the systemic risks and issues were which pervaded the organisation and the wider system, and to benefit from that.

26. The fact that HSSIB will be resourced to undertake approximately 30 investigations a year underlines that there is no intention for it to become a body which adjudicates on individual cases. This was acknowledged by Keith Conradi.

**Enforcement of recommendations**

27. Nor is it intended that HSSIB will be the enforcement body for the safety recommendations that it makes. Dr Macrae argued: “as soon as it is required to enforce
and hold to account organisations for recommendations it has made, it is no longer independent—it becomes part of the system it is investigating.Keith Conradi described how HSSIB will approach its role in relation to enforcement of safety recommendations:

I am keen that our recommendations are not mandated. Our expertise is only in the investigation. [...] Throughout the investigation, we are already discussing what we think needs to be done and what the problems are. By the time we make it—this is certainly so for the ones to date—we have had an understanding from the addressee of what it is we are after. The key thing then is that we make them public. We require response. I like in the draft Bill where it talks about us being able to dictate the time within which there has to be a response back to us.

28. Echoing Dr Macrae, Mr Conradi emphasised that HSSIB should guard against extending its remit into enforcement and regulation of recommendations. He said HSSIB will:

have to be careful about taking HSIB any further than that, because we are not an enforcing branch or a regulator. It is important that we have the distinction between the two.

29. We welcome the clarity about HSSIB’s role. It is intended that HSSIB will be a wholly new statutory and independent capability, separate from the rest of the healthcare system, for conducting investigations into patient safety incidents. HSSIB will not be part of the complaints system. HSSIB may undertake individual investigations, but not because patients and families are dissatisfied with the outcomes of existing processes. Equally, as the Chief Investigator makes clear, HSSIB will not act as a regulator or an enforcement agency as either responsibility would compromise its role and independence from the system it is meant to be investigating.

Culture in healthcare: attitudes and behaviours

30. The term culture, can mean different things in different contexts and can be confusing. In this report, when we discuss the culture of any profession or organisation, we mean the attitudes and behaviour which the people that work in the profession or organisation tend to adopt. Attitudes and behaviour are related to the values and habits common to groups of people working in a shared environment. Therefore talk of culture change is about promoting the right values, attitudes and behaviour, and discouraging the wrong ones.

31. The Government says that the presence of HSSIB, and the undertaking of ‘safe space’ investigations are intended to contribute to a broader culture change in the NHS. The Government’s impact assessment, which sits alongside the draft Bill, said that the intended effects of the legislation are to “encourage a culture of learning and safety improvement throughout the NHS.” The impact assessment added:

34 Q279
35 Q448
36 Q448
38 Department of Health, Health Service Safety Investigations Bill: Impact Assessment (June 2017), p 1
Patients and NHS staff deserve to have patient safety incidents investigated immediately so that the facts, evidence and underlying risks of an incident are established early, without the need to find blame, and regardless of whether a complaint has been raised.\textsuperscript{39}

32. This, the Government contends, will help “act as a catalyst to promote a just and open culture across the whole health system.”\textsuperscript{40} At present, the Department of Health states, there are cultural barriers which prevent investigation and learning within the NHS:

Staff involved in investigations may be uncomfortable with speaking openly and could possibly hold back information for fear of blame and litigation. NHS staff leading investigations do not have the time or skills or necessary support to uncover the root cause of what led to the incident. Organisational and cultural barriers could prevent thorough investigation and learning.\textsuperscript{41}

33. Professor Clare Gerada, a GP and medical director of the NHS Practitioners Health Programme, a free and confidential service concerned with the mental wellbeing of doctors, told us that fear has become “part of the fabric” of daily working life for people at all levels of the NHS.\textsuperscript{42} This, Professor Gerada argued, was because of a blame culture attached to investigative attitudes and practices. Her evidence also highlighted her campaign for a new code of conduct to be introduced within the NHS and implemented by all trusts. She argued that all investigations conducted by trusts should be initiated with the protections of ‘safe space’. In addition, her proposal would require trusts:

\begin{itemize}
  \item to operate within a time limit with the obligation that [they] should provide support for clinicians. These measures will protect both patients from further harm and clinicians from harm to their mental health.\textsuperscript{43}
\end{itemize}

34. The Government asserts that HSSIB will contribute to a ‘just and open culture’ which our witnesses explained is not the same as a ‘no blame’ culture. The CQC’s written evidence said that a just culture embodies a “commitment to learning from mistakes but also allows for people and organisations to be held to account [emphasis added] for reckless behaviour that causes harm.”\textsuperscript{44} The Royal College of Physicians said that “HSSIB will need to uphold the principle of a ‘no blame’ culture in practice if it is to gain the confidence of healthcare professionals”.\textsuperscript{45} Indeed, HSSIB investigations will not seek to find or apportion blame or responsibility for adverse events. Nor will it replace other regulatory or investigatory processes which do seek to establish whether individuals or organisations are culpable and need to be held to account.\textsuperscript{46}

35. Commenting on the wider perception related to the culture which tends to persist in trusts, the Government noted that there had been considerable support from consultees for HSSIB’s leadership role in creating a learning culture, and a recognition that HSSIB’s credibility rests on its ability to do this job well.\textsuperscript{47}

\textsuperscript{39} Ibid, para 22  
\textsuperscript{40} Ibid  
\textsuperscript{41} Ibid, para 23  
\textsuperscript{42} Professor Clare Gerada (SIB0048), para 16  
\textsuperscript{43} Professor Clare Gerada (SIB0048), para 55  
\textsuperscript{44} Care Quality Commission (SIB0040), para 2.7  
\textsuperscript{45} Royal College of Physicians (SIB0019), para 9  
\textsuperscript{46} Department of Health,\textit{ Fact sheet 6: the investigation process} (September 2017), para 21  
\textsuperscript{47} Department of Health,\textit{ Health Service Safety Investigations Bill: Impact Assessment} (June 2017), para 103
36. Dr Simon Fleming, a trauma and orthopaedic registrar, argued that there is a fundamental problem within the NHS of a bullying culture based on hierarchical structures. For HSSIB to gain credibility, he said:

The HSSIB will need to be seen by patients, their families and staff alike, to be part of a ‘just culture’ whereby those in the NHS are not punished for actions, omissions or decisions taken by them which are commensurate with their experience and training, but where gross negligence, wilful violations and destructive acts are not tolerated.  

37. Harry Cayton, Chief Executive of the Professional Standards Authority (PSA), however, said that recent initiatives such as the application of the duty of candour have started to change the culture in the NHS.

I do not believe we have to have a blame culture. I am not sure that I agree with those who always say we do. I know lots of clinicians who are involved in Schwartz rounds and a whole range of activities of self-analysis and reflection in groups. I know lots of trusts where there is this kind of positive thinking about sharing things that have gone wrong with each other. I have done training sessions with trusts myself, where I have found clinicians extremely willing to be open and frank about past problems.

Furthermore, Mr Cayton said that the professional regulators had taken steps to adapt their fitness to practice framework so that it was consistent with a just and learning culture, moving it away from blame and towards remediation. He noted that this was an issue addressed in the Government’s recent consultation on reforming professional regulation.

38. We also heard that some local investigations into serious incidents had moved away from simply seeking to apportion blame. Professor Brian Toft, Emeritus Professor of Patient Safety, Coventry University, told us:

Recently I reviewed about 20 or 30 different investigation reports, from different places, including Oxford University Trust. There was only one case where a person was wrongly accused of having made that mistake, but for the rest, they haven’t pointed the finger at anybody. They said that where there had been systemic failures, they had spotted them themselves, which I thought was rather good.

39. Peter Walsh of Action against Medical Accidents (AvMA) provided anecdotal evidence of improvements in the culture within the NHS which had developed as a consequence of the introduction of the professional duty of candour:

It takes time for that cultural change to bed in, but I think we are beginning to see the difference that people are increasingly going to full openness as the natural approach.

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48 Mr Simon Fleming (SIB0026), pp 1–2
49 ‘Schwartz Rounds’ provide a forum where all staff discuss the emotional and social aspects of working in healthcare: The Point of Care Foundation, ‘About Schwartz Rounds’, accessed 24 July 2018
50 O135
51 O145
52 O240
53 O167
40. This, however, was not the universal view, and the Clinical Human Factors Group said the duty of candour had not changed attitudes and behaviours within the NHS:

Anecdotal evidence from organisations our members work for, suggests that the majority of organisations have not fully embraced the spirit of openness and transparency, enshrined in the DoC [Duty of Candour] Regulations. Rather they have implemented mechanisms to provide assurance to regulators they are complying with the DoC regulations, taking a tick-box approach, rather than a humane one.\(^4^4\)

41. Keith Conradi warned against expecting HSSIB to achieve too much in changing the culture:

It is managing expectations again. We are but a small part of the safety system, and that is a really important message for us to get over. We are here to do highly professional investigations and make recommendations to the system. We play our part, but it needs everybody to play their part for the whole system to work.\(^5^5\)

42. The NHS in England employs over 1.2 million people. It is not a single organisation but a complex system composed of multiple cultures across varied organisations and geographies. By the term, culture, it is important to understand that we are talking about attitudes and behaviour. Culture change is about changing attitudes and behaviour; encouraging the right attitudes and behaviour, and discouraging the wrong ones (such as bullying). This is the responsibility of every individual in healthcare and, in the NHS in particular, clinical and system leaders must take responsibility for demonstrating attitudes and behaviour consistent with a just culture.

43. It is impossible for any single organisation to change the established values and habits prevalent within the NHS. We also recognise the work already being done by trusts—and through initiatives such as Freedom to Speak Up Guardians—to improve the culture within the NHS. HSSIB should not, on its own, be expected to achieve culture change; but, as a new and independent capability, it can provide leadership and demonstrate behaviour which will lead to a healthier and more open culture in healthcare.

44. HSSIB investigations will operate in the ‘safe space’ which will reduce the fear of talking openly. The objective of HSSIB investigations is not to find blame. Other investigatory activity in healthcare will still focus on making assessments of responsibility and accountability for errors. In the long–term, HSSIB’s contribution to culture change will be by demonstrating to patients, clinicians, providers, regulators and other investigators the value of patient safety investigations which examine context, focus on learning, and which do not find or apportion blame. In doing so, HSSIB can influence the development of a just culture where learning is paramount and errors are understood within the context of ‘human factors’ and the environment in which individual health professionals provide care.

\(^{54}\) Clinical Human Factors Group (SIB0017), pp 3–4

\(^{55}\) Q447
Box 2: Legal protection of doctors’ reflections

Several witnesses described concerns about the use of doctors’ reflections in investigations. The purpose of self–reflection is to enhance learning and professional development, but Dr Chaand Nagpaul, Chair of Council at the British Medical Association (BMA), told us that doctors were concerned that their written reflections on their own clinical practice could be used against them in fitness to practice or criminal proceedings. 56 Significantly, this concern was also described in the evidence submitted by the General Medical Council (GMC):

For reflection to be an effective tool for learning, doctors need to feel confident that they can reflect on their practice, including errors and mistakes, in the knowledge that these reflections will not later be used in evidence against them in criminal or other proceedings. 57

The GMC said that doctors’ reflections would not be required by the GMC as part of a fitness to practice investigation, 58 but noted that there is no restriction in relation to criminal cases. They have called on the Government to provide legal privilege to doctors’ reflections so that they cannot be admitted in court. 59

This draft Bill is not the vehicle by which doctors’ reflections could be offered legal protection, but we recognise that the concerns of doctors mirror their wider fears about speaking openly. If reflections were legally protected then this protection might share some of the characteristics and potential benefits of the ‘safe space’. We note, however, that Sir Norman Williams’ rapid review into gross negligence manslaughter in healthcare did not support the legal protection of reflections made by doctors or any other professional group in healthcare. 60

56 Q109
57 General Medical Council (SIB0030) para 14
58 General Medical Council (SIB0030) para 16. Professor Sir Norman Williams, Gross negligence manslaughter in healthcare: The report of a rapid policy review (June 2018) recommended that professional regulators in healthcare should lose the power to require reflective material from registrants: see para 10.11 and recommendation on p 34.
59 General Medical Council (SIB0030) para 15
60 Professor Sir Norman Williams, Gross negligence manslaughter in healthcare: The report of a rapid policy review (June 2018), para 10.5
3 The ‘safe space’ (the prohibition on disclosure)

Introduction

45. In this chapter, we explain what is referred to as the ‘safe space’, which is the prohibition on disclosure of information in the draft Bill, and we consider:

- what outcome the Government hopes to achieve, whether it is what patients want, and whether the ‘safe space’ is likely to help;
- possible side-effects of having this;
- the material which is, or ought to be, protected by the ‘safe space’;
- exceptions to the prohibition, i.e. what ought to be disclosable from within the ‘safe space’;
- how such disclosed information and HSSIB reports can be used for such purposes as evidence before the courts, or for disciplinary purposes; and
- how the draft Bill will interact with data protection legislation.

46. The proposal that NHS trusts be ‘accredited’ to conduct ‘safe space’ investigations is addressed in Chapter 4. In the draft Bill as it stands, references are to HSSIB or an accredited trust. In the light of our recommendation in Chapter 4 that NHS trusts should not be accredited to conduct ‘safe space’ investigations, in this chapter we refer only to HSSIB.61

47. The term ‘safe space’ is not used in the draft Bill, but is widely understood to mean the prohibition, in clauses 28 to 30, of “the disclosure of any information, document, equipment or other item held by the HSSIB […] in connection with an investigation, apart from in certain limited circumstances”.62 It is designed, the Government says, to “encourage NHS staff and other medical professionals to speak freely during the course of an investigation in the knowledge that information they provide will not be passed on” unless an exception applies.63 The draft Bill also provides for exceptions to this prohibition, which are listed in clause 29. They allow for disclosure to the police, to various NHS bodies, or to professional regulators, in defined circumstances. We examine these below.

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61 Except when discussing an effect of ‘safe space’ which is particularly relevant to investigations carried out by an accredited trust. See paragraph 81.

62 Department of Health, Factsheet 3: The Draft Health Service Safety Investigations Bill ‘Safe space’: what is it, why we need it and how it will work (September 2017), para 1

63 Ibid, para 4
Box 3: Expert Advisory Group recommendations: ‘safe space’

The Expert Advisory Group proposed that information should not—generally—be disclosed by the HSIB. It said that a bar on disclosure of information and its use in court would "underpin a just culture that ensures the continued provision of safety information and the confidence of healthcare professionals".64

The group made the following recommendations of direct relevance to the issue of ‘safe space’:

9. The Branch must provide families and patients with all relevant information relating to their care, reflecting the responsibilities of healthcare providers to uphold the duty of candour. To ensure the continued provision of safety information and the confidence of healthcare professionals, all other evidence collected solely for the purposes of safety investigation will be protected and will not be passed to any other body or be admissible as part of another body’s proceedings, other than when required on the instruction of a court of law.

10. Safety information must be provided to investigators honestly and openly in the understanding that it will not be used inappropriately. However, hiding or interfering with evidence is unacceptable and should be made an offence. Similarly, when safety investigations uncover indications of wrongdoing, negligence, unlawful activity or other concerns that constitute an immediate danger to present or future patients, the Branch must inform the relevant responsible body and/or regulator, who may undertake their own inquiry and remedial action.

The Expert Advisory Group thought legislation should “give powers to compel organisations and individuals to participate” in investigations and share information in a timely fashion, and that it should be an offence to conceal or tamper with evidence.65 It also concluded HSIB should notify relevant authorities where it identified concerns that might endanger future patients.66

Justification for the ‘safe space’ (the prohibition on disclosure)

The desired outcome

48. William Vineall, Director, Acute Care and Policy at the Department of Health and Social Care (DHSC), explained that, “in having a pretty sealed safe space, we will be able to produce reports that get to the bottom of things in the way that the NHS isn’t able to at the moment.”67 But there is a tension, which we explore later, between maintaining confidentiality in order to get to the truth and sharing information with patients, so we were particularly keen to try to understand what patients themselves want.

67 Q400
49. Some patients, and patient representative organisations, told us that lessons should be learnt to avoid repetition of mistakes. Susanna Stanford, who suffered an immensely painful and traumatic incident as a mother undergoing a caesarean section, told us:

Like so many patients who seek answers, I was desperate that other patients should not experience a similar situation if it could be avoided.  

and

‘Safe space’ is vital for clinicians to be able to trust the system and it should help achieve what most patients want when they complain: simply that learning can take place so the same error is not repeated with someone else.

50. A mother told us in harrowing detail about the painful death of her 14-year-old daughter following surgery in 2015. Her view was that:

Although a duty of candour had been introduced in 2014 the process, certainly in my experience in 2015, was that the system worked against showing any candour. A safe space would encourage people to speak honestly …

51. We note that it is important to understand that some patients may not want their patient information to be shared with their families or others.

52. John Tingle, Associate Professor at Nottingham Law School, Nottingham Trent University, told us: “Often patients just want an apology, an explanation of what occurred and an assurance that it will not happen again.” The Equality and Human Rights Commission thought it important that there be “a presumption of disclosure in the investigation report of all information necessary to ensure that the patient and/or their family understands why the incident occurred and the steps which are required to ensure that similar incidents do not happen in the future.”

53. We nevertheless recognise and have taken into consideration the strong and natural desire on the part of patients to obtain all information possible about treatment—investigations ultimately are all about what has happened to them—and to seek justice. The Association of Personal Injury Lawyers thought that a ‘safe space’ might lead to necessary information not being obtained before proceedings were started:

negligent failings may not come to light. A case that should be pursued may not be, leading to a denial of access to justice, and a failure to bring those responsible for the negligence to account.

As AvMA told us, “there is nothing ‘unfair’ about injured patients seeking compensation for harm caused, and NHS staff are not personally liable as the NHS takes vicarious liability.”

68 Susanna Stanford (SIB0016), para 5
69 Susanna Stanford (SIB0016), para 15.2
70 Anonymous (SIB0011), para 22
71 Mr John Tingle (SIB0003), p 4
72 Equality and Human Rights Commission (SIB0008), para 19
73 Association of Personal Injury Lawyers (SIB0006), para 10
74 Action against Medical Accidents (AvMA) (SIB0021), p 2
54. We are persuaded by patients, and their representative organisations, that there is nothing unreasonable about injured patients seeking compensation or other redress. Therefore, this Bill and HSSIB should place nothing in the way of patients and their families’ ability to seek compensation. The importance of this principle is reflected in the recommendations we make.

55. We also have been guided by a second principle, namely that the primary and overriding purpose of this Bill is to put in place arrangements that will lead to learning and improvement arising from objective and comprehensive analysis of the causes of clinical mistakes and incidents, leading to better and safer outcomes for users of the healthcare system. We do not think this second principle is incompatible with obtaining justice in individual cases, which may and should be pursued by other means.

56. It is in the wider public interest, and in the interest of patients and everyone in healthcare, that procedures be pursued that will assist in improving patient safety. Subject to the reservations set out below, we are therefore supportive of the proposal to provide for ‘safe space’.

**Likelihood of achieving the desired outcome**

57. Most of our witnesses considered providing a ‘safe space’ to be an effective way of eliciting all the information necessary to learn lessons and improve patient safety. NHS Providers referred to “a wide body of research” supporting this conclusion. Dr Simon Fleming said:

> You cannot learn unless you are in a safe space. Anywhere there is a fear of recrimination or of your own reflections being used against you, by definition people will not reflect. You cannot ask people to talk openly and honestly about their experiences, knowing that that will then immediately be visited upon them.

The Patients Association suggested that the consequences experienced by some who had raised concerns provided “ample justification for those fears” and concluded that it was right to try the new approach of ‘safe space’ during HSSIB investigations.

58. The Nursing and Midwifery Council (NMC) explained how their views had changed:

> although our initial response to these regulations was very much aligned with the PSA’s and we were concerned that by creating a safe space we might, as regulators, be regarded as an unsafe space, we recognise that this middle stage that HSSIB can develop probably needs to happen. It should then become a model for good investigation. Eventually, we can almost remove the safe space boundary because people will feel confident that, if they say to HSSIB that they did something wrong, we as the NMC will then recognise that nothing will happen to them because they showed insight, remediation; they don’t need regulatory action.
59. Pharmacist Nick Butler told us: “the pressure for the recent change in the law decriminalising dispensing errors made by some pharmacy staff demonstrates how the risk of prosecution affects what individuals will disclose.”\textsuperscript{79} The Royal College of Midwives thought the prohibition on disclosure will reassure patients, families and staff, “particularly where concerns about fear or reprisals from management can prevent someone from speaking out on patient safety issues.”\textsuperscript{80}

60. By contrast, Solicitors Mills & Reeve LLP thought the ‘safe space’, as drafted, will be ineffective because the “risk of criminal liability and regulatory referral will still result in individuals being wary of speaking freely.”\textsuperscript{81} The Royal College of Physicians and Surgeons of Glasgow gave similar evidence\textsuperscript{82} And the Campaign for Freedom of Information cast doubt on the provision’s efficacy:

The exceptions rightly permit information about misconduct or continuing risk to patients to be passed to professional regulatory bodies or NHS employers who can suspend, strike off or dismiss a health professional. To the health professional who fears that they or a colleague may have made a serious mistake, the consequences of the permitted disclosures are likely to be a far greater deterrent to frank admission, than any concern about a possible FOI disclosure.\textsuperscript{83}

61. AvMA suggested there was no need to prohibit disclosure of information from investigations to patients:

no evidence has been put forward to show that staff are not […] taking part in investigations because of the fear of their evidence being shared with key parties such as the patient or family concerned, or of unfair consequences being experienced by someone who has given evidence to an investigation as a result of this being shared with the patient or family concerned.

We believe it is true to say that some staff are anxious about taking part in investigations fully and frankly. However, we have canvassed health professionals widely and when asked what they are worried about, it is almost always the case that they are worried about how they will be treated by their boss/employer.\textsuperscript{84}

The PSA also thought that “although concerns about personal repercussions, for example risk of litigation or effect on career do figure, there are a range of other factors which appear to be at least as important if not more so.”\textsuperscript{85}

62. In the Committee’s view, Professor Murray Anderson-Wallace, and his fellow independent members of the HSIB Advisory Panel, captured the position neatly:

\textsuperscript{79} Mr Nick Butler (SIB0005)
\textsuperscript{80} Royal College of Midwives (SIB0029), para 4.1
\textsuperscript{81} Mills & Reeve LLP (SIB0022), p 3
\textsuperscript{82} Royal College of Physicians and Surgeons of Glasgow (SIB0007), p 3
\textsuperscript{83} The Campaign for Freedom of Information (SIB0039), para 13
\textsuperscript{84} Action against Medical Accidents (AvMA) (SIB0021), p 1. See also Qq194–195; and the Professional Standards Authority for Health and Social Care (SIB0031), para 2.6.
\textsuperscript{85} The Professional Standards Authority for Health and Social Care (SIB0031), para 3.11
A legally protected ‘safe space’ in healthcare is as yet completely untested and it is therefore impossible to say with absolute certainty if this will promote greater learning to improve safety. Speaking freely and feeling confident to be honest is a product of a healthy and just workplace culture, where learning and accountability are well balanced. This type of culture does not exist in too many healthcare environments and much work needs to be done to foster it.\(^6\)

63. **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.**

**Other justification**

64. Another possible justification for providing ‘safe space’, albeit not one the Government believes it has incorporated into the Bill, is compulsion of witnesses. This is discussed in Chapter 6.

**Other perceived effects of the ‘safe space’**

**On patients**

65. Several witnesses expressed concern that information currently available to patients and their families would in future be kept from them, both by accredited trusts and by HSSIB, because of the legal requirement to respect the ‘safe space’.\(^7\) Professor Brian Toft told us:

> One of my problems with safe space is that people may not believe they are getting justice because they cannot have access to the data that is being used to derive the report.\(^8\)

and

> It is very personal to them, and they want to know, generally speaking; in fact, in some cases they want more than that—they want to see somebody put in jail.\(^9\)

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\(^6\) Professor Murray Anderson-Wallace (SIB0036), para 29

\(^7\) Or gave evidence that this would be the effect of the Bill. See The Professional Standards Authority for Health and Social Care (SIB0031), paras 3.3–3.4 and The Campaign for Freedom of Information (SIB0039), para 8; and Medical Defence Union (SIB0044), para 2.

\(^8\) Q252

\(^9\) Q263
66. The Association of Personal Injury Lawyers was concerned that a ‘safe space’ could mean necessary information about negligent failings not coming to light, “leading to a denial of access to justice, and a failure to bring those responsible for the negligence to account”.  

67. These accounts quite understandably focus on blame rather than learning. Matthew McGrath, of DAC Beachcroft LLP, observed that:

> If certain material is not disclosable, prima facie under the Act, it will invariably—and I am sure you have heard from those who act on behalf of claimants—create a suspicion among patients that they are not being told the full story.

However, he countered that much information will still be available and said: “it is in the interests of the public to see that there is still a lot of information that is potentially disclosable”.  

The Clinical Human Factors Group told us that any protection in the draft Bill will not alter the information patients can obtain.  

68. The information and material to which the prohibition would apply is in addition to any information or material to which access currently exists. It would not change the legal status of any information that would exist or continue to be acquired outside a ‘safe space’ investigation. Only HSSIB would be prohibited from disclosing the material or information from its ‘safe space’. It would consist only of information or material created by, or given to, HSSIB, and only while held by HSSIB. The prohibition would include, as the NMC pointed out, all the information generated during an HSSIB investigation, for example transcripts, witness statements and recordings. But it would not, it seems to us, apply to documents or other information already in existence and held by others. These would be unavailable from HSSIB (unless already in the public domain), but would remain available from whoever holds them, as they are now.

69. Assuming the Government accepts our recommendation regarding the accreditation of trusts, nothing about the ‘safe space’ would prevent patients (or regulators, the police, or the public) from acquiring anything to which they currently have access. We are absolutely clear that the sole purpose of the ‘safe space’ is to facilitate gathering evidence for HSSIB’s ‘no-blame’ investigations. It does not interfere with any other investigation or inquiry procedure which already exists.

70. The Patients Association were concerned that as a result of ‘safe space’, patients will not discover what had happened to them:

> In NHS trust investigations into patient complaints and serious incidents, the full findings must be made available to the patient and/or their family members (if, for instance, the patient has died). It cannot be acceptable for these investigations to identify what happened to a patient, but then be barred from telling the patient or their family what has been discovered.

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90 Association of Personal Injury Lawyers (SIB0006), para 10
91 Q295
92 Q300
93 Clinical Human Factors Group (SIB0017), p 5
94 Draft Bill, clause 28(2)
95 Nursing and Midwifery Council (SIB0032), para 14
96 The Patients Association (SIB0043), para 15. This concern appeared to be shared by Action against Medical Accidents (AvMA) (SIB0021), p 6.
71. But Scott Morrish, whose son Sam tragically died in avoidable circumstances, thought a family will be told what had happened:

   The expectation, and my hope for HSSIB doing a good job, would be that it would then include everything that is relevant in its final report, and thereby it will come back to the family. The family is benefiting from this as much as everybody else.  

72. Patients will not be supplied with the new evidence that HSSIB will obtain or compile. That is not the purpose of HSSIB. But we expect HSSIB to provide sufficient detail in its reports for patients and their families to understand, in clear terms: what happened, what went wrong, why, and what should be done to make sure it does not happen again. In our view, this is the purpose of HSSIB. At the same time, we recognise that some patients may not wish their information or testimony to be shared with others.

73. AvMA was concerned that, because HSSIB will be prohibited from sharing information connected with an inquiry, patients will be unable to “challenge erroneous evidence provided”, resulting in “poorer investigations and less learning”. Nevertheless, we are reassured that the draft Bill will require HSSIB, before it publishes a report, to send a draft of the report to everyone who participated in the investigation, and to notify them that they have the opportunity to comment on the draft.

74. The Patients Association suggested it might be desirable “to mandate the HSSIB to develop a programme of patient engagement, both to inform how safe space will be used and to develop information to provide clarity and reassurance to patients and families”. We discuss elsewhere the intended resources of HSSIB; it is enough here to note that they are currently intended to be modest.

75. We agree with The Patients Association that it will be very helpful to engage with patients to help them better understand what ‘safe space’ means, why it is important, and how such investigations will be conducted. It is not clear to us whether HSSIB will have the resources to sustain this important role, which is vital for patient and public confidence in HSSIB. We recommend that the Department for Health and Social Care and HSSIB engage with patients and families, and their advocates or representatives, to ensure that the ‘safe space’ is widely understood by them.

On the duty of candour

76. We considered in Chapter 2 the effect that the duty of candour has had on culture in healthcare. The healthcare sector is subject to two such obligations to reveal what has happened when things go wrong.

   a) There is a professional duty of candour to which healthcare professionals are subject by their regulators.

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97 Q171
98 Action against Medical Accidents (AvMA) (SIB0021), p 2
99 The Patients Association (SIB0043), para 10
100 See para 168.
101 Explained by the GMC and NMC in Openness and honesty when things go wrong: the professional duty of candour (June 2015), and embodied in the regulatory bodies’ joint statement on the professional duty of candour. Robert Francis QC, in his Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, recommended that practitioners be subject to a statutory duty of candour (para 1.181).
b) There is also a legal duty, imposed on health and social care providers and managers, and enforced by the CQC, to tell people when they could have been harmed. The provider (or manager) must explain, truthfully, all they know about the incident, what further enquiries are appropriate, and the results of those enquiries. They must also include an immediate apology, and a written apology.

The professional duty of candour

77. Some of our witnesses suggested that the ‘safe space’ non-disclosure requirements might prevent practitioners from complying with their professional duty of candour. The PSA’s Harry Cayton told us, for example, there was a danger of creating:

both for health professionals and for patients, [the] dilemma of, ‘What do I disclose openly under my duty of candour? Do I withhold some information because there is going to be a safe space investigation? Do I withhold all the information because there is going to be a safe space investigation?’ […]

I think there is a duty of confidentiality once a safe space investigation has commenced. Does that apply to patients who give evidence within that framework? Can they not repeat their evidence in public?

78. The Campaign for Freedom of Information thought the prohibition will also apply to information supplied by any patients, family members or staff, even those who were willing for their information to be made public.

79. Consistently with the Government’s fact sheet on ‘safe space’, Jennifer Benjamin explained this was not the case. Scott Morrish told us the argument that ‘safe space’ will drive “a coach and horses through the duty of candour” was “little more than scare-mongering”. DAC Beachcroft LLP confirmed that the Bill “does not restrict what clinicians may disclose to patients about information provided to the HSSIB”, though there will be no positive duty on professionals to share with patients everything said to HSSIB. Clause 28 prohibits disclosure by HSSIB (or an accredited trust conducting a ‘safe space’ investigation) only.

80. While the evidence of the effect of the duty of candour on changing the culture in the NHS may be mixed, we believe it is contributing to positive change. It is clear that HSSIB, and only HSSIB, is prevented from disclosing information under the draft Bill’s prohibition on disclosure (clause 28). The healthcare professional’s duty

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102 “Registered persons” under the Health and Social Care Act 2008.
104 Q140. See also The Professional Standards Authority for Health and Social Care (SIB0031), paras 3.4 and 3.35.
105 The Campaign for Freedom of Information (SIB0039), para 8
106 Department of Health, Fact sheet 3: ‘Safe space’—what is it, why we need it and how it will work (September 2017)
107 Q410
108 Scott Morrish (SIB0035), para 10
109 DAC Beachcroft LLP (SIB0050), para 7
110 Clause 28(2)
of candour is not diluted by the ‘safe space’ in any way. Nor would other contributors to an investigation, such as patients, be barred from sharing with others the evidence they gave to HSSIB.

**The statutory duty of candour**

81. AvMA made a compelling case that information now shared with patients by providers in accordance with their statutory duty of candour will have to be withheld if a trust were conducting an internal ‘safe space’ investigation. Peter Walsh explained:

> if you have a safe space investigation, the information goes into a black hole. If the trust has that information before the investigation, they are under a statutory obligation to share it with the patient and the family. If you create a safe space investigation, it becomes a black hole.\(^{111}\)

82. This concern was echoed by the PSA, the Campaign for Freedom of Information, the Patients Association and the CQC.\(^{112}\) The National Guardian’s Office (NGO) pointed out it could affect information shared with the NGO when conducting a case review.\(^{113}\)

83. It would not be right for this draft Bill to restrict information which is freely available at present and, in respect of HSSIB investigations, it does not do so. HSSIB’s purpose is not to provide a hiding place for uncomfortable truths, but—in the interests of patient safety—to provide the greatest possible assurance that its investigations will have no negative consequence for participants. We look at accreditation in Chapter 4, but this provides an initial, and compelling, reason why we do not support the accreditation of trusts to conduct ‘safe space’ investigations.

**Relationship with duties of NHS trusts and other bodies**

84. NHS Providers emphasised to us that NHS trusts have a range of duties to comply with when things go wrong. They referred to duties relating to employment, duties to ensure good standards of care, and statutory duties to liaise with police, coroners, the Health and Safety Executive, the NMC and the General Medical Council (GMC), to answer patient complaints, and to manage financial liability that may result from an incident. They told us there was a “danger of preventing them from meeting other bits of law that they are required to meet”.\(^{114}\) It became clear, though, that NHS Providers’ concern was about HSSIB conducting “local investigations in place of trusts”,\(^{115}\) as the present HSIB has been required to do by the Secretary of State in relation to 1,000 maternity investigations.\(^{116}\) Whether or not these investigations cut across the duties of NHS trusts (Keith Conradi told us the HSIB investigators took a “very collaborative” approach),\(^{117}\) we have other concerns about the present HSIB having been asked to conduct these additional investigations. We set out our concerns in Chapter 5.\(^{118}\)

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\(^{111}\) See also *Action against Medical Accidents* (AvMA) (SIB0021), p 2.

\(^{112}\) See also *The Professional Standards Authority for Health and Social Care* (SIB0031), paras 2.7 and 3.39; *The Campaign for Freedom of Information* (SIB0039), para 12; *Care Quality Commission* (SIB0040) para 6.2.2; *The Patients Association* (SIB0043), para 19.

\(^{113}\) See paras 163ff.

\(^{114}\) See also *National Guardian’s Office* (SIB0037), para 16(ii).

\(^{115}\) See also *Q4Q36 and 38.*

\(^{116}\) See paras 163ff.

\(^{117}\) See paras 163ff.
85. In any event, we expect the duties of co-operation on practical matters between HSSIB and others will ensure that any tension with existing statutory duties will be avoided. We consider the draft Bill’s duty of co-operation in Chapter 6.

**Material protected**

**Extent of the ‘safe space’ (prohibition on disclosure)**

86. The prohibition will apply to “any information, document, equipment or other item”, or any information about such things. Dr Carl Macrae understood the prohibition to cover “things like statements that are made to the investigators”. Keith Conradi considered “the protected piece [to be] the piece of paper that [sensitive information] is written on”, and that the witness statements HSSIB will take must remain confidential. The Clinical Human Factors Group told us that, in other industries, the protection of information applies to statements gathered by investigators, and that “all existing notes, records, documentation and data remain available to the law enforcement agencies and the regulators/organisation who may choose to investigate in parallel to the independent body.”

87. On the face of the draft Bill, it applies to “any information [or] document […] held by [HSSIB or the accredited trust] in connection with [an] investigation”. The Campaign for Freedom of Information thought the description capable of including, “[p]olicy or procedural documents, information about staffing levels, recruitment problems, financial difficulties, lessons learnt from past incidents [and] information supplied by equipment or product manufacturers”. AvMA pointed out the prohibition “applies literally to any information held in connection with the investigation which is not already in the public domain”, and indeed to information about that information.

88. As the Bill is drafted, it is clear that the prohibition on disclosure (by HSSIB or an accredited trust) goes much further than just witness statements. Nevertheless, and in the light of our conclusion in paragraph 63, we conclude that this blanket ban on HSSIB disclosing the evidence that it gathers or generates—with specific exceptions—is the solution most likely to achieve the aim of getting to the truth, in the interests of patient safety.

**Information not leading to an investigation**

89. The prohibition on disclosure in clause 28 applies only where HSSIB “is carrying out, or has carried out, an investigation”, and only to information, etc, held by HSSIB “in connection with” the investigation. As drafted, the ‘safe space’ will not cover information given to HSSIB unless and until a connected investigation is launched.

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119 Clause 28(2) and 28(6)(c)
120 Q258
121 Q466
122 Q487
123 Clinical Human Factors Group (SIB0017), p 5
124 Clause 28(2)
125 The Campaign for Freedom of Information (SIB0039), para 7
126 Action against Medical Accidents (AvMA) (SIB0021), p 4
127 Action against Medical Accidents (AvMA) (SIB0021), p 5
128 Clause 28(1) and (2)
But HSSIB is expected to conduct, initially, only around 30 investigations a year, while it will receive—and want to receive—information about many more. The present HSIB says “every case is logged into our database and becomes an important part of helping us identify patterns of safety issues over time.”

90. There is a question over whether any information, however it is received by HSSIB, in connection with a patient safety incident, or about patient safety, should be considered to be held in the ‘safe space’. The Minister thought “whistleblowers” would be able to raise concerns and be protected by ‘safe space’. If this is the intention, it is not reflected in the present draft of the Bill. The Minister and her officials agreed the Bill as drafted did not cover information where no investigation resulted.

Chris Hopson of NHS Providers and Harry Cayton of PSA both supported the extension of the ‘safe space’ to cover this situation. Keith Conradi told us that HSIB has a system allowing anonymous referrals, but accepted that it was possible the referral might contain enough information for a case to be identifiable, though HSIB would want to protect that.

91. We recommend that the ‘safe space’ protection be extended, so that the prohibition on disclosure in clause 28 covers any information and material disclosed to HSSIB (other than by the Secretary of State or a healthcare provider) which HSSIB reasonably considers to have been provided for the purpose of promoting patient safety, or of inviting HSSIB to investigate a matter relevant to patient safety, whether or not it leads to an investigation.

### How safe is the ‘safe space’? (Exceptions to prohibition on disclosure)

92. According to the draft Bill, HSSIB will be able to disclose information from the ‘safe space’ in the following circumstances:

<table>
<thead>
<tr>
<th>If information might be evidence of...</th>
<th>HSSIB may disclose to...</th>
<th>Clause</th>
</tr>
</thead>
<tbody>
<tr>
<td>a criminal offence</td>
<td>Police</td>
<td>29(2)–(3)</td>
</tr>
<tr>
<td>a serious ongoing risk to patient safety</td>
<td>NHS trusts, various other NHS bodies, or the Secretary of State</td>
<td>29(4)–(5)</td>
</tr>
<tr>
<td>serious misconduct</td>
<td>Regulator</td>
<td>29(6)–(7)</td>
</tr>
<tr>
<td>any of the above</td>
<td>NHS trust, person providing NHS services, NHS Commissioning Board, or clinical commissioning group to safeguard any patient</td>
<td>29(8)–(9)</td>
</tr>
<tr>
<td>or to a party in proceedings, where the High Court decides the interests of justice outweigh any adverse impact on future investigations or the Secretary of State’s ability to improve NHS safety</td>
<td></td>
<td>30</td>
</tr>
</tbody>
</table>

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129 Healthcare Safety Investigation Branch, ‘What we investigate & why’, accessed 5 July 2018
130 Q365
131 Q374
132 Q71
133 Q161
134 Qq467–468
93. The Department told us these exceptions reflected “the balance struck between ensuring HSSIB investigations are effective by protecting information appropriately, and ensuring that very serious or ongoing risks to patients or public can be disclosed and acted upon.”

94. We considered two distinct questions:

a) the circumstances in which HSSIB should be entitled (or required) to disclose anything from the ‘safe space’; and

b) whether such disclosure should extend to the detailed evidence gathered by HSSIB or some more limited class of information.

When HSSIB should be able to disclose

95. In relation to disclosure to the police, Dr Chaand Nagpaul, Chair of Council at the BMA, told us he understood “the criminal bit”. The Patients Association also thought it “essential”. But disclosure to the police of a criminal offence is not contemplated by HSIB’s current directions; the Chief Investigator is to inform regulators or other investigatory bodies should HSIB become aware “of evidence of a serious, continuing risk to patient safety.”

96. Regulators broadly welcomed the exception allowing disclosure to them, with some qualifications. Paul Buckley, Director of Strategy and Policy at the GMC, put it this way:

We think that the current threshold in the draft Bill is both too narrow and too low. We think that a better test would be in terms of there being a serious current risk to patients—that is, not just misconduct, but a serious risk.

The NMC supported this. Others shared the view that ongoing risk was the key.

97. The GMC would have preferred to see a duty on HSSIB to disclose in these cases, rather than a discretionary power, as would the CQC and AvMA. Indeed, Dr Nagpaul highlighted the uncertainty about who at HSSIB will decide whether to refer a person to the regulator.

98. The CQC felt they needed to know that there were incidents in a particular provider that HSSIB was investigating (without wanting any detail about individuals) before they
carried out their inspection, so as to direct them to the right things to look at.\textsuperscript{146} Harry Cayton called for “a set of rules that are much clearer about what is to be shared, how it is to be shared and what the threshold is that HSSIB is going to apply.”\textsuperscript{147}

99. The Medical Defence Union thought the balance was about right, telling us the exceptions, “are reasonable and proportionate in balancing the harms of diluting the individual protection afforded in a safe space against the harms of failing to act on the basis of either the public interest or patient safety.”\textsuperscript{148}

100. Dr Simon Fleming, a Trauma and Orthopaedic registrar, said he:

\begin{quote}
would have real concerns if HSSIB were to feed in to regulatory bodies, because people will not report. People will not report someone speeding if they know that they themselves will have to then speak to the DVLA. It is human nature.\textsuperscript{149}
\end{quote}

101. The Royal College of Physicians and Surgeons of Glasgow thought there was not enough protection.\textsuperscript{150} Solicitors Mills & Reeve LLP felt the “risk of criminal liability and regulatory referral will still result in individuals being wary of speaking freely.”\textsuperscript{151}

102. 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.

103. The evidence sent to us by Professor Gerada described the extent of poor mental health amongst doctors.\textsuperscript{152} \textit{We recognise that problems associated with mental wellbeing can affect all professional groups in healthcare, all of whom play a critical role in ensuring patient safety. We believe that the protections afforded by the ‘safe space’ will be important to health professionals who are under stress from patient safety investigations or complaints, or who may be managing mental health problems. They will be able to speak more freely in the ‘safe space’ about the nature of their work, its impact on them, and the consequences for patient safety.}

\textbf{What should be disclosed}

104. Dr Nagpaul was concerned at the lack of clarity about what will be disclosed: the fact of concern about a particular professional, or the content of the evidence they had provided.\textsuperscript{153} The NMC thought it ought to be the evidence, otherwise:

\begin{quote}
a) patients and family members will have to give their account more than once, and
\end{quote}

\begin{thebibliography}{99}
\bibitem{146} Qn2–4
\bibitem{147} Q134; see also The Professional Standards Authority for Health and Social Care (\textit{SIB0031}), para 2.18.
\bibitem{148} Medical Defence Union (\textit{SIB0044}), p 1
\bibitem{149} Q105
\bibitem{150} Royal College of Physicians and Surgeons of Glasgow (\textit{SIB0007}), p 5
\bibitem{151} Mills & Reeve LLP (\textit{SIB0022}), p 3
\bibitem{152} Professor Clare Gerada (\textit{SIB0048}), para 13
\bibitem{153} Q109
\end{thebibliography}
b) there might be conflicting accounts provided, making evidence unreliable.\footnote{Q147}

105. They were also concerned at having to “expend further resource on conducting [their] own parallel investigations”.\footnote{Nursing and Midwifery Council \((\text{SIB0032})\), para 14} On the other hand, the Medical and Dental Defence Union of Scotland pointed out that by disclosing evidence:

an individual health practitioner may have lost some of the legal rights and protection they would otherwise enjoy. That is to say, by disclosing information, potentially without the benefit of formal legal advice and support, to a ‘safe space’, that is subsequently shared with the police the health practitioner has in effect given an indirect interview to the police without being cautioned about their legal rights. Similarly, if information is released to the GMC (or other health regulator) the health practitioner has essentially lost the right not to comment that would otherwise be afforded them under the regulator’s rules.\footnote{MDDUS \((\text{SIB0041})\), p 2}

106. Keith Conradi told us that he thought there should be no exceptions from the prohibition, save for HSSIB being able to “inform the authorities”. He did not want a discretion to hand over information. He said, “I think we could provide some detail but not the actual paperwork that goes with it”, but agreed with the description: “enough information to let the employer, the police or the regulator set off their inquiry, but no more than is necessary.”\footnote{Qq462–463}

107. We conclude from the evidence that the risk of patients having to give their account twice should be minimised by practical co-operation between the regulators and HSSIB; perhaps an agreed format or set of questions for obtaining a patient’s account, with a copy retained by the patient. We discuss how HSSIB should operate in order to address this later in this Report.

108. We have considered the concern that there is a risk of conflicting accounts rendering evidence unreliable. But we are assured it is unfounded. Any account provided to HSSIB would be protected by the ‘safe space’. Healthcare professionals will remain subject to their professional duties, not least the duty of candour. The ‘safe space’ will have no impact on these duties.

109. We see no reason for HSSIB to disclose evidence it has received, unless it believes there is a serious and continuing risk to the safety of a patient, or to the public. The Chief Investigator of the present HSIB does not think it would be appropriate otherwise. The regulators rightly want greater certainty about what will be disclosed and this should be made clear in the Bill.

110. \textbf{We recommend that the Government amend clause 29 to permit HSSIB to disclose to police, regulators, and/or trusts:}

\begin{itemize}
\item[a)] solely on the grounds that there is a serious and continuing risk to the safety of a patient, or to the public; and,
\end{itemize}
b) no more than the information necessary to enable the recipient of the information to set in train its own enquiries.

111. In relation to the power of the High Court, the NMC said they were “unclear how the considerations set out at section 30(4)(a) and (b) could ever be evidenced other than by a statement to the effect that they apply in a particular case”.\(^{158}\) We understand the concern, but do not share it: the Court has faced and resolved a similar exercise before.\(^ {159}\)

112. We are satisfied with the provision in clause 30 setting out the power of the High Court to order HSSIB to disclose information, and the test it is to apply. The High Court will only be able to do so if it determines that the interests of justice served by disclosure outweigh any adverse impact on the ability of the Secretary of State to improve the safety of NHS services, or on people’s willingness to participate in future HSSIB investigations. This should only be in the most exceptional circumstances.

**Exceptions outside the draft Bill**

**The Parliamentary and Health Service Ombudsman (PHSO)**

113. The PHSO, which fulfils the role of the Parliamentary Commissioner for Administration (PCA) and the Health Service Commissioner for England (HSCE), says it has power to access the HSSIB’s evidence:

> Our legislation affords us the same powers as [the] High Court to call for information. We would therefore be able to access information held by the HSSIB and, by extension, NHS Bodies accredited by them. We, therefore, welcome that the Bill does not affect our ability to investigate and remedy injustice in respect of complaints about safety incidents.\(^ {160}\)

114. Scott Morrish felt this was wrong and shared his concern that “if you leak information via one route or another, be it to the PHSO or to regulators or anybody else, it is not a safe space. As soon as word gets out, it is redundant.”\(^ {161}\)

115. In its role as PCA, the PHSO will be entitled (subject to various requirements) to investigate maladministration by HSSIB.\(^ {162}\) But it may well be wrong about its entitlement to disclosure from the ‘safe space’, at least as regards information held by HSSIB, which is not to be regarded as “the servant or agent of the Crown”.\(^ {163}\)

116. PHSO is part of the redress and grievance system, which HSSIB will not be, and it would be unhelpful if it could circumvent the prohibitions on disclosure or was perceived as a means of doing so.

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\(^{158}\) Nursing and Midwifery Council \(\text{(SIB0032)}\), para 15

\(^{159}\) See Chief Constable of Sussex Police v Secretary of State for Transport \(\text{[2016] EWHC 2280 (QB).}\)

\(^{160}\) Parliamentary and Health Service Ombudsman \(\text{(SIB0010)}\), para 20

\(^{161}\) Q213

\(^{162}\) By virtue of Schedule 2, para 3 of the draft Bill, it will not be entitled to investigate a failure of service by the HSSIB as the Health Service Commissioner for England.

\(^{163}\) Draft Bill, Schedule 1, para 1(1). Thus the prohibition on disclosure will not be disappplied by s 12(3) of the Health Service Commissioners Act 1993, or s 8(3) of the Parliamentary Commissioner Act 1967, which disapply any restriction on the disclosure of information obtained by or supplied to persons in Her Majesty’s service.
117. 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.

The coroner

118. A recent issue before the courts was whether a coroner could call for investigation material from the AAIB. It was held that she could not, but this decision was based on an interpretation of coroners’ powers at least in part influenced by EU and international law. There are no such influences for the interpretation of this Bill.

119. 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.

120. In the light of the two preceding recommendations and 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.

Use of information for patient safety reasons

121. Keith Conradi referred to the desirability of being able to share some information without waiting until publication of a formal report, something he told us he could do at the AAIB:

   One of the mantras that we have is that there should be no surprises to the addressee of a safety recommendation. Throughout the investigation, we are already discussing what we think needs to be done and what the problems are. By the time we make it—we are doing this in maternity—we have had an understanding from the addressee of what it is we are after.

   and

   To go back to aviation, when we were uncovering something with one of the big manufacturers, they were really concerned because commercially it could have been very damaging to them. We make a big point that as we come across factual information, we share it immediately—we are doing this in maternity. We will not hang on to information until the very end, when the report comes out.

164 Under Schedule 5 to the Coroners and Justice Act 2009.
165 R (Secretary of State for Transport) v HM Coroner for Norfolk [2016] EWHC 2279 (Admin)
166 Q448
167 Q498
122. There is currently no statutory prohibition on disclosure, and the maternity investigations are taking place without any 'safe space' protection in any event. Once enacted, there will be no opportunity for such informal sharing of information, however much it might benefit patient safety and however unlikely it might be that release of this factual information will deter professionals from being frank with HSSIB.

123. Under EU law, air accident investigators are under a duty to communicate any information relevant to accident prevention to those responsible for aircraft manufacture or maintenance, aircraft operation, or training. They are also bound to release to aviation authorities “relevant factual information obtained during the safety investigation”, except for sensitive information such as witness statements.

124. HSSIB needs the freedom (but should not be under any obligation) to release factual information during an investigation which could be of benefit to patient safety. We note that this reflects the way the HSIB currently operates. We therefore recommend the Bill be amended to allow disclosure, where in the view of HSSIB there may be a benefit to patient safety, to regulators, NHS bodies, suppliers, manufacturers, or the Secretary of State, of the information HSSIB deems of potential benefit, but not including—

   a) statements taken from any person in the course of an investigation, or submitted to HSSIB for the purpose of inviting it to investigate;

   b) any information likely to reveal the identity of—

      i) an individual who has given evidence, or

      ii) any individual involved in an incident; or

   c) drafts of interim or final reports.

125. The Government should consider whether some of the other categories of material ought to be added to the above list of exclusions, and it should be guided by EU air accident investigation provisions.

**Use as evidence in court**

126. By clause 33, HSSIB’s reports on its investigations will not be available to use in court (unless the High Court were to give permission). This reflects the principle in clause 2(3) that HSSIB investigations are not to assess blame or liability.

127. It is a prohibition which attracted criticism from patient groups, particularly in the context of 'safe space' investigations by trusts. Peter Walsh told us: “[i]t would […] be creating a bureaucratic—and costly—nightmare if people know that they will not be able to use the information gleaned from investigations” and patients will be “prevented, at both ends, from being a part of the investigation”.

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168 Regulation (EU) No 996/2010, art 15(2)
169 Regulation (EU) No 996/2010, art 15(3)
170 Q187
171 Q172
Even when the investigation draws its conclusions, findings of fact and recommendations, you are not allowed to do anything with it. You can see what has happened, but if you had, for example, a clinical negligence claim, you would not be able to use that information.\textsuperscript{172}

128. Nevertheless, Matthew McGrath of DAC Beachcroft LLP thought that once the information had been published in a report, “it would be very difficult in some respects for it not to be used in some way in civil proceedings”.\textsuperscript{173} Keith Conradi did not think there was a problem with reports being used in evidence, but it was “important that the caveats that go with the report—the fact that the evidence is not collected in accordance with police standards and the rest of it—are understood”.\textsuperscript{174}

129. The Royal College of Nursing, meanwhile, welcomed clause 33 and said “[i]nformation gathered by the HSSIB should not be admissible to patients and families, as this may undermine the safe space principle.” They called for the clause to be strengthened to allow application only in “exceptional circumstances”.\textsuperscript{175}

130. \textbf{We understand the concern of some patient groups that they will not be able to use the information published by HSSIB to obtain justice or compensation. However, this does not prevent anyone from using knowledge gained from HSSIB published material to inform the framing of a case for legal redress. As previously stated, we are committed to the principle that this Bill should do nothing to restrict patients’ ability to seek redress. We are satisfied that it does not do so.}

\textit{Evidence given by HSSIB investigators in coroners’ proceedings}

131. Professor Brian Toft pointed out to us that a coroner can call HSSIB investigators to give evidence.\textsuperscript{176} Keith Conradi said HSIB do not think the use of their reports in inquests is a problem, characterising it as “reasonable and helpful”. He did, however, consider it difficult if reports were used in an “adversarial system” or if HSSIB “got pulled into an adversarial court and then had to make some sort of determination”.\textsuperscript{177} As Chief Inspector at the AAIB he gave evidence to the Court of Appeal to the effect that, if investigators had to mention to interviewees that any report would be admissible in civil proceedings, it “would likely restrict the free flow of information”.\textsuperscript{178} By extension, it seems unlikely that HSSIB would be comfortable if reports of evidence given by its investigators to coroners were used in a more adversarial setting. This would also run counter to the prohibition on use of reports in clause 33.

132. There is precedent for evidence given to coroners by HSSIB investigators to be used in other proceedings. The Court of Appeal has observed that in relation to the AAIB the practice is common, and “It is difficult to believe that professional investigators will be inhibited, or the work of the AAIB impaired, by the admissibility in evidence of AAIB reports that have already been made public and are likely to have featured in any coronial

\begin{itemize}
  \item \textsuperscript{172} Q172
  \item \textsuperscript{173} Q204
  \item \textsuperscript{174} Q478
  \item \textsuperscript{175} Royal College of Nursing (SIB0038), para 4.6
  \item \textsuperscript{176} Q234
  \item \textsuperscript{177} Q477
  \item \textsuperscript{178} Hoyle v Rogers [2014] EWCA Civ 257, at [76]
\end{itemize}
investigation. The outcome of that case was to allow the AAIB report to be admissible without balancing the interests of justice against prejudice caused to investigations. The same court emphasised the importance of reports—and where appropriate, evidence from investigators—being available to coroners to avoid duplication of investigation.

133. As coroners’ investigations are not conducted with a view to establishing criminal or civil liability, it seems unlikely that this will have a ‘chilling effect’ on co-operation with HSSIB. There is no difficulty with coroners using reports from HSSIB and, where appropriate, hearing from its investigators to avoid duplication of investigations.

134. We recommend that any evidence given to the coroner by HSSIB, including that given by investigators in oral evidence, be subject to the same test for admissibility in other proceedings as are reports of HSSIB, so that evidence given to the coroner does not become a ‘back door’ means of using in court information that was shared in the ‘safe space’.

**Freedom of information and data protection**

135. The News Media Association suggested that the effect of the draft Bill will be to prohibit patients accessing information about themselves, contrary to the EU General Data Protection Regulation (GDPR) and the Data Protection Act 2018.

136. DAC Beachcroft LLP’s view was, in summary, that they were “not convinced that a bar on patients (as data subjects) accessing personal data held by the HSSIB would be disproportionate and contrary to EU law.”

137. The Department told us it considered HSSIB’s proposed functions:

> would fall within the exemption in paragraph 7 of Schedule 2 to the Data Protection Act 2018. In particular HSIB’s functions include (a) protecting the public against dishonesty, malpractice or other seriously improper conduct or unfitness or incompetence and (b) protecting persons other than those at work against risk to health or safety arising out of or in connection with the action of persons at work.

They also said the relevant GDPR provisions will not apply so as to require data to be disclosed in response to subject access requests.

138. We raised with the Government the question of the draft Bill’s compatibility with data protection legislation (including EU law). There should be no question that the ‘safe space’ could be subject to any data access or freedom of information requests. We are satisfied with the Government’s assurance that ‘safe space’ information would be exempt from access requests under data protection legislation and invite the Government to give us the same assurance in relation to freedom of information requests.

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179. Hoyle v Rogers [2014] EWCA Civ 257, at [94]
180. Hoyle v Rogers [2014] EWCA Civ 257, at [79] and [98]
181. Coroners and Justice Act 2009, section 10(2)
182. Regulation (EU) 2016/679
183. News Media Association (SIB0012), paras 13–14
184. DAC Beachcroft LLP (SIB0050), para 19
185. See Appendix 3.
4 ‘Safe space’ investigations by accredited NHS trusts

139. Previous chapters in this report considered how HSSIB will operate. In this chapter, we give separate consideration to the question of whether NHS trusts should be able to become ‘accredited’ to conduct ‘safe space’ investigations.

Accreditation of trusts

140. In addition to granting HSSIB the power to undertake ‘safe space’ investigations, Part 3 of the draft Bill proposes that some NHS trusts or NHS foundation trusts should be empowered to undertake ‘safe space’ investigations. The Government’s evidence explained:

The overarching aim for extending safe space investigations beyond national investigations is to improve local safety investigations and spread a just culture of learning within the NHS.\[^{186}\]

141. The Government has said that “[o]nly NHS trusts and foundation trusts which have satisfied the highest standards will be considered” for accreditation.\[^{187}\] Trusts will be accredited to undertake internal investigations, external investigations or both:

Initially, under Stage One accreditation, NHS trusts and foundation trusts would only conduct safety investigations into the services of other NHS bodies upon the request of that other body or NHS Improvement, if there appears to be risks to patient safety.

Over time, these accredited trusts which have demonstrated excellent investigative practice and capability and meet HSSIB criteria, can apply for Stage Two accreditation to conduct investigations into their own organisation and service provision.\[^{188}\]

142. The impact assessment published alongside the draft Bill was revealing in the extent to which it limits expectations relating to the capacity of accredited trusts to undertake local ‘safe space’ investigations:

our expectation is that accredited bodies will carry out a minimum of one investigation a year and the number of accredited bodies will be very small. We do not yet know how many NHS Trusts or NHS [foundation trusts] will seek to become accredited but, applications are only likely to come from the top performing Trusts such as those rated ‘outstanding’ by Care Quality Commission (CQC), of which there are only five. Given additional funding will not be made available to accredited Trusts to undertake investigations, it is unlikely that their volume of investigation activity will be high, perhaps no more than four to five cases a year. […]

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\[^{186}\] Department of Health and Social Care (SIB0034), para 39
\[^{187}\] Department of Health, Fact sheet 7: accreditation of NHS trusts (September 2017), para 11
\[^{188}\] Ibid, paras 15–16
We do expect the number of accredited Trusts to grow over time, although we envisage there being no more than 10-20 such accredited Trusts in the system at most.189

143. To achieve accreditation trusts will have to demonstrate that they have the “capacity and capability”190 to meet the standards of accreditation. What the standards will be is, however, unclear and the draft Bill provides for this to be determined by HSSIB once it has been established.

Conflict of interest

144. The evidence we heard was overwhelmingly opposed to the notion of trusts undertaking local ‘safe space’ investigations. Speaking as a representative of patients, AvMA said that these arrangements represent a conflict of interest and they expressed concern about the process that will be applied to the accreditation of trusts.191 A number of organisations, including AvMA, also argued that allowing trusts to conduct their local investigations within the ‘safe space’ will fundamentally conflict with professional and statutory obligations under the duty of candour.192

145. The argument that accreditation may be perceived by patients and the public as creating a conflict of interest was highlighted by Niall Dickson, Chief Executive of the NHS Confederation. He said that perception was central to the credibility of local investigations:

> From a patient’s point of view, I suspect HSSIB would be a better model than one trust investigating another, because the perception would be, “Oh, well, it’s all part of the club.” I don’t think that would be fair, but I think that is how it would be viewed.193

Commenting on the same issue, Dr Chaand Nagpaul of the BMA said,

> There is no doubt that if a trust is considered to be accredited to investigate itself, there will be a perception that it is conflicted. You cannot get round that perception.194

146. NHS Providers said in their written evidence that this was more than a matter of perception and that a conflict of interest will be an intrinsic feature of the system:

> Accreditation—wherein lies an inherent conflict of interest in NHS bodies investigating themselves and their peers—would seem to undermine these core requirements and risk engendering further distrust in the NHS’ capacity to learn and improve.195

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189 Department of Health, *Health Service Safety Investigations Bill: Impact Assessment* (June 2017), paras 55–56
190 Department of Health and Social Care (SIB0034), para 37
191 Action against Medical Accidents (AvMA) (SIB0021), p 3
192 See paras 77ff above.
193 Q60
194 Q116
195 NHS Providers (SIB0023), para 32
147. The Association of Personal Injury Lawyers (APIL) agreed with NHS Providers that, whether a local ‘safe space’ investigation is undertaken by another trust or by a trust investigating itself, there will be a clear conflict of interest:

If it is the intention of the Government to create an independent body, we fail to understand why, in the same legislation, the Government will allow certain NHS Trusts to conduct internal investigations. These will not be truly independent, and we do not see how patients and their families can have confidence in an NHS Trust to investigate itself.\textsuperscript{196}

\textbf{Local ‘safe space’ investigations}

148. Witnesses were also concerned about the concept of accrediting trusts to undertake local investigations with the protection of ‘safe space’. Dr Kathy McLean, Executive Medical Director and Chief Operating Officer of NHS Improvement, noted that accreditation could not even be contemplated unless it was established that a trust embodied the right culture, and if trusts were to be successful in this initiative they will require “more dedicated resource”.\textsuperscript{197} However, as noted above, the Government does not intend to provide additional funding to accredited trusts. Sir David Behan of the CQC was more forthright, cautioning that trusts investigating themselves with ‘safe space’ will “erode public trust and confidence.”\textsuperscript{198}

149. John Tingle, of Nottingham Law School, said that “to give local trusts a safe investigative space, is akin to giving a child a loaded gun.”\textsuperscript{199}

150. Keith Conradi expressed disquiet at the prospect of some trusts being afforded the power to investigate themselves with the protections of ‘safe space’. Discussing the independence of investigations, Mr Conradi said “we have to be extremely careful about delegating some of the powers, particularly the ‘safe space’ powers.”\textsuperscript{200} His remarks built on comments reported in January 2018, where Mr Conradi noted that allowing NHS bodies to investigate themselves under the auspices of ‘safe space’ would not correspond to any precedent in the transport sector, from where ‘safe space’ originates:

To me it is akin, in the aviation world, to giving powers to the British Airways flight safety team to be able to use those powers to do their own investigations.

I have said [to the Department of Health and Social Care] that I can’t envisage how that is going to work. HSIB is impartial, we are not going in with a side. I struggle to see how, with the British Airways team investigating themselves, they can be said to be impartial and independent. They just can’t be and the same would apply to trusts.\textsuperscript{201}

\textsuperscript{196} Association of Personal Injury Lawyers (SIB0006), para 14
\textsuperscript{197} Q7, Q11
\textsuperscript{198} Q12
\textsuperscript{199} Mr John Tingle (SIB0003), p 2
\textsuperscript{200} Q489
\textsuperscript{201} “HSIB chief rejects plan for trusts to investigate themselves”, Health Service Journal, 4 January 2018
Supporting best practice

151. NHS Providers said in its written evidence that local investigations will benefit if HSSIB focussed on supporting trusts in improving their investigative practices:

The intention behind accrediting trusts, that of developing a learning culture, would be better directed towards investing in the HSSIB’s role in setting standards of investigations and of training and accrediting local investigators to support its own work.\(^{202}\)

152. Dr Carl Macrae echoed this view, arguing that HSSIB will model “good investigative practice”.\(^{203}\) Professor Charles Vincent of the University of Oxford agreed with this assessment and said that this would be how HSSIB could make a practical difference to the operation of local investigations conducted by the NHS:

I think it would be enormously powerful not for HSSIB to do a lot of investigations, but for it to model how they might be done, in terms of conduct—ethics, if you like—and methodology, instead of what I see, frankly, as often a quite amateurish approach within the NHS.\(^{204}\)

153. Professor Vincent’s criticisms of local investigations were in keeping with much of the evidence we heard. Sir David Behan said “the standard of investigatory skills across trusts is quite low”,\(^{205}\) while Niall Dickson of the NHS Confederation told us that local investigations in the NHS tend to be “patchy, variable and sometimes not very good.”\(^{206}\)

Clarity of purpose

154. In its written evidence DHSC said that HSSIB will be responsible for ensuring that accreditation functions successfully:

The HSSIB will have clear powers under the legislation to review and revoke a trust’s accreditation, if at any time there are concerns and the trust is not meeting the criteria.\(^{207}\)

Dr Kathy McLean emphasised the amount of time, resource and effort HSSIB will need to devote to accrediting individual trusts.\(^{208}\)

155. We heard convincing arguments that imposing this responsibility will alter the purpose of HSSIB from that of an investigatory body to one of a quasi–regulator. Dr Macrae said:

having HSSIB essentially act as a regulator to accredit, inspect and review local trusts on their ability to conduct investigations or performance—that to me fundamentally blurs the line of HSSIB needing to be an independent,
overarching organisation. Having to accredit and review or inspect trusts that they then might need to investigate independently is, to my mind, a very difficult circle to square.\textsuperscript{209}

156. Accreditation of NHS trusts to undertake ‘safe space’ investigations risks creating conflicts of interest, since trusts have an interest in the information held in the ‘safe space’. An NHS trust may be the employer of those who are subject to the investigation, and may be subject to civil or even criminal proceedings. These conflicts would undermine public trust that the principle of ‘safe space’ was being used solely in the interest of patient safety, and this would damage the whole perception of ‘safe space’ investigations.

157. NHS trusts have an obligation to continue to investigate complaints and patient safety incidents in a transparent and open way, but they cannot be as objective and independent as HSSIB will be. If ‘safe space’ investigations prove as valuable as we expect, and there is demand for more capacity for such investigations, accrediting trusts to conduct them is not a credible solution. The Government would have to choose whether or not to grow the capacity of HSSIB to do more. There is no other option.

158. Furthermore, accreditation of trusts to conduct ‘safe space’ investigations will turn HSSIB into the de facto regulator of accredited trusts. HSSIB should not be a regulator in any sense or there will be confusion about its primary function. HSSIB represents a new capability for investigating patient safety incidents, and that is all. We established in Chapter 2 that the purpose of HSSIB is to be an independent investigatory body.

159. HSSIB does, however, have an important role to play in promoting better standards for local investigations, which trusts and other bodies will continue to conduct without the ‘safe space’ We believe that improvements to patient safety can be best achieved by HSSIB working with providers to:

a) model best practice and develop methodologies which enhance the quality and consistency of local investigations conducted by trusts;

b) train local investigative staff in conducting investigations which find fact and identify learning but do not apportion blame; and

c) support the development of a curriculum, courses, examinations, and qualifications so that a new profession is developed, namely one of professional medical investigators.

In doing this HSSIB could help lead progress towards the wider culture change that witnesses to our inquiry have called for, but it will require additional resources.

160. We believe that accreditation of trusts to conduct ‘safe space’ investigations is wholly misconceived. As has been noted, it would be like allowing an airline to investigate their own air accidents in place of the Air Accident Investigation Branch of the Department of Transport. Accredited trusts could not be objective. Accredited trust ‘safe space’ investigations would also risk undermining public confidence in the whole idea of ‘safe space’ investigations.
161. We recommend Part 3 of the draft Bill (Investigations by accredited foundation or NHS trusts) be removed altogether. The Government’s policy should not be for HSSIB to accredit ‘safe space’ investigations at local level but to support HSSIB in improving the quality of all local investigations. We recommend that the Government should also be ready to grow the capacity of HSSIB once the value of ‘safe space’ investigations is established, and if there is demand for HSSIB to do more.

162. All of the recommendations set out in this Report are predicated on the Government accepting our recommendation to remove the accreditation of NHS trusts from the draft Bill.
5 Scope of HSSIB and the additional 1,000 maternity cases

Maternity investigations

163. In November 2017, the then Secretary of State for Health and Social Care, Rt Hon Jeremy Hunt MP, announced that HSIB would be made responsible for investigating all cases of “stillbirth, neonatal death, suspected brain injury or maternal death”:

From next year, every case of a stillbirth, neonatal death, suspected brain injury or maternal death that is notified to the Royal College of Obstetricians and Gynaecologists’ ‘Each Baby Counts’ programme—that is about 1,000 incidents annually—will be investigated not by the trust at which the incident happened, but independently, with a thorough, learning-focused investigation conducted by the healthcare safety investigation branch.\(^{210}\)

164. The HSIB has been required to undertake the additional 1,000 investigations as a consequence of directions made by the Secretary of State to the Trust Development Authority.\(^{211}\) We note that it was the HSIB’s present status that allowed the Secretary of State to instruct the HSIB to assume these responsibilities.\(^{212}\)

165. The Government confirmed that the HSIB has been directed to conduct the maternity investigations outside of ‘safe space’.\(^{213}\) Highlighting the difference between a local serious incident investigation and a patient safety review which utilises ‘safe space’, William Vineall said that this decision had been made because the maternity investigations “are meant to be the single investigation that covers both the clinical uncovering of the information and satisfaction for the families.”\(^{214}\)

166. Swift and satisfactory resolution of individual cases should be the priority of maternity investigations. We were struck by evidence submitted to us by Baroness Cumberlege and Prof Sir Cyril Chantler, Chair and Vice Chair of the NHS England Maternity Review, which outlined Rapid Resolution and Redress (RRR), a process for quickly resolving complaints related to injuries at birth. RRR is structured around an immediate no blame safety investigation when birth injuries occur.\(^{215}\) The priorities of the investigation are to establish the facts of the case for the family involved and to provide health professionals with certainty that they can be completely open without risk of action being taken against them. Baroness Cumberlege and Professor Chantler said in their evidence that this model has been applied successfully in Sweden where “a 50% reduction in avoidable serious birth

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\(^{210}\) HC Deb, 28 November 2017, col 179 [Commons Chamber]

\(^{211}\) The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2018, made under the National Health Service Act 2006 on 23 April 2018.

\(^{212}\) HSIB is part of the NHS Trust Development Authority, a special health authority subject to Secretary of State Direction which (together with Monitor) operates under the umbrella body, NHS Improvement.

\(^{213}\) Department of Health and Social Care (SIB0034), para 12. See also the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2018, para 2(4).

\(^{214}\) Q335

\(^{215}\) NHS England National Maternity Review (SIB0053)
injuries over a period of 6–7 years” had been recorded. The RRR model serves as an illustration of how investigations which do not seek blame can be central to improving patient safety.

167. Furthermore, the Government suggested that the draft Bill may be the vehicle by which non-‘safe space’ HSSIB investigations could be established in statute, saying the “intention is that these investigations should be reflected in the remit of the proposed new body and in the Bill more generally.” Evidence from NHS Providers, however, outlined the uncertainty and potential confusion that could arise within the existing system if HSSIB was required to carry out investigations which essentially replace those that would ordinarily be conducted by a trust:

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).  

168. As well as proceeding without the core feature of an HSSIB investigation, namely ‘safe space’, we heard evidence that the maternity investigations will transform the resource required by HSSIB to discharge its duties. In addition to its annual budget of £4.1 million, HSSIB will be allocated £9.5 million to conduct maternity investigations and the organisation’s headcount will also expand. Keith Conradi said that HSSIB’s planned establishment had been for a team of 18 investigators to work on 30 investigations per year, but maternity investigations will more than quadruple the proposed workforce and compel HSSIB to develop a different staffing structure:

We are recruiting 126 maternity investigators in a regional set-up. We have already recruited about half of those. […] Most or a great majority are seconded from trusts.

169. It is understandable that the former Secretary of State should have wanted to leverage the expertise and capability of the present HSIB for the maximum benefit of patient safety improvement in the NHS. However, the imposition of 1,000 local maternity investigations outside of ‘safe space’ risks completely misconstruing the function of the statutory HSSIB. This decision has the potential to distort the perception of what HSSIB is for, within the health sector. We are concerned that HSSIB should be understood across healthcare. Its purpose and function is the conduct of ‘safe space’
investigations of incidents without finding blame in order to promote patient safety and learning. It is not an organisation to be tasked by others to deliver local NHS investigations.

170. The confusion about HSSIB’s intended purpose created by the direction to oversee the investigation of 1,000 maternity cases underscores the importance of HSSIB’s independence. We regard the draft Bill as an opportunity to confirm the independent status of HSSIB and to secure it in statute.

171. We recommend that the conduct of the 1,000 maternity investigations should be recognised as the responsibility of NHS Improvement, which in legal terms it already is. Once established in statute, HSSIB can continue to provide advice and guidance to NHS Improvement so that best investigative practice can be applied to maternity, or any other, investigations. However, responsibility for the maternity investigations should remain with NHS Improvement and should not be transferred to the new body. It would risk creating confusion about its role and undermine clarity and trust in HSSIB. HSSIB’s funding should be adjusted to reflect the costs of providing advice to the NHS, but it should only have responsibility for conducting its own investigations.

172. We do not believe that the draft Bill should be recast to allow HSSIB to conduct investigations which do not have the protection of ‘safe space’.

173. In Chapter 7 we make further recommendations about the role of the Secretary of State in relation to HSSIB’s freedom to choose what to investigate.

**Limitation to NHS services**

**Independent sector**

174. By clause 2(1), the draft Bill applies only to incidents which occur during the provision of NHS services or at premises where such services are carried out. This means that an independent sector organisation providing NHS funded care will fall under HSSIB’s remit but privately funded care delivered by the same provider at different premises will not. In its 2015 report, PASC recommended that the investigating body should be able to investigate non-NHS funded healthcare as well:

> In order to be able to carry out comprehensive investigations in all cases, it must be free to investigate non-NHS funded healthcare as well as the NHS. Exclusion of the independent sector from the jurisdiction of the new body would not be consistent with a whole system approach, which many witnesses regard as essential.\(^{222}\)

175. A recent CQC report on the inspection of 206 independent hospitals found 41% “required improvement” in safety (and 1% were rated inadequate).\(^{223}\) In response, the Secretary of State wrote to leading independent healthcare providers seeking:

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223 CQC, *The state of care in independent acute hospitals* (April 2018), p 26
urgent assurances that you will get your house in order on safety, as well as a commitment to take rapid action to match the NHS’s world-recognised progress on transparency.\[224\]

176. One independent provider, Spire Healthcare, replied that they “would welcome the ability to refer our incidents to HSIB for investigation to ensure all relevant data is available to the healthcare system as a whole, regardless of the funding source”.\[225\] The Independent Sector Complaints Adjudication Service said:

HSSIB will only command the confidence of patients and their families and healthcare professionals if it has a remit across healthcare, whether this is the NHS or in the independent sector. […]

… patients do not follow the funding boundaries established by governments, but increasingly choose care from different providers including NHS funded care in the NHS or independent sector, as well as through self-funded care or through insurance schemes in the independent sector.\[226\]

177. Witnesses representing a broad range of opinion all endorsed this view. Amongst others, organisations and representative bodies as diverse as the Royal College of Physicians, the Royal College of Surgeons, NHS Providers, the Equality and Human Rights Commission and the Clinical Human Factors Group all said that independently funded and provided care should be subject to HSSIB investigations.\[227\]

178. Niall Dickson supported the extension of HSSIB’s investigatory scope to privately funded and provided care, but noted that this raises a question as to how this aspect of HSSIB’s work will be funded.\[228\] Dr Chaand Nagpaul of the BMA warned that “we cannot and should not have the NHS subsidising private providers”\[229\] and Professor Brian Toft agreed that private providers should be charged for the work HSSIB undertakes in relation to the sector.\[230\] Professor Charles Vincent warned that direct charges for investigations could create a conflict of interest and both he and Dr Carl Macrae were supportive of a general levy that could be applied to private providers.\[231\] Dame Donna Kinnair of the Royal College of Nursing also said that a levy on private providers may be a suitable source of funding.\[232\]

179. Our evidence was clear that HSSIB’s remit should extend beyond just NHS-funded services to the whole healthcare system. We recommend that the draft Bill should be amended to extend HSSIB’s remit to the provision of all healthcare in England, however funded. Implementing this recommendation will demand consequential amendments, including reflecting it in the title of the Bill and the name of the investigative body. We

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224 Secretary of State letter to chief executives of leading independent healthcare providers, 8 May 2018
225 Spire Healthcare letter to Secretary of State, 21 May 2018
226 ISCAS (SIB0033), paras 1.1–1.2
227 Royal College of Physicians (SIB0019), para 2; The Royal College of Surgeons of England (SIB0018), para 12; NHS Providers (SIB0023), para 3; Equality and Human Rights Commission (SIB0008), para 13; and Clinical Human Factors Group (SIB0017), p 3
228 Q47
229 Q121
230 Q277
231 Q278
232 Q122
recommend that the legislation should be called the ‘Healthcare Safety Investigations Bill’ and, consequently, it would establish the ‘Healthcare Safety Investigations Body’ (HSIB) in statute.

180. **NHS funding should not be used to subsidise investigative work that will also apply to the private sector.** We recommend that the Government should undertake a formal consultation to explore how private providers can make a proportionate contribution to the patient safety work undertaken by HSSIB. We do, however, warn against charging fees for investigations.

**Social care**

181. Not only is HSSIB’s proposed scope limited to NHS provided or commissioned care, there is also no provision in the draft Bill for HSSIB to extend its investigations into local authority or privately funded social care. Sir David Behan of the CQC said that HSSIB should “have the freedom to look at the whole system”. He explained how the integration of NHS services and other aspects of care, such as adult social care, has reshaped the environment for inspection and investigative bodies:

> If we look at how people with complex co-morbid conditions are going to be served by health care and social care services in the future, it means that more than one agency needs to operate together. Where care breaks down, it is often in the hand-offs between different bits of the system.

182. Chris Hopson of NHS Providers agreed that HSSIB should be able to look at the entirety of a patient’s journey through the health and social care system but cautioned against it becoming the investigatory body for adult social care:

> we are saying that HSSIB cannot do its job unless it has the ability to follow that whole care pathway, but that does not mean that somehow it should become a body that is equally concerned about social care. Our view would be that the scope should allow it to follow the pathway, wherever the pathway goes.

183. Offering a perspective on behalf of patients and the public, Imelda Redmond, National Director of Healthwatch England, highlighted the frustrations that patients and their families experience when complaints and investigation systems operate in their own institutional “silos” and do not follow the patient pathway. Discussing the limitations of HSSIB’s scope, the Minister said that HSSIB will only be able to follow a patient pathway “where care is funded by the NHS and a patient is taken into the social care sector.”

184. We do not believe that the draft Bill reflects the integrated nature of modern healthcare. The development of NHS Vanguards, integrated care pioneers, sustainability and transformation partnerships, and integrated care systems (amongst many other initiatives) have all sought to bring together multiple NHS services with

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233 Q27
234 Q24
235 Q47
236 Q174
237 Q379
local authority commissioned social care. In many areas adult social care staff are now working in concert with NHS teams on a daily basis, be that in primary and community services or enabling discharge from secondary care.238

185. **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. Nonetheless, we do recommend that 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.**

**HSSIB’s territorial scope**

186. Clause 38 of the draft Bill specifies that HSSIB’s remit is limited to England. There are no provisions in the draft Bill to deal with cross-border healthcare issues. Jennifer Benjamin emphasised that it is not within the gift of the Department for Health and Social Care to draft health legislation which applies to the devolved nations.239 HSSIB will, however, be able to provide assistance to the devolved Governments and their health systems, if requested. ‘Giving assistance’ is defined as:

- (a) disseminating information about best practice in carrying out investigations;
- (b) developing standards to be adopted in carrying out investigations;
- (c) giving advice, guidance or training.240

187. We asked about the implications of HSSIB’s territorial limitations in relation to cross-border NHS care, which is commonplace in the UK, and the Department assured us that HSSIB’s remit should extend to any provider commissioned by the NHS in England to provide care and “there should not be a restriction in terms of geography.”241 Jennifer Benjamin acknowledged that whether or not a patient’s treatment is funded by the NHS in England is central to determining whether it falls within HSSIB’s remit.242

188. William Vineall said that, as the draft Bill stands, a patient from Scotland, Wales or Northern Ireland, who receives a component of their care in England, may not have all aspects of their patient pathway covered by HSSIB.243 The Minister added: “We can only really deal with complaints about care pathways that start in English hospitals.”244 but this does not address the key concern that problems connected to patient safety can often occur at the ‘hand-offs’ between different services.245 Therefore, a degree of uncertainty would remain for a patient whose GP service is based, for example, in Wales but who is receiving specialist secondary care in England.

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238 Health and Social Care Integration, Briefing Paper 7902, House of Commons Library, October 2017
239 Q346
240 Clause 16(1)
241 Q345
242 Q346
243 Q347
244 Q349
245 Q24
189. Questions remain about HSSIB’s scope as it relates to investigating patient pathways that cross borders between the nations of the UK. In addition, there is a lack of clarity about the scope of HSSIB to investigate incidents which occur in satellite services of English trusts based in hospitals outside of England.\textsuperscript{246}

190. How the devolved Governments will respond to the development of HSSIB is yet to be seen. The Minister told us that the Scottish Government is considering establishing an equivalent to HSSIB,\textsuperscript{247} but DHSC officials confirmed that there have been no discussions as to whether any devolved Government may wish to legislate to extend HSSIB’s remit to their nations. William Vineall emphasised the importance of respecting the devolution arrangements:

> It is quite important that the devolved Administrations make their own decisions, because they are devolved Administrations. That is not just an official’s answer, it is a fact of the governance that we have.\textsuperscript{248}

Discussing how HSSIB will tackle investigations which have a cross-border component, Keith Conradi said that the body had already engaged with the Welsh Government and that a pragmatic response to these challenges would be for HSSIB to operate in the devolved nations.\textsuperscript{249}

191. It will be for the devolved nations to determine how they wish to respond to the development of HSSIB in England. Nonetheless, we expect the devolved health systems to develop mechanisms which allow for cross-border co-operation between HSSIB and appropriate bodies in Scotland, Wales and Northern Ireland when an HSSIB investigation includes aspects of cross-border care.

192. The Government should also clarify that HSSIB’s investigation functions can be conducted in relation to any incidents occurring in England, wherever a patient may originate from, including where any significant causative factor takes place in England.

193. To address the uncertainties that will remain around the provision of cross-border services we recommend that the draft Bill should be amended to:

\begin{enumerate}
\item enable reciprocal arrangements between HSSIB and the devolved health systems in cases of cross-border care; and
\item allow devolved administrations to choose whether HSSIB’s remit should be extended to their territory, if they so wish.
\end{enumerate}

\textsuperscript{246} Q352–358
\textsuperscript{247} Q360
\textsuperscript{248} Q362
\textsuperscript{249} Q460
6 Powers and procedures of HSSIB

HSSIB investigations: criteria, principles and processes

‘Qualifying incidents’

194. Clause 2 of the draft Bill provides for HSSIB to investigate “qualifying incidents” with the aim of addressing patient safety risks by “facilitating the improvement of systems and practice in the provision of NHS services”. The draft Bill leaves the criteria, principles and processes for what the body investigates and how it carries out these investigations—including the involvement of key stakeholders such as NHS service providers, patients and their families—up to HSSIB to determine.250

195. In order to fulfil its role of detecting and investigating patterns of patient safety problems, HSSIB needs to be alerted to such problems. The AAIB receives notifications of all accidents or serious incidents.251 However, there are comparatively few of these: there are 24,000 such incidents in the NHS each year. Moreover, there are already comprehensive systems in place for recording incidents (the Strategic Executive Information System,252 ‘StEIS’, and the National Reporting and Learning System,253 ‘NRLS’), and CQC conducts extensive analysis of this data. Jennifer Benjamin said the Department anticipated that not only will NHS bodies, regulators or individuals draw HSSIB’s attention to incidents of concern, but HSSIB will also “operate a surveillance system that allows it to understand what incidents are being reported by the NHS.”254 This might include, for example, use of mortality data.255 Keith Conradi said that the HSIB already had an intelligence section, led by its medical director, one of its key roles being to look proactively for events that ought to be investigated.256

196. As we have already made clear, it is vital that healthcare professionals and others feel able to use the HSSIB ‘safe space’ to report any matters of concern about patient safety, whether or not an incident has actually occurred. We have considered whether to go further: whether there should be a requirement on healthcare providers to report serious incidents directly to HSSIB. We are cautious about adding to the reporting burden on healthcare professionals—who are already obliged to report patient safety incidents, including ‘near misses’—particularly since this is unlikely to increase the amount of useable information available to HSSIB.

197. HSSIB will require access to existing reporting systems as well as full and practical co-operation with the bodies already collecting and categorising information, but this should not require legislation. It is up to HSSIB to promote itself as an organisation to which healthcare professionals should feel they can turn, in complete confidence, when they need to raise a patient safety issue which is not being addressed satisfactorily elsewhere.

250 Draft Bill, clause 3
251 The Civil Aviation (Investigation of Air Accidents and Incidents) Regulations 2018 (SI 2018 No 321), reg 20
252 NHS Improvement, ‘Reporting a Serious Incident to the Strategic Executive Information System (StEIS)’, accessed 9 July 2018
253 NHS Improvement, ‘Learning from patient safety incidents’, accessed 9 July 2018
254 Q338
255 Qq368–369
256 Q456
198. The Royal College of Anaesthetists noted the Bill’s lack of “a clear definition of what would constitute a qualifying incident for investigation” and how this will be shaped by existing guidance and protocols, such as the soon-to-be-merged NHS Improvement frameworks for ‘serious incidents’ and ‘never events’. The RCN called for greater clarity on the term ‘qualifying incidents’ and the criteria HSSIB will use “to determine which patient safety incidences they opt to investigate”.

199. Other witnesses had specific views on how HSSIB should define a ‘qualifying incident’. The Equality and Human Rights Commission, for example, thought this should encompass “incidents that lead to deaths for which the State may be responsible or where there are clear indications that serious ill-treatment may have occurred.”

I think they need to have freedom to investigate what they think—the decision should be theirs—but the criteria should be that there is some wider learning.

200. Several witnesses emphasised the need for HSSIB to communicate clearly to the public the distinct nature and purpose of its investigations, compared to those carried out by trusts and regulators. Dr Carl Macrae was confident, though, that HSSIB will be “a very different proposition” from trusts and other organisations with investigatory functions, as it will operate “at a system safety level” with its investigations comprising “the top 30 systemic risks each year.”

201. Keith Conradi envisaged HSSIB will set its own criteria against which to select its 30 investigations each year out of incidents referred to it as well as those proactively identified by HSSIB. Mr Conradi explained how the current HSIB had an intelligence section tasked with identifying—from all the information the Branch received—whether incidents were “worthy of the top 30”. He noted this was “a difficult call to make” so HSIB tried to clarify the criteria used to select investigations on its website (see Box 4) in order to manage expectations.

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257 Royal College of Anaesthetists (SIB0013)
258 Royal College of Nursing (SIB0038)
259 Equality and Human Rights Commission (SIB0008)
260 Q237
261 See, for example, written evidence from the CQC (SIB0040); NHS Providers (SIB0023); and the Royal College of Midwives (SIB0029).
262 Q237
263 Q441, Q456, and Q444
Box 4: How HSIB decides to start an investigation (extracts from HSIB’s website)

There are many factors that inform our decision to start an investigation … To give you some insight, here are the main areas we look at when we’re making our decision to investigate.

**Outcome impact**

Assessing the impact on people is a crucial part of our process. It helps us to identify the most serious issues as they’ve often had the most impact. We’ll always look at the physical and emotional harm that might have been suffered by anyone involved … We also look at the impact on services, and whether the safety issues have, for example reduced the ability to deliver safe and reliable care. We also consider the public view and whether there has already been a broader loss of confidence in that area of healthcare.

**Systemic risk**

We always look at the wider system risk associated to the safety issues—effectively how common or widespread is it, and does it span different areas of healthcare and different locations. Some of the areas we consider include:

- do various care settings or organisations change the way they work to address a safety issue
- have the issues taken a while to be recognised and are they recognised at the right level
- has the issue existed over a long period time, and are concerns about that issue consistently raised
- will it get worse or spread into different areas of the system if not addressed.

**Learning potential**

We aim to put learning at the heart of everything we do. HSIB wants to drive positive change to improve patient safety and part of that is being able to clearly show that our investigations will produce new information about safety issues. We always look at whether we have a new perspective so that we can develop meaningful, influential and effective recommendations that benefit all of those working in or being cared for by the health service. We’ll always evaluate at key points during investigations to ensure they are still meeting our criteria and reflecting our main objectives and principles.

Source: Healthcare Safety Investigation Branch, ‘How we decide to investigate’, accessed 5 July 2018

202. While noting the concern some witnesses expressed at the lack of a clear definition of ‘qualifying incident’, we do not consider that any such definition should be inserted in the draft Bill. HSSIB should be able to determine what incidents it investigates according to specified patient safety benefit criteria. Based on the approach taken by the current HSIB, we are confident that HSSIB will endeavour to communicate these clearly to the public and other investigatory bodies to maximise certainty and manage expectations.
**Thematic reviews**

203. We were initially concerned that the draft Bill could restrict HSSIB’s freedom to undertake thematic reviews of cross-cutting patient safety issues on its own initiative, without necessarily having the ‘trigger’ of a specific qualifying incident. We raised this with the Minister and her officials who confirmed:

[HSSIB] will have jurisdiction to decide what it investigates … our intention is that [HSSIB] should not be constrained in any way in terms of the type of incidents that it chooses to investigate, so it does not have to be notified or it does not have to receive a complaint.²⁶⁴

204. Keith Conradi was also confident that the legislation, as drafted, will not constrain HSSIB’s ability to conduct thematic reviews.²⁶⁵ He was of the view that, if HSSIB was concerned about an issue but no particular relevant incident had been notified to HSSIB, it would be able to find an event to act as the ‘hook’ for an inquiry.²⁶⁶ These assurances have addressed our concerns. We are content that the draft Bill is sufficiently flexible to enable HSSIB to investigate any patient safety issue, including by initiating thematic reviews without there necessarily being a ‘qualifying incident’.

**Consulting on the criteria for investigations**

205. The draft Bill specifies that, when determining or revising the criteria, principles and processes for its investigations—a review is required within three years of their publication and subsequently every five years—HSSIB must consult with the Secretary of State and “any other persons the HSSIB considers appropriate.”²⁶⁷

206. Several witnesses felt that clause 3(6) should be more specific regarding who should be consulted in the development of the criteria, principles and processes of HSSIB investigations. The RCN recommended it should include health care professionals, patients and families in order to benefit from their expertise and ensure that “any investigation remains patient focused, with learning as the goal.”²⁶⁸ The General Pharmaceutical Council thought that bodies such as professional and systems regulators should be included due to their “potential cross-over of functions”, while the PHSO believed consultation should extend to all those listed in clause 15(4) of the draft Bill “at a minimum”.²⁶⁹

207. We agree that HSSIB should consult as widely as possible in developing the criteria, principles and processes for its investigations, in order to benefit from a broad range of experiences and expertise. However, we are not convinced there is value in being prescriptive about this in the legislation. We are content that clause 3(6) as drafted will facilitate appropriate consultation with all relevant stakeholders, and expect this to include patients and families, or their representatives.

²⁶⁴ Qn338–339. See also Q342.
²⁶⁵ Q490
²⁶⁶ Q443
²⁶⁷ Clause 3(6)-(7)
²⁶⁸ Royal College of Nursing (SIB0038)
²⁶⁹ General Pharmaceutical Council (SIB0024); Parliamentary and Health Service Ombudsman (SIB0010)
Consulting with patients and families before HSSIB investigations

208. When asked about consulting with patients and families before deciding whether or not to undertake an HSSIB investigation, Keith Conradi did not consider this to be problematic, although he did not think that HSSIB should need their consent to initiate an investigation. Mr Conradi confirmed that many of the investigations referred to the HSIB are referred by families in any case, and that the HSIB would inform families when they were considering an investigation.\(^{270}\) Indeed, with regard to preliminary investigations, the HSIB’s website confirms:

> As a patient, family member or carer, we’ll make sure you know what we’re looking at and how you might be involved.\(^{271}\)

209. While it is clear that Keith Conradi and the HSIB are already engaging openly with patients, families, and carers in advance of initiating investigations, we believe that the new HSSIB’s commitment to this approach should be reflected in the draft Bill. **We recommend that clause 4 be amended to include the requirement that HSSIB must inform any person who has, or may have, been harmed by the incident (or their families), as far as reasonably practicable, before deciding whether to investigate a qualifying incident.**

210. Clause 4(1)(a) and 4(2) regarding representations to HSSIB by the Secretary of State are considered in Chapter 7 of this report.

Involvement of patients and families during HSSIB investigations

211. The importance of involving patients and families in HSSIB investigations was a central theme throughout our inquiry. Scott Morrish described the impact of poorly handled incident investigations as “a prison sentence” for family members, the consequences of which “affect your whole family and every friendship you have had.”\(^{272}\) This devastating emotional impact—and the consequences for patient safety when the concerns of patients and families are not heard, or they feel shut out of incident investigations—were further evidenced by two reports published during the course of our inquiry: the Report of the Gosport Independent Panel on the care of patients at Gosport War Memorial Hospital, and the PSA’s review of how the NMC handled concerns about midwives’ fitness to practise at Furness General Hospital.\(^{273}\)

212. When asked about the PSA review, Matthew McClelland, the NMC’s Director of Fitness to Practise, openly acknowledged: “We did not listen effectively to families, and even when we had heard their concerns, we did not act on them sufficiently swiftly”. Mr McClelland also highlighted the relevance of the PSA’s recommendation that the NMC improve its engagement with patients and families for HSSIB and other investigatory bodies, suggesting it was critical to “put patient voices right at the centre of investigations, so that we all really understand the issues and can … take action and encourage learning based on those experiences and voices.”\(^{274}\)

\(^{270}\) Q443–445

\(^{271}\) Healthcare Safety Investigation Branch, ‘How an investigation works’, accessed 5 July 2018

\(^{272}\) Q221


\(^{274}\) Q163
213. The organisations representing patients were understandably anxious that patients and their families should be involved in HSSIB’s investigations as much as possible. Imelda Redmond of Healthwatch England suggested “you can only learn if you really engage people properly in that process”, while AvMA envisaged patients and families as “equal partners”. But healthcare professionals were also firmly of the view that patient involvement was vital. Dame Donna Kinnair was clear that individuals who had suffered some harm and their families must be part of the investigation: “that is what makes it a whole investigation.” Dr Fleming told us that, if done correctly, HSSIB’s involvement of patients and families could make them “part of the team and part of the solution, rather than making them feel like they are on the outside shouting in.” Professor Vincent agreed, noting: “The reason for engaging patients is no longer that it is the right thing; it is actually fundamental to the conduct of the investigation, in many cases.”

214. We were struck by Professor Vincent’s aspiration for HSSIB to provide a powerful model of candour and transparency in incident investigations, showing other organisations: “it can be done. You can be open to patients and families, and you can display what you are doing.”

215. The draft Bill requires HSSIB to ensure that its processes secure the involvement of patients and families in its investigations “if, and so far as, reasonable and practicable”. HSSIB must publish these processes and must also publish a document explaining how the processes are to operate in practice. This document must be easily understood by, and easily accessible to, patients and their families.

216. For an indication of how HSSIB may involve patients and families in its investigations, it is illustrative to examine the approach of the current HSIB. As noted above, the HSIB appears to involve patients and their families right from the preliminary stages of its investigations. HSIB’s website indicates that patients, family members and carers can further expect:

- to be kept informed at key stages of an investigation;
- to receive, and have the opportunity to comment on, a pre-publication copy of any interim bulletins the HSIB makes;
- to be contacted on completion of an investigation so that the HSIB can share its findings with them and get their feedback and input on the draft report; and,
- to receive a copy of the final report and recommendations.

217. We endorse the HSIB’s open and transparent approach to engaging with patients, their advocates, families and carers, and welcome the draft Bill’s particular focus on the involvement of patients and families with regard to the investigations that will be undertaken by the new body.

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275 Q170
276 Action against Medical Accidents (AvMA) (SIB0021)
277 Q117
278 Q254
279 Q240
280 Q240
281 Clause 3(3)
282 Clause 3(1)(d), 3(3), and 3(9)
283 Healthcare Safety Investigation Branch, ‘How an investigation works’, accessed 5 July 2018
218. In addition to the moral imperative to be open with patients, their families, and patient advocates, we agree with witnesses to this inquiry that engaging with patients and families will be critical to ensuring HSSIB investigations capture the ‘whole picture’ of events in any given incident. We are satisfied that the provisions outlined in clause 3 will facilitate this.

219. It will also be essential to ensure that the processes developed to determine the involvement of patients, families and carers in HSSIB investigations are as simple and accessible as possible, so that no additional burden is placed on them during an already difficult and distressing time.

Co-operation between HSSIB and other investigative bodies

The potential for parallel investigations

220. As described in Chapter 2, HSSIB will be a new, additional investigative capability in healthcare. As such, investigations carried out by local trusts, system and professional regulators—and other system bodies with an investigative function (see Appendix 4)—will continue to take place, and may occur in parallel to those conducted by HSSIB.

221. The draft Bill foresees this possibility and clause 15 provides for a mutual duty of co-operation regarding logistical issues, between HSSIB and a range of persons (listed in subsection 4) when they are carrying out investigations into the same or a related incident. ‘Logistical issues’ are defined as issues relating to “practical arrangements for co-ordinating the investigations”, such as the sequencing of those investigations.284

222. The regulators and professional membership bodies who gave evidence to our inquiry emphasised the importance of co-operation during concurrent investigations. The Association of Optometrists, for example, highlighted “a growing tendency for different bodies to investigate the same events” which could be “inefficient, confusing and stressful for all parties involved.”285 Clare Padley, the NMC’s General Counsel, was concerned about the impact that HSSIB investigations might have on regulators’ powers to put interim orders in place to restrict the practice of an unsafe professional while an investigation was ongoing.286

223. Clare Padley also drew our attention to the implications of parallel investigations for patients and family members who have to give an account of their experiences to one organisation and are then told they need to give it again: “They are going to say, ‘Why can’t you just use the account I gave to that organisation?’ It would lead to this confusion.”287 Matthew McClelland agreed, noting that patients and family members not only found it confusing but “distressing” to have to “give their account over and over again … to different organisations”.288

284 Clause 15
285 Association of Optometrists (SIB0020)
286 Qq154–155
287 Q147
288 Q147
224. Sir David Behan of the CQC argued that co-operation, and the exchange of information, will be important to ensure HSSIB and regulators could discharge their different responsibilities, “in the common interest of patient safety.”

225. A further concern was the length of time that might be taken by multiple investigations. Harry Cayton of the PSA told us he would “hate to see sequencing happen”, as regulators already faced criticism from patients, families and healthcare professionals about the time taken to complete investigations that were “put off” while another investigation took place.

226. Matthew McClelland of the NMC cautioned:

I think it is hard to have a hard and fast rule here. I think we have learned lessons around putting our investigations on hold for others in the past. The critical point is not to undermine the role of employers here to look at the issue sensibly and carefully themselves and to make referrals … to regulators and others who need to know. I think each case needs to be looked at very carefully to determine whether there is a sequencing or whether they have to happen in parallel. That will just depend very much on the circumstances of the case and the issues that we are looking at.

A duty to collaborate?

227. The CQC argued that the requirement for “co-operation on logistical matters” set out in clause 15 of the draft Bill should be widened and deepened into a duty to collaborate—a call that was supported by several of the Royal Colleges. Such a duty, Sir David Behan suggested, should be supplemented by the development of memoranda of understanding (MOU) as a way of codifying and defining what the various bodies will do when reviews are taking place. Other witnesses welcomed the existing general duty of co-operation in clause 15, but agreed that additional detail set out in an MOU will be necessary to establish how co-operation will work in practice.

228. Several regulators and professional membership bodies told us that they were already in the process of developing MOU with the current HSIB, with Paul Buckley of the GMC noting that the GMC had had “very productive discussions with Keith Conradi and his team”. Harry Cayton explained that regulators were also engaging with HSIB more broadly, including at meetings of the Health and Social Care Regulators Forum. Clare Padley hoped that this MOU would enable investigative bodies to cross-refer incidents for investigation—particularly, with regard to HSIB, matters that appeared systemic rather than a result of individual poor practice.
The distinct purpose of HSSIB

229. While acknowledging the concerns of professional and system regulators, Scott Morrish emphasised that HSSIB investigations “must not be thought of as a substitute for, alternative or barrier to any other kind of investigation or process.” Professor Brian Toft thought that, as a system-level investigator, HSSIB should be able to go about its work and “not have to step on the toes of anybody.”

230. Keith Conradi confirmed that the AAIB had no similar duty of co-operation placed upon it. He expressed concern that this duty could compromise HSSIB’s independence and cause difficulties in terms of the perception of HSSIB’s separation from the existing regulatory and complaints system. This separation, he argued, was essential for HSSIB to be effective.

231. Mr Conradi hoped that the concerns felt by other bodies will be addressed once it became clear that HSSIB is not intended to stop them carrying out their respective functions as they do now. HSSIB’s distinct function, he said, will be “the safety investigation”, noting:

I think it comes back to … education about what [HSSIB is] trying to do. The aims have to be really clear: this is what we do; this is what we don’t do. What I really want over the years is for the investigations to speak for themselves.

232. We agree that co-operation, and the establishment of effective working relationships, with other investigative bodies will be essential to ensure co-ordination during parallel investigations, and for HSSIB to be able to fulfil its functions. Nonetheless, we are concerned about the implications of imposing a statutory duty to co-operate on HSSIB given the fundamental importance—as emphasised by Keith Conradi and earlier in this report—of the body’s independence and separation from the existing system. Consequently, we recommend that clause 15(2) be removed from the draft Bill.

Lessons from the AAIB

233. While there is no duty on the AAIB to co-operate with other bodies, the EU Regulations concerning air accident investigations do call for air safety investigation authorities to establish “advance arrangements” with other authorities likely to be involved in the activities related to the safety investigation—such as the judicial, civil aviation, search and rescue authorities—to facilitate the coordination of investigations (see Box 5).
Box 5: Article 12(3) Regulation (EU) No 996/2010

Member States shall ensure that safety investigation authorities, on the one hand, and other authorities likely to be involved in the activities related to the safety investigation, such as the judicial, civil aviation, search and rescue authorities, on the other hand, cooperate with each other through advance arrangements.

Those arrangements shall respect the independence of the safety investigation authority and allow the technical investigation to be conducted diligently and efficiently. Among others, the advance arrangements shall cover the following subjects:

- access to the site of the accident;
- preservation of and access to evidence;
- initial and ongoing debriefings of the status of each process;
- exchange of information;
- appropriate use of safety information;
- resolution of conflicts.


234. We consider that article 12(3) of Regulation (EU) No 996/2010 could be usefully adapted for the draft Bill, to provide for the development of MOU between HSSIB and relevant bodies. We therefore recommend that a requirement similar to that in Article 12(3) be inserted into clause 15 of the draft Bill.

235. We are content that, if our recommendation is accepted, the Bill will facilitate the necessary levels of co-operation between HSSIB and other investigative bodies. As noted in Chapter 3, we call on all parties involved to develop appropriate processes to minimise the burden of participating in parallel investigations on patients, families and healthcare professionals.

Power to interview witnesses

Compulsion of witnesses

236. Professor Vincent told us that a justification for ‘safe space’ would be the ability to compel witnesses to contribute to investigations. Dr Macrae also saw it as a “quid pro quo”, but did not believe the Bill “has a strong enough requirement to participate in an investigation”. The Clinical Human Factors Group thought “more focus should be placed on compelling witnesses to give evidence as the principal reason and justification for the ‘safe space’ function as is seen in similar legislation in other industries”, and that:
Patients and families will have little patience or understanding with a system which allows people to withhold their co-operation from a major safety investigation. HSIB must have the power, hopefully used only sparingly, to compel people to contribute to investigations.  

237. Scott Morrish’s evidence was that “[c]ompulsion makes clear that professional expectations—and both moral and ethical responsibilities—demand that everyone contributes to safety.”  

238. Dr Michael Devlin, head of professional standards and liaison at the Medical Defence Union, thought clause 7 did allow the HSSIB to compel individuals to assist if they were providing NHS services. He did, however, (with Michael McGrath agreeing):

wonder what benefit there would be to HSSIB in trying to extract that type of information, because it would not be given voluntarily and it may cause the general public and doctors to mistrust them if that power was used in that way.  

239. Keith Conradi saw it similarly. Although he had that power when Chief Investigator at the AAIB, he thought it unlikely he had received “good quality information” as a result of using it. He could not think where it will be of “huge benefit”. But Scott Morrish felt:

‘Safe space’ and ‘compulsion’ are both capabilities that may not be needed in all cases … but the very knowledge that they exist and have a legislative underpinning is transformative in terms of the practical and moral authority for the investigative body in question—in this case the HSSIB.  

240. The Minister told us there had been a deliberate decision not to compel individuals to attend interviews, “because we felt that we wanted to very much put the duties on an organisation rather than an individual, because when HSSIB is making its final recommendations, they will be to organisations and not to individuals.” The Department told us that clause 7 was not intended to capture individual employees but rather “any body” providing NHS services or sub-contractors “such as cleaning companies”. We doubt that this is in fact the effect of clause 7, which refers to “any person providing NHS services” but the Department agreed to review the drafting to ensure it meets the policy intention.  

241. We believe HSSIB should have power to compel individuals. Clause 7 as drafted probably gives it this power, but we think it should be put beyond doubt. The experience

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Footnotes:

303 Clinical Human Factors Group (SIB0017), para 4 and p 2
304 Scott Morrish (SIB0035)
305 Q323
306 Q324
307 Q473
308 Q473
309 Scott Morrish (SIB0035)
310 Q398
311 Our emphasis.
312 See Appendix 3.
313 “Person”, in law includes both individuals and bodies of persons (corporate or unincorporate): Interpretation Act 1978, Sch 1. It is expressly contemplated, for example in clause 29 of the draft Bill, that an individual may provide NHS services.
314 See Appendix 3.
of equivalent bodies in other safety critical industries is that it will almost certainly never be needed, but its existence will help to establish the authority of HSSIB and make clear that assisting it is not optional. It is, as was put to us, the quid pro quo for affording people who work in healthcare a ‘safe space’.

242. **We recommend that the Government should amend clause 7 to reserve to HSSIB the power to issue a summons to compel individuals to answer its questions.**

### Attendance of a colleague or union rep in interviews

243. The Royal College of Anaesthetists was concerned that clause 5(3)(d) meant that HSSIB could insist on interviewing healthcare professionals without a colleague or union representative present. 315 Keith Conradi assured us: “I think it should be up to the individual whom they want to be in that room.” 316 The AAIB says “interviewees may, if they wish, have a colleague / friend present subject to AAIB approval.” 317

244. **Clause 5(3)(d) could be interpreted by HSSIB to exclude an interviewee’s representative or supporting colleague. That does not appear to be the intention of HSSIB, and we think it unlikely investigators will do so, other than in rare circumstances, if they want to secure the co-operation of a witness. Nonetheless, we think that an interviewee’s right to be accompanied should be expressed in the legislation.**

### Penalty for non-compliance

245. Clauses 9–12 set out a scheme under which HSSIB can issue a financial penalty for non-compliance with its powers (in clause 7) to require information, etc. The maximum penalty is a financial penalty of £20,000 (clause 9(3)). This is not a criminal fine; rather it is enforceable as a civil debt (clause 11(2)).

246. Dr Macrae observed:

> I do not believe that the legislation, as it stands, has a strong enough requirement to participate in an investigation. My understanding is that in other sectors, such as aviation or rail, it is a criminal offence to essentially obstruct an investigation or to not provide information. As the legislation is currently drafted, there is a fairly low-level fine. 318

247. Scott Morrish also urged there to be an offence of non-compliance. 319 The Clinical Human Factors Group pointed out that it is an offence not to comply with a requirement made by a Railway Accident Investigation Branch inspector. 320 Obstructing or impeding an AAIB inspector, or failing to comply with an AAIB witness summons, are offences punishable by a fine or imprisonment of up to three months. 321

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315 Royal College of Anaesthetists (SIB0013), para 4.3
316 Q491
317 AAIB, Aircraft accidents and serious incidents: Guidance for airline operators (June 2013), p 14
318 Q259
319 Scott Morrish (SIB0035)
320 Clinical Human Factors Group (SIB0017)
321 The Civil Aviation (Investigation of Air Accidents and Incidents) Regulations 2018 (SI 2018 No 321), regs 21 and 23, and Civil Aviation Act 1982, section 75(5)
248. The Hampton Review and the Macrory Report concluded that criminal prosecution could be “costly, time-consuming and slow”, and might not always be the most appropriate (or even adequate) sanction and more flexible, risk-based tools might achieve “better regulatory outcomes”. These resulted in the enactment of the Regulatory Enforcement and Sanctions Act 2008 “enabling Ministers to confer new civil sanctioning powers on regulators in relation to specific offences”.

249. It is imperative that HSSIB be seen as a body with which individuals and bodies must co-operate. Despite recent moves away from criminal prosecution, strong powers of coercion are, in this instance, appropriate. We sincerely hope that such powers will never need to be exercised.

250. We recommend that non-compliance with clause 7 be made a criminal offence, punishable by a fine or imprisonment of up to three months, as is the case with safety investigation bodies in other safety critical industries.

Right of appeal

251. Under clause 12, a person can appeal to the First-tier Tribunal against the issue by HSSIB of a penalty notice. An appeal can only be made on the grounds that the person is not liable, or the amount of penalty is too high. If our previous recommendation is followed, any appeal will instead lie within the criminal courts.

252. Even if our previous recommendation is not followed, the existing right of appeal may be inadequate to comply with human rights law, at least insofar as individuals can be compelled to assist. Imposition of a financial penalty may be akin to a criminal conviction for the purposes of human rights law. By issuing a penalty notice, the Chief Inspector will decide whether an “offence” had been committed, and the relevant penalty. In these circumstances, we think the First-tier Tribunal should have the power to decide any appeal as a complete rehearing (i.e. by substituting its own discretion).

253. If the Government does not make non-compliance a criminal offence, we recommend that the First-tier Tribunal be given jurisdiction to entertain an appeal against a penalty notice as a complete rehearing.

Powers of entry and inspection

254. Clause 5 of the draft Bill will give HSSIB power to enter certain premises (but not premises mainly used as a private home) and to inspect, copy and/or seize documents (or other items), or interview witnesses, provided the NHS body owning, controlling or using the premises, or the person providing NHS services, agrees. Under clause 6, if the relevant NHS body or provider of NHS services does not agree, the Chief Investigator will have power to apply for a warrant to carry out specified actions.

322 Philip Hampton, Reducing administrative burdens: effective inspection and enforcement (March 2005)

323 Professor Richard Macrory, Regulatory Justice: Making Sanctions Effective (November 2006), paras E.9 and 1.5

324 Regulatory Enforcement and Sanctions Act 2008, Explanatory Notes, para 5

325 See European Court of Human Rights (Research and Library Division), Guide on Article 6 of the European Convention on Human Rights: Right to a fair trial (criminal limb) (December 2013), paras 1–9.

326 See also, in a different context, the Housing and Planning Act 2016, Sched 1 para 10(4) (not yet in force) and Housing Act 2004, Sched 13A para 10(3); and Housing, Communities and Local Government Committee, Third Report of Session 2017–19, Pre-legislative scrutiny of the draft Tenant Fees Bill, HC 583, paras 126–129.
255. Niall Dickson of the NHS Confederation and Chris Hopson of NHS Providers agreed HSSIB should have unqualified power to enter any premises, though, this contrasted with NHS Providers’ written evidence that HSSIB should not enter private dwellings without permission. Keith Conradi said he would be “quite happy” without the power to enter residential premises, but accepted it would be “fine” if HSSIB needed a warrant to enter them.

256. An AAIB investigator may “enter and inspect any land or premises (including any dwelling …)” where the investigator-in-charge thinks it “necessary for the purposes of the … investigation.”

257. We have considered whether allowing entry without a warrant will risk damaging trust and confidence in HSSIB. We do not think it will. What will matter is how HSSIB exercises its power.

258. There seems little justification for requiring HSSIB to obtain a warrant before entering premises (other than residential premises) or inspecting, copying or seizing things, or interviewing witnesses. The requirement for a warrant would invite people to misconstrue HSSIB as a prosecuting authority, rather than an organisation that is investigating without finding blame. Although the current Chief Inspector of HSIB does not seek the power to enter residential premises, we think it would be better—subject to appropriate safeguards—to have this power and not use it than to need it but be powerless to act. Indeed, there may well be cases in which healthcare services are provided from premises which are used mainly as a private dwelling, and an investigation could be hampered without access. In these cases, the requirement for a warrant would respect the significance of forcing entry to a private dwelling.

259. The Government should remove from the Bill the need for HSSIB to obtain a warrant before taking an action under clause 5(1) or (3) to which the relevant person does not agree. Instead, investigators should be allowed to carry out an action in clause 5(1) or (3) where, in the opinion of the investigator-in-charge, it is necessary for the purposes of the investigation. HSSIB’s inspectors should have the power to enter residential premises, provided they obtain a warrant before doing so.

260. Clause 6 is unusual in that it does not specify expressly ‘of what’ a Justice of the Peace must be satisfied before issuing a warrant. A provision dealing with warrants would usually (a) expressly grant on the judge the power to issue a warrant, and (b) guide the judge as to what they need to be satisfied about (and whether the application must be in writing, on oath, etc). Instead, the draft Bill leaves the reader to infer that the magistrate:

a) has power to issue a warrant (this would probably be easy enough when construing clause 6); and

b) “would need to be persuaded by the reasons set out in the application and consider that it is proportionate to issue the warrant.”

327 Q92
328 NHS Providers (SI80023), para 11
329 Q474–476
330 The Civil Aviation (Investigation of Air Accidents and Incidents) Regulations 2018 (SI 2018 No 321), reg 14(1)
331 See, for example, the Police and Criminal Evidence Act 1984, section 8; the Data Protection Act 2018, Schedule 15; the Space Industry Act 2018, section 32; the Cultural Property (Armed Conflicts) Act 2017, section 23; and the Counter-Terrorism and Border Security Bill, clause 12, and the Ivory Bill, clause 18.
332 See Appendix 3.
We do not see any good reason to make the reader embark on such a course of interpretative gymnastics when a more straightforward solution is available.

261. The Government should ensure that any provision in the revised Bill dealing with the issue of a warrant specifies:

a) that a Justice of the Peace may issue the warrant; and

b) of what the Justice of the Peace must be satisfied (and whether on oath) before issuing the warrant.

Reports

262. A recurring theme of the evidence we received was an expectation that HSSIB’s reports on its investigations will be comprehensive (with no ‘no go’ areas), impartial and transparent. It was also stressed that they should make practical recommendations addressed to specific organisations. The RCN, BMA and CQC expressed the hope that HSSIB will feel confident enough to report frankly on any constraints in staffing levels or facilities that might have led to incidents. Dr Chaand Nagpaul of the BMA highlighted HSSIB’s independence from any management or regulatory responsibilities for NHS services, suggesting this meant it could be “the one body that is not trying to score political points; it is not about politics.”

263. AvMA emphasised its perception that the combination of patients not being able to see the information collected by HSSIB, with the fact that HSSIB’s reports could not be used in any civil proceedings, meant that in effect families will be excluded from HSSIB investigations. In contrast, the Medical Defence Union noted that HSSIB’s reports will “distil down a lot of complex evidence”. They added that, though the inability to have access to the information on which the conclusions were based would be frustrating to some people, the key issue was that the reports were likely to give enough pointers to where one should look for further information on any particular issue.

264. Dr McLean of NHS Improvement suggested that HSSIB should involve the bodies that will have to ensure implementation of its recommendations in the formulation of the recommendations, to ensure that they are practicable and effective. Keith Conradi stated that this was already the approach adopted by the HSIB:

Our expertise is only in the investigation. [...] The key thing for us is to identify who the right people are to bring about that change. One of the mantras that we have is that there should be no surprises to the addressee of a safety recommendation. Throughout the investigation, we are already discussing what we think needs to be done and what the problems are. By the time we make it—this is certainly so for the ones to date—we have had an understanding from the addressee of what it is we are after.
265. Clause 31 of the draft Bill requires HSSIB to report findings of fact from its investigations and an analysis of those findings, and to identify what actions should be taken as a result, by whom and when. It also provides that HSSIB must circulate a draft of its report to all organisations and individuals who participated in the investigation, seeking their comments by a set deadline and, if it did not take their comments into account in the final report, it would have to explain why. We consider that the provisions in clause 31 are satisfactory.

266. The HSIB has already published reports on two of its investigations. We do not intend to comment on them: they were not published in time for us to seek the views of our witnesses on them. We note, however, that they give an indication of the likely approach of HSSIB.

267. The draft Bill provides that any person to which HSSIB addresses a recommendation must respond with a report stating what action they will take (clause 34); but there is nothing on the face of the Bill about reviewing whether the required actions have been taken or are in train. Although our witnesses agreed it was vital that HSSIB’s recommendations be carried out, they had different views on whether HSSIB should have any role in enforcing implementation. Keith Conradi was firmly of the view that HSSIB should not be responsible for ensuring implementation of its recommendations. The Minister identified NHS Improvement as being the key body. NHS Improvement emphasised how implementation could be spread down to, for example, the boards of individual trusts and then, internally, through mechanisms like Champions. NHS Providers argued:

   An important distinction needs to be drawn between recommendations and solutions. It will be for the persons and organisations identified in the HSSIB’s recommendations to determine the solutions. We support the current wording of the draft Bill in clause 34, and would welcome parliamentary recognition of the importance of maintaining organisational autonomy and accountability.

268. The CQC was seen as having a particularly important role in enforcing long-term adherence to the recommendations. William Vineall told us that the DHSC “will have CQC include [HSSIB’s recommendations] in inspections in the future.”

269. We have already stated our view that, not least to avoid confusion over its role, HSSIB should not be responsible for ensuring implementation of its recommendations. We recommend that the Care Quality Commission incorporate the implementation of HSSIB recommendations into its quality standards, so that there will be assurance about their implementation.

340 Healthcare Safety Investigation Branch, Investigation into the implantation of wrong prostheses during joint replacement surgery (I2017/010) (June 2018); and Investigation into the transition from child and adolescent mental health services to adult mental health services (I2017/008) (July 2018)
341 See, for example, the differing views of Professors Toft and Dr Macrae: Q279.
342 Q448
343 Q437 and Q439
344 Q18
345 NHS Providers (SIB0023), para 41
346 Q18 (NHS Improvement) and Q280 (Dr Macrae and Professor Vincent)
347 Q437
7 Governance and accountability of HSSIB

Independence

270. Our witnesses were united in stating that HSSIB will be neither trusted nor effective unless it is, and is seen to be, independent of both health service bodies (e.g. trusts, NHS England & NHS Improvement) and the Department of Health and Social Care. Only this will provide confidence that HSSIB will neither cover up failures by clinicians and trusts nor conceal issues that might cause political embarrassment. The PSA spoke for a number of witnesses in expressing concerns that the structure of governance and accountability envisaged for HSSIB might create an impression that the Secretary of State had “a level of direct responsibility for decisions made by HSSIB and the way that it operates.”

271. While we were assured by officials that HSSIB will “not [be] in anybody’s pocket, and can therefore do things openly and transparently and ask the difficult questions”, a number of provisions in the draft Bill relating to the ability of HSSIB to make its own decisions and to the governance of HSSIB caused concern. A particular focus was the provision requiring HSSIB to take into account representations made by the Secretary of State about launching an investigation and any requests made by the Secretary of State to investigate an incident. The draft Bill provides:

   (1) Before deciding whether or not to investigate a qualifying incident, the HSSIB must consider any representations made by—

      (a) the Secretary of State, and

      (b) any other persons the HSSIB considers appropriate.

   (2) The HSSIB must consider any request made to it by the Secretary of State to carry out an investigation into a particular qualifying incident or qualifying incidents falling within a particular description.

272. Professor Murray Anderson-Wallace, a member of the Advisory Panel for the present HSIB, suggested that this clause “calls into question the independence of the HSSIB, and may erode public and professional confidence in its decisions to investigate”, adding that any suggestion that these decisions were influenced by political interests would be “wholly unacceptable”. The Expert Advisory Group that provided advice on the establishment of the HSIB had expressed concerns that “direct referrals from Ministers or others in authority may be perceived as jeopardising HSIB’s independence and raise questions as to why another case was not referred.” William Vineall told us that HSSIB will

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348 The Professional Standards Authority for Health and Social Care (SIB0031), para 3.21
349 Q420
350 Clause 4
351 Professor Murray Anderson-Wallace (SIB0036), para 10; see also Royal College of Physicians (SIB0019), para 6, and Scott Morrish (SIB0035), para 12.
choose what it investigates: “That is not dictated by the Government Department”; and that the Secretary of State will not have the power to stop HSSIB from carrying out an investigation.353

273. Professor Brian Toft, Professor Charles Vincent and Dr Carl Macrae all drew a distinction between the right of the Secretary of State to make a request—which HSSIB could refuse—and the power to direct or mandate.354 Professor Toft suggested a link with the governance and accountability of HSSIB: “If [the Secretary of State] was not in charge of it, he could make a request that would be a request, as opposed to a request that is really a direction”.355

274. We do not consider that the current provision requiring HSSIB to “consider” representations or requests made by the Secretary of State about investigations amounts to a direction by the Minister. Confidence in the ability of HSSIB to say “No” to such representations or requests will be increased, however, if it has clearer independence from the Secretary of State.

275. While the draft Bill provides for HSSIB to regulate its own procedures (in paragraph 10(1) of schedule 1), it makes no such provision in respect of what it investigates. HSSIB should decide its priorities objectively and on the basis of what will best serve the interest of patient safety. We recommend that the Bill be amended expressly to preserve HSSIB’s independence of judgement in this regard. We also recommend that clause 4(1) be amended to remove the reference to the Secretary of State.

276. Clause 18(2) of the draft Bill gives the Secretary of State power to “direct the HSSIB to exercise such of its functions, in such manner and within such a period, as the direction specifies.” This power is intended to apply if the Secretary of State considers that HSSIB is failing or has failed to exercise any of its functions, including failing to exercise them properly, and that the failure is significant.356 When we asked the Minister and her officials about this limitation on HSSIB’s independence, they told us that it was not an unusual provision: there was an equivalent power in CQC legislation so that “[i]f the body turned out to be rogue”, the Secretary of State would have the ability to act. It was not the intention of the Secretary of State to use the power to intervene on a regular basis, or in an individual investigation.357

277. Although we accept that there is no intention to use this power to intervene frequently in HSSIB’s activities, this clause gives a broad-based authority to the Secretary of State. HSSIB’s ‘functions’ might be held to include how it carried out its investigations, or the substantive content of its reports or recommendations. It will be for the Secretary of State to determine what a ‘proper’ exercise of these functions might be. We therefore consider that the power in clause 18 should be limited to prevent the Secretary of State from directing how HSSIB should investigate, or the content of its reports or recommendations.

353 Qq421 and (together with Jennifer Benjamin) 425
354 Qq245–247 and Q250
355 Q247
356 Clause 18(1) and (4)
357 Q425 [Mr Vineall]
Governance and accountability

278. The Minister and her officials assured us that HSSIB is intended to have as much independence as is possible given that it will be in receipt of public money. It is proposed that HSSIB should be set up as a non-departmental public body, in contrast to the current Healthcare Safety Investigation Branch (HSIB) which is part of NHS Improvement.

279. Schedule 1 of the draft Bill makes provisions concerning the membership of HSSIB’s Board, including the appointment of the Chief Investigator (its chief executive), and its financial obligations. The Bill specifies that the chair of HSSIB’s board and at least four other non-executive members will be appointed by the Secretary of State. The Chief Investigator will be appointed by the non-executive members, with the consent of the Secretary of State. The other executive board members will be appointed by the non-executives. The number of executive members must be less than the number of non-executive members. HSSIB will have to make an annual report on how it has exercised its functions, including the use of its financial resources; this report must be sent to the Secretary of State, who is required to lay it before Parliament, and HSSIB must then publish it.

280. The provisions for the funding of HSSIB and its financial responsibilities appear to be standard for such a body.

281. We considered the process for appointment of the members of HSSIB’s Board in the context of ensuring that HSSIB will have sufficient independence from the DHSC. We focused in particular on the appointment of the Chief Investigator and the power for the Secretary of State to remove members of the board from office.

282. Paragraph 5 of Schedule 1 to the draft Bill provides that the Secretary of State may at any time remove a person from office as a non-executive member of the board on the grounds of incapacity, misbehaviour, or failure to carry out the duties of a non-executive member. The executive members of the board are, however, employees of HSSIB and as such will be subject to normal employment law and protections.

283. We note that the Chief Investigator will be appointed by the non-executive members of the board, with the consent of the Secretary of State. The non-executive members of the board will also be appointed by the Secretary of State. While we acknowledge that the Chief Investigator must be responsible to the Secretary of State for the expenditure of public money and the general exercise of his or her responsibilities, we consider that there should be wider accountability, through Parliament. We recommend 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.

284. There was widespread agreement among our witnesses that there would be more confidence in HSSIB’s independence were it to be accountable to Parliament rather than to the Secretary of State. When asked whether accountability to Parliament might not also be seen as political influence, Professor Toft responded that accountability through a

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358 Schedule 1, paras 2-4
359 Schedule 1, para 21
360 The Doctors’ Association UK indicated these aspects were serious concerns for them: (SIB0015), para 3. EHRC also highlighted them as one of its major criticisms of the draft Bill: (SIB0008), para 11. See also NHS Providers (SIB0023), paras 18 and 21; and Professor Murray Anderson-Wallace (SIB0036), para 9.
361 Qq131–132 (GMC and PSA), Q243 (Professor Toft), NHS Providers (SIB0023), paras 18–21
cross-party committee was more likely to inspire confidence than to a single Minister, and that a committee was more likely to scrutinise and not to give directions.\textsuperscript{362} Harry Cayton of the PSA agreed:

\begin{quote}
We have seen that accountability to Parliament helps to build public acceptance of these models. There was discussion this morning about the extent to which patients and the public will feel confident in this new model. There is an issue relating to accountability, and the answerability of HSSIB to Parliament would be a preferable model, in my view.\textsuperscript{363}
\end{quote}

\textbf{285.} We note that HSSIB will be required to make an annual report, which will be presented to Parliament. This will afford an opportunity for the Commons Health and Social Care Committee to scrutinise the quality of HSSIB’s investigations and reports, and their effect on patient safety.

\textbf{Reviewing the effectiveness of HSSIB}

286. There is, understandably, some concern about how HSSIB will operate in practice, and we have paid careful attention to the issues raised by our witnesses. HSSIB is based upon an innovative concept for investigating patient safety incidents in the healthcare sector. There should be provision in the Bill for a mechanism for reviewing the effectiveness of the new body, after a suitable period for it to establish itself, and then a review of the effectiveness of the legal framework for HSSIB. \textit{We recommend that the legislation establishing HSSIB be subject to a post-legislative review, three years after HSSIB starts its work (rather than three years after enactment).}
Conclusions and recommendations

Introduction

1. *The Government should implement the technical recommendations listed in the final column of Appendix 3.* *(Paragraph 18)*

Purpose of HSSIB

2. We welcome the clarity about HSSIB’s role. It is intended that HSSIB will be a wholly new statutory and independent capability, separate from the rest of the healthcare system, for conducting investigations into patient safety incidents. HSSIB will not be part of the complaints system. HSSIB may undertake individual investigations, but not because patients and families are dissatisfied with the outcomes of existing processes. Equally, as the Chief Investigator makes clear, HSSIB will not act as a regulator or an enforcement agency as either responsibility would compromise its role and independence from the system it is meant to be investigating. *(Paragraph 29)*

3. The NHS in England employs over 1.2 million people. It is not a single organisation but a complex system composed of multiple cultures across varied organisations and geographies. By the term, culture, it is important to understand that we are talking about attitudes and behaviour. Culture change is about changing attitudes and behaviour; encouraging the right attitudes and behaviour, and discouraging the wrong ones (such as bullying). This is the responsibility of every individual in healthcare and, in the NHS in particular, clinical and system leaders must take responsibility for demonstrating attitudes and behaviour consistent with a just culture. *(Paragraph 42)*

4. It is impossible for any single organisation to change the established values and habits prevalent within the NHS. We also recognise the work already being done by trusts—and through initiatives such as Freedom to Speak Up Guardians—to improve the culture within the NHS. HSSIB should not, on its own, be expected to achieve culture change; but, as a new and independent capability, it can provide leadership and demonstrate behaviour which will lead to a healthier and more open culture in healthcare. *(Paragraph 43)*

5. HSSIB investigations will operate in the ‘safe space’ which will reduce the fear of talking openly. The objective of HSSIB investigations is not to find blame. Other investigatory activity in healthcare will still focus on making assessments of responsibility and accountability for errors. In the long-term, HSSIB’s contribution to culture change will be by demonstrating to patients, clinicians, providers, regulators and other investigators the value of patient safety investigations which examine context, focus on learning, and which do not find or apportion blame. In doing so, HSSIB can influence the development of a just culture where learning is paramount and errors are understood within the context of ‘human factors’ and the environment in which individual health professionals provide care. *(Paragraph 44)*
The ‘safe space’ (the prohibition on disclosure)

6. We are persuaded by patients, and their representative organisations, that there is nothing unreasonable about injured patients seeking compensation or other redress. Therefore, this Bill and HSSIB should place nothing in the way of patients and their families’ ability to seek compensation. The importance of this principle is reflected in the recommendations we make. (Paragraph 54)

7. We also have been guided by a second principle, namely that the primary and overriding purpose of this Bill is to put in place arrangements that will lead to learning and improvement arising from objective and comprehensive analysis of the causes of clinical mistakes and incidents, leading to better and safer outcomes for users of the healthcare system. We do not think this second principle is incompatible with obtaining justice in individual cases, which may and should be pursued by other means. (Paragraph 55)

8. It is in the wider public interest, and in the interest of patients and everyone in healthcare, that procedures be pursued that will assist in improving patient safety. Subject to the reservations set out below, we are therefore supportive of the proposal to provide for ‘safe space’. (Paragraph 56)

9. 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. (Paragraph 63)

10. Assuming the Government accepts our recommendation regarding the accreditation of trusts, nothing about the ‘safe space’ would prevent patients (or regulators, the police, or the public) from acquiring anything to which they currently have access. We are absolutely clear that the sole purpose of the ‘safe space’ is to facilitate gathering evidence for HSSIB’s ‘no-blame’ investigations. It does not interfere with any other investigation or inquiry procedure which already exists. (Paragraph 69)

11. Patients will not be supplied with the new evidence that HSSIB will obtain or compile. That is not the purpose of HSSIB. But we expect HSSIB to provide sufficient detail in its reports for patients and their families to understand, in clear terms: what happened, what went wrong, why, and what should be done to make sure it does not happen again. In our view, this is the purpose of HSSIB. At the same time, we recognise that some patients may not wish their information or testimony to be shared with others. (Paragraph 72)

12. We are reassured that the draft Bill will require HSSIB, before it publishes a report, to send a draft of the report to everyone who participated in the investigation, and to notify them that they have the opportunity to comment on the draft. (Paragraph 73)
13. We agree with The Patients Association that it will be very helpful to engage with patients to help them better understand what ‘safe space’ means, why it is important, and how such investigations will be conducted. It is not clear to us whether HSSIB will have the resources to sustain this important role, which is vital for patient and public confidence in HSSIB. We recommend that the Department for Health and Social Care and HSSIB engage with patients and families, and their advocates or representatives, to ensure that the ‘safe space’ is widely understood by them. (Paragraph 75)

14. While the evidence of the effect of the duty of candour on changing the culture in the NHS may be mixed, we believe it is contributing to positive change. It is clear that HSSIB, and only HSSIB, is prevented from disclosing information under the draft Bill’s prohibition on disclosure (clause 28). The healthcare professional’s duty of candour is not diluted by the ‘safe space’ in any way. Nor would other contributors to an investigation, such as patients, be barred from sharing with others the evidence they gave to HSSIB. (Paragraph 80)

15. It would not be right for this draft Bill to restrict information which is freely available at present and, in respect of HSSIB investigations, it does not do so. HSSIB’s purpose is not to provide a hiding place for uncomfortable truths, but—in the interests of patient safety—to provide the greatest possible assurance that its investigations will have no negative consequence for participants. We look at accreditation in Chapter 4, but this provides an initial, and compelling, reason why we do not support the accreditation of trusts to conduct ‘safe space’ investigations. (Paragraph 83)

16. As the Bill is drafted, it is clear that the prohibition on disclosure (by HSSIB or an accredited trust) goes much further than just witness statements. Nevertheless, and in the light of our conclusion in paragraph 63, we conclude that this blanket ban on HSSIB disclosing the evidence that it gathers or generates—with specific exceptions—is the solution most likely to achieve the aim of getting to the truth, in the interests of patient safety. (Paragraph 88)

17. We recommend that the ‘safe space’ protection be extended, so that the prohibition on disclosure in clause 28 covers any information and material disclosed to HSSIB (other than by the Secretary of State or a healthcare provider) which HSSIB reasonably considers to have been provided for the purpose of promoting patient safety, or of inviting HSSIB to investigate a matter relevant to patient safety, whether or not it leads to an investigation. (Paragraph 91)

18. 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. (Paragraph 102)

19. We recognise that problems associated with mental wellbeing can affect all professional groups in healthcare, all of whom play a critical role in ensuring patient safety. We believe that the protections afforded by the ‘safe space’ will be important
to health professionals who are under stress from patient safety investigations or complaints, or who may be managing mental health problems. They will be able to speak more freely in the ‘safe space’ about the nature of their work, its impact on them, and the consequences for patient safety. (Paragraph 103)

20. We conclude from the evidence that the risk of patients having to give their account twice should be minimised by practical co-operation between the regulators and HSSIB; perhaps an agreed format or set of questions for obtaining a patient’s account, with a copy retained by the patient. We discuss how HSSIB should operate in order to address this later in this Report. (Paragraph 107)

21. We have considered the concern that there is a risk of conflicting accounts rendering evidence unreliable. But we are assured it is unfounded. Any account provided to HSSIB would be protected by the ‘safe space’. Healthcare professionals will remain subject to their professional duties, not least the duty of candour. The ‘safe space’ will have no impact on these duties. (Paragraph 108)

22. We see no reason for HSSIB to disclose evidence it has received, unless it believes there is a serious and continuing risk to the safety of a patient, or to the public. The Chief Investigator of the present HSIB does not think it would be appropriate otherwise. The regulators rightly want greater certainty about what will be disclosed and this should be made clear in the Bill. (Paragraph 109)

23. We recommend that the Government amend clause 29 to permit HSSIB to disclose to police, regulators, and/or trusts:

   a) solely on the grounds that there is a serious and continuing risk to the safety of a patient, or to the public; and,

   b) no more than the information necessary to enable the recipient of the information to set in train its own enquiries. (Paragraph 110)

24. We are satisfied with the provision in clause 30 setting out the power of the High Court to order HSSIB to disclose information, and the test it is to apply. The High Court will only be able to do so if it determines that the interests of justice served by disclosure outweigh any adverse impact on the ability of the Secretary of State to improve the safety of NHS services, or on people’s willingness to participate in future HSSIB investigations. This should only be in the most exceptional circumstances. (Paragraph 112)

25. 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. (Paragraph 117)
26. 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. (Paragraph 119)

27. In the light of the two preceding recommendations and 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. (Paragraph 120)

28. HSSIB needs the freedom (but should not be under any obligation) to release factual
information during an investigation which could be of benefit to patient safety. We
note that this reflects the way the HSIB currently operates. We therefore recommend
the Bill be amended to allow disclosure, where in the view of HSSIB there may be
a benefit to patient safety, to regulators, NHS bodies, suppliers, manufacturers, or
the Secretary of State, of the information HSSIB deems of potential benefit, but not
including—

a) statements taken from any person in the course of an investigation, or
submitted to HSSIB for the purpose of inviting it to investigate;

b) any information likely to reveal the identity of—

i) an individual who has given evidence, or

ii) any individual involved in an incident; or

c) drafts of interim or final reports. (Paragraph 124)

29. The Government should consider whether some of the other categories of material
ought to be added to the above list of exclusions, and it should be guided by EU air
accident investigation provisions. (Paragraph 125)

30. We understand the concern of some patient groups that they will not be able to use
the information published by HSSIB to obtain justice or compensation. However,
this does not prevent anyone from using knowledge gained from HSSIB published
material to inform the framing of a case for legal redress. As previously stated, we
are committed to the principle that this Bill should do nothing to restrict patients’
ability to seek redress. We are satisfied that it does not do so. (Paragraph 130)

31. There is no difficulty with coroners using reports from HSSIB and, where appropriate,
hearing from its investigators to avoid duplication of investigations. (Paragraph 133)

32. We recommend that any evidence given to the coroner by HSSIB, including that given
by investigators in oral evidence, be subject to the same test for admissibility in other
proceedings as are reports of HSSIB, so that evidence given to the coroner does not
become a ‘back door’ means of using in court information that was shared in the ‘safe
space’. (Paragraph 134)

33. We raised with the Government the question of the draft Bill’s compatibility with
data protection legislation (including EU law). There should be no question that the
‘safe space’ could be subject to any data access or freedom of information requests.
We are satisfied with the Government’s assurance that ‘safe space’ information would be exempt from access requests under data protection legislation and invite the Government to give us the same assurance in relation to freedom of information requests. (Paragraph 138)

‘Safe space’ investigations by accredited NHS trusts

34. Accreditation of NHS trusts to undertake ‘safe space’ investigations risks creating conflicts of interest, since trusts have an interest in the information held in the ‘safe space’. An NHS trust may be the employer of those who are subject to the investigation, and may be subject to civil or even criminal proceedings. These conflicts would undermine public trust that the principle of ‘safe space’ was being used solely in the interest of patient safety, and this would damage the whole perception of ‘safe space’ investigations. (Paragraph 156)

35. NHS trusts have an obligation to continue to investigate complaints and patient safety incidents in a transparent and open way, but they cannot be as objective and independent as HSSIB will be. If ‘safe space’ investigations prove as valuable as we expect, and there is demand for more capacity for such investigations, accrediting trusts to conduct them is not a credible solution. The Government would have to choose whether or not to grow the capacity of HSSIB to do more. There is no other option. (Paragraph 157)

36. Furthermore, accreditation of trusts to conduct ‘safe space’ investigations will turn HSSIB into the de facto regulator of accredited trusts. HSSIB should not be a regulator in any sense or there will be confusion about its primary function. HSSIB represents a new capability for investigating patient safety incidents, and that is all. We established in Chapter 2 that the purpose of HSSIB is to be an independent investigatory body. (Paragraph 158)

37. HSSIB does, however, have an important role to play in promoting better standards for local investigations, which trusts and other bodies will continue to conduct without the ‘safe space’. We believe that improvements to patient safety can be best achieved by HSSIB working with providers to:

   a) model best practice and develop methodologies which enhance the quality and consistency of local investigations conducted by trusts;

   b) train local investigative staff in conducting investigations which find fact and identify learning but do not apportion blame; and

   c) support the development of a curriculum, courses, examinations, and qualifications so that a new profession is developed, namely one of professional medical investigators.

In doing this HSSIB could help lead progress towards the wider culture change that witnesses to our inquiry have called for, but it will require additional resources. (Paragraph 159)

38. We believe that accreditation of trusts to conduct ‘safe space’ investigations is wholly misconceived. As has been noted, it would be like allowing an airline to investigate
their own air accidents in place of the Air Accident Investigation Branch of the Department of Transport. Accredited trusts could not be objective. Accredited trust ‘safe space’ investigations would also risk undermining public confidence in the whole idea of ‘safe space’ investigations. (Paragraph 160)

39. We recommend Part 3 of the draft Bill (Investigations by accredited foundation or NHS trusts) be removed altogether. The Government’s policy should not be for HSSIB to accredit ‘safe space’ investigations at local level but to support HSSIB in improving the quality of all local investigations. We recommend that the Government should also be ready to grow the capacity of HSSIB once the value of ‘safe space’ investigations is established, and if there is demand for HSSIB to do more. (Paragraph 161)

40. All of the recommendations set out in this Report are predicated on the Government accepting our recommendation to remove the accreditation of NHS trusts from the draft Bill. (Paragraph 162)

Scope of HSSIB and the additional 1,000 maternity cases

41. It is understandable that the former Secretary of State should have wanted to leverage the expertise and capability of the present HSIB for the maximum benefit of patient safety improvement in the NHS. However, the imposition of 1,000 local maternity investigations outside of ‘safe space’ risks completely misconstruing the function of the statutory HSSIB. This decision has the potential to distort the perception of what HSSIB is for, within the health sector. We are concerned that HSSIB should be understood across healthcare. Its purpose and function is the conduct of ‘safe space’ investigations of incidents without finding blame in order to promote patient safety and learning. It is not an organisation to be tasked by others to deliver local NHS investigations. (Paragraph 169)

42. The confusion about HSSIB’s intended purpose created by the direction to oversee the investigation of 1,000 maternity cases underscores the importance of HSSIB’s independence. We regard the draft Bill as an opportunity to confirm the independent status of HSSIB and to secure it in statute. (Paragraph 170)

43. We recommend that the conduct of the 1,000 maternity investigations should be recognised as the responsibility of NHS Improvement, which in legal terms it already is. Once established in statute, HSSIB can continue to provide advice and guidance to NHS Improvement so that best investigative practice can be applied to maternity, or any other, investigations. However, responsibility for the maternity investigations should remain with NHS Improvement and should not be transferred to the new body. It would risk creating confusion about its role and undermine clarity and trust in HSSIB. HSSIB’s funding should be adjusted to reflect the costs of providing advice to the NHS, but it should only have responsibility for conducting its own investigations. (Paragraph 171)

44. We do not believe that the draft Bill should be recast to allow HSSIB to conduct investigations which do not have the protection of ‘safe space’. (Paragraph 172)

45. Our evidence was clear that HSSIB’s remit should extend beyond just NHS-funded services to the whole healthcare system. We recommend that the draft Bill should be
amended to extend HSSIB’s remit to the provision of all healthcare in England, however funded. Implementing this recommendation will demand consequential amendments, including reflecting it in the title of the Bill and the name of the investigative body. We recommend that the legislation should be called the ‘Healthcare Safety Investigations Bill’ and, consequently, it would establish the ‘Healthcare Safety Investigations Body’ (HSIB) in statute. (Paragraph 179)

46. NHS funding should not be used to subsidise investigative work that will also apply to the private sector. We recommend that the Government should undertake a formal consultation to explore how private providers can make a proportionate contribution to the patient safety work undertaken by HSSIB. We do, however, warn against charging fees for investigations. (Paragraph 180)

47. We do not believe that the draft Bill reflects the integrated nature of modern healthcare. The development of NHS Vanguards, integrated care pioneers, sustainability and transformation partnerships, and integrated care systems (amongst many other initiatives) have all sought to bring together multiple NHS services with local authority commissioned social care. In many areas adult social care staff are now working in concert with NHS teams on a daily basis, be that in primary and community services or enabling discharge from secondary care. (Paragraph 184)

48. 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. Nonetheless, we do recommend that 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. (Paragraph 185)

49. Questions remain about HSSIB’s scope as it relates to investigating patient pathways that cross borders between the nations of the UK. In addition, there is a lack of clarity about the scope of HSSIB to investigate incidents which occur in satellite services of English trusts based in hospitals outside of England. (Paragraph 189)

50. It will be for the devolved nations to determine how they wish to respond to the development of HSSIB in England. Nonetheless, we expect the devolved health systems to develop mechanisms which allow for cross-border co-operation between HSSIB and appropriate bodies in Scotland, Wales and Northern Ireland when an HSSIB investigation includes aspects of cross-border care. (Paragraph 191)

51. The Government should also clarify that HSSIB’s investigation functions can be conducted in relation to any incidents occurring in England, wherever a patient may originate from, including where any significant causative factor takes place in England. (Paragraph 192)

52. To address the uncertainties that will remain around the provision of cross-border services we recommend that the draft Bill should be amended to: (Paragraph 193)
   a) enable reciprocal arrangements between HSSIB and the devolved health systems in cases of cross-border care; and (Paragraph 193.a))
   b) allow devolved administrations to choose whether HSSIB’s remit should be extended to their territory, if they so wish. (Paragraph 193.b))
Powers and procedures of HSSIB

53. As we have already made clear, it is vital that healthcare professionals and others feel able to use the HSSIB ‘safe space’ to report any matters of concern about patient safety, whether or not an incident has actually occurred. We have considered whether to go further: whether there should be a requirement on healthcare providers to report serious incidents directly to HSSIB. We are cautious about adding to the reporting burden on healthcare professionals—who are already obliged to report patient safety incidents, including ‘near misses’—particularly since this is unlikely to increase the amount of useable information available to HSSIB. (Paragraph 196)

54. HSSIB will require access to existing reporting systems as well as full and practical co-operation with the bodies already collecting and categorising information, but this should not require legislation. It is up to HSSIB to promote itself as an organisation to which healthcare professionals should feel they can turn, in complete confidence, when they need to raise a patient safety issue which is not being addressed satisfactorily elsewhere. (Paragraph 197)

55. While noting the concern some witnesses expressed at the lack of a clear definition of ‘qualifying incident’, we do not consider that any such definition should be inserted in the draft Bill. HSSIB should be able to determine what incidents it investigates according to specified patient safety benefit criteria. Based on the approach taken by the current HSIB, we are confident that HSSIB will endeavour to communicate these clearly to the public and other investigatory bodies to maximise certainty and manage expectations. (Paragraph 202)

56. We are content that the draft Bill is sufficiently flexible to enable HSSIB to investigate any patient safety issue, including by initiating thematic reviews without there necessarily being a ‘qualifying incident’. (Paragraph 204)

57. We agree that HSSIB should consult as widely as possible in developing the criteria, principles and processes for its investigations, in order to benefit from a broad range of experiences and expertise. However, we are not convinced there is value in being prescriptive about this in the legislation. We are content that clause 3(6) as drafted will facilitate appropriate consultation with all relevant stakeholders, and expect this to include patients and families, or their representatives. (Paragraph 207)

58. We recommend that clause 4 be amended to include the requirement that HSSIB must inform any person who has, or may have, been harmed by the incident (or their families), as far as reasonably practicable, before deciding whether to investigate a qualifying incident. (Paragraph 209)

59. We endorse the HSIB’s open and transparent approach to engaging with patients, their advocates, families and carers, and welcome the draft Bill’s particular focus on the involvement of patients and families with regard to the investigations that will be undertaken by the new body. (Paragraph 217)

60. In addition to the moral imperative to be open with patients, their families, and patient advocates, we agree with witnesses to this inquiry that engaging with
patients and families will be critical to ensuring HSSIB investigations capture the ‘whole picture’ of events in any given incident. We are satisfied that the provisions outlined in clause 3 will facilitate this. (Paragraph 218)

61. It will also be essential to ensure that the processes developed to determine the involvement of patients, families and carers in HSSIB investigations are as simple and accessible as possible, so that no additional burden is placed on them during an already difficult and distressing time. (Paragraph 219)

62. We agree that co-operation, and the establishment of effective working relationships, with other investigative bodies will be essential to ensure co-ordination during parallel investigations, and for HSSIB to be able to fulfil its functions. Nonetheless, we are concerned about the implications of imposing a statutory duty to co-operate on HSSIB given the fundamental importance—as emphasised by Keith Conradi and earlier in this report—of the body’s independence and separation from the existing system. Consequently, we recommend that clause 15(2) be removed from the draft Bill. (Paragraph 232)

63. We consider that article 12(3) of Regulation (EU) No 996/2010 could be usefully adapted for the draft Bill, to provide for the development of MOU between HSSIB and relevant bodies. We therefore recommend that a requirement similar to that in Article 12(3) be inserted into clause 15 of the draft Bill. (Paragraph 234)

64. We are content that, if our recommendation is accepted, the Bill will facilitate the necessary levels of co-operation between HSSIB and other investigative bodies. As noted in Chapter 3, we call on all parties involved to develop appropriate processes to minimise the burden of participating in parallel investigations on patients, families and healthcare professionals. (Paragraph 235)

65. We believe HSSIB should have power to compel individuals. Clause 7 as drafted probably gives it this power, but we think it should be put beyond doubt. The experience of equivalent bodies in other safety critical industries is that it will almost certainly never be needed, but its existence will help to establish the authority of HSSIB and make clear that assisting it is not optional. It is, as was put to us, the quid pro quo for affording people who work in healthcare a ‘safe space’. (Paragraph 241)

66. We recommend that the Government should amend clause 7 to reserve to HSSIB the power to issue a summons to compel individuals to answer its questions (Paragraph 242)

67. Clause 5(3)(d) could be interpreted by HSSIB to exclude an interviewee’s representative or supporting colleague. That does not appear to be the intention of HSSIB, and we think it unlikely investigators will do so, other than in rare circumstances, if they want to secure the co-operation of a witness. Nonetheless, we think that an interviewee’s right to be accompanied should be expressed in the legislation. (Paragraph 244)

68. It is imperative that HSSIB be seen as a body with which individuals and bodies must co-operate. Despite recent moves away from criminal prosecution, strong powers of coercion are, in this instance, appropriate. We sincerely hope that such powers will never need to be exercised. (Paragraph 249)
69. We recommend that non-compliance with clause 7 be made a criminal offence, punishable by a fine or imprisonment of up to three months, as is the case with safety investigation bodies in other safety critical industries. (Paragraph 250)

70. If the Government does not make non-compliance a criminal offence, we recommend that the First-tier Tribunal be given jurisdiction to entertain an appeal against a penalty notice as a complete rehearing. (Paragraph 253)

71. There seems little justification for requiring HSSIB to obtain a warrant before entering premises (other than residential premises) or inspecting, copying or seizing things, or interviewing witnesses. The requirement for a warrant would invite people to misconstrue HSSIB as a prosecuting authority, rather than an organisation that is investigating without finding blame. Although the current Chief Inspector of HSIB does not seek the power to enter residential premises, we think it would be better—subject to appropriate safeguards—to have this power and not use it than to need it but be powerless to act. Indeed, there may well be cases in which healthcare services are provided from premises which are used mainly as a private dwelling, and an investigation could be hampered without access. In these cases, the requirement for a warrant would respect the significance of forcing entry to a private dwelling. (Paragraph 258)

72. The Government should remove from the Bill the need for HSSIB to obtain a warrant before taking an action under clause 5(1) or (3) to which the relevant person does not agree. Instead, investigators should be allowed to carry out an action in clause 5(1) or (3) where, in the opinion of the investigator-in-charge, it is necessary for the purposes of the investigation. HSSIB’s inspectors should have the power to enter residential premises, provided they obtain a warrant before doing so. (Paragraph 259)

73. The Government should ensure that any provision in the revised Bill dealing with the issue of a warrant specifies:

   a) that a Justice of the Peace may issue the warrant; and

   b) of what the Justice of the Peace must be satisfied (and whether on oath) before issuing the warrant. (Paragraph 261)

74. Clause 31 of the draft Bill requires HSSIB to report findings of fact from its investigations and an analysis of those findings, and to identify what actions should be taken as a result, by whom and when. It also provides that HSSIB must circulate a draft of its report to all organisations and individuals who participated in the investigation, seeking their comments by a set deadline and, if it did not take their comments into account in the final report, it would have to explain why. We consider that the provisions in clause 31 are satisfactory. (Paragraph 265)

75. We have already stated our view that, not least to avoid confusion over its role, HSSIB should not be responsible for ensuring implementation of its recommendations. (Paragraph 269)

76. We recommend that the Care Quality Commission incorporate the implementation of HSSIB recommendations into its quality standards, so that there will be assurance about their implementation. (Paragraph 269)
Governance and accountability of HSSIB

77. We do not consider that the current provision requiring HSSIB to “consider” representations or requests made by the Secretary of State about investigations amounts to a direction by the Minister. Confidence in the ability of HSSIB to say “No” to such representations or requests will be increased, however, if it has clearer independence from the Secretary of State. (Paragraph 274)

78. While the draft Bill provides for HSSIB to regulate its own procedures (in paragraph 10(1) of schedule 1), it makes no such provision in respect of what it investigates. HSSIB should decide its priorities objectively and on the basis of what will best serve the interest of patient safety. We recommend that the Bill be amended expressly to preserve HSSIB’s independence of judgement in this regard. We also recommend that clause 4(1) be amended to remove the reference to the Secretary of State. (Paragraph 275)

79. Although we accept that there is no intention to use this power to intervene frequently in HSSIB’s activities, this clause gives a broad-based authority to the Secretary of State. HSSIB’s ‘functions’ might be held to include how it carried out its investigations, or the substantive content of its reports or recommendations. It will be for the Secretary of State to determine what a ‘proper’ exercise of these functions might be. We therefore consider that the power in clause 18 should be limited to prevent the Secretary of State from directing how HSSIB should investigate, or the content of its reports or recommendations. (Paragraph 277)

80. We note that the Chief Investigator will be appointed by the non-executive members of the board, with the consent of the Secretary of State. The non-executive members of the board will also be appointed by the Secretary of State. While we acknowledge that the Chief Investigator must be responsible to the Secretary of State for the expenditure of public money and the general exercise of his or her responsibilities, we consider that there should be wider accountability, through Parliament. We recommend 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. (Paragraph 283)

81. We note that HSSIB will be required to make an annual report, which will be presented to Parliament. This will afford an opportunity for the Commons Health and Social Care Committee to scrutinise the quality of HSSIB’s investigations and reports, and their effect on patient safety. (Paragraph 285)

82. We recommend that the legislation establishing HSSIB be subject to a post-legislative review, three years after HSSIB starts its work (rather than three years after enactment). (Paragraph 286)
Appendix 1: Members and interests

Members

Sir Bernard Jenkin MP (Chair)  Baroness Billingham
Diana Johnson MP            Baroness Chisholm of Owlp
David Jones MP              Baroness Eaton
Andrew Selous MP            Lord Elder
Dr Philippa Whitford MP     Lord Kirkwood of Kirkhope
Dr Paul Williams MP         Baroness Watkins of Tavistock

Declarations of interest (Lords)

Baroness Billingham

No relevant interests

Baroness Chisholm of Owlp

No relevant interests

Baroness Eaton

No relevant interests

Lord Elder

No relevant interests

Lord Kirkwood of Kirkhope

Former Chair of the General Medical Council’s ad hoc Advisory Committee on fitness to practise

Chair of General Pharmaceutical Council’s ad hoc Advisory Committee on fitness to practise

Member of the Professional Advisory Committee for VOPULUS Limited (a medical education technology company)

Member of the VOPULUS Healthcare Leadership Academy

Baroness Watkins of Tavistock

Nurse Adviser, BUPA Medical Advisory Panel and Global Quality Committee

Registered Nurse (non-practising)

Emeritus Professor of Nursing, Plymouth University

Visiting Professor of Nursing, King’s College London
President, Florence Nightingale Foundation (registered charity) (nursing scholarships)

Full lists of Members’ interests are recorded in the Commons Register of Members’ Financial Interests:

https://www.parliament.uk/business/publications/commons/

and the Register of Lords’ Interests:

Appendix 2: Call for Evidence

The Joint Committee on the Draft Health Service Safety Investigations Bill was appointed in May 2018 to consider the Government’s draft Bill to establish the Health Service Safety Investigations Body (HSSIB). The Committee invites interested individuals and organisations to submit written evidence to this inquiry. The deadline for written evidence is 8 June 2018.

The Committee will make recommendations in a report to both Houses by 24 July 2018. In the short time available to us, the Committee will focus on the content of the draft Bill, and its scope, rather than other more general policy aspects. We will not consider the merits of individual cases which have been, or are now, subject to formal proceedings in courts or tribunals.

Guidance on the format of submissions is given at the end of this document.

Draft Health Service Safety Investigations Bill

The draft Bill would change how serious incidents within NHS-commissioned services in England are investigated. The Government’s aim is to establish the HSSIB as an independent body and give it powers to gather evidence. The proposal is to conduct investigations in a ‘safe space’, prohibiting disclosure of information except in limited circumstances. The HSSIB would also be empowered to accredit NHS trusts so that they can undertake their own ‘safe space’ investigations.

Our aims

In scrutinising the draft Bill we aim to:

Clarify and examine the Government’s policy objectives
Assess whether the Bill as drafted would achieve the Government’s objectives
Identify any unintended consequences of the Bill
Make recommendations to improve the drafting of the Bill

Areas of interest

We shall explore, and would welcome views on any or all of, the key questions outlined below.

General issues

Will the HSSIB command the confidence of patients and their families and healthcare professionals?
Should the HSSIB’s remit extend to private healthcare?
Can patients and the public be confident that ‘safe space’ investigations will remedy the deficiencies of existing NHS complaints mechanisms?
Are there any deficiencies in the drafting of the Bill that would prevent it from achieving the Government’s objectives?

**Establishment and powers**

Will the establishment of the HSSIB add to confusion about the responsibilities of the various bodies currently dealing with complaints and safety concerns in healthcare?

Would the draft Bill equip the HSSIB with adequate powers to achieve the Government’s objective of improving patient safety, or the ability of the Secretary of State to secure the improvement of the safety of the NHS? Does it go too far in any respect?

Would it be appropriate to model the powers and status of the HSSIB more closely on similar bodies which investigate safety incidents in the aviation, rail or maritime industries?

Does the draft Bill ensure that the HSSIB is sufficiently independent of both the NHS and the Government?

**Safe space**

Is a legally protected ‘safe space’ necessary to successfully undertake NHS investigations?

Will creating a ‘safe space’ for safety investigations “encourage patients, families, NHS staff and other participants in an HSSIB investigation to speak freely for the purposes of promoting learning and improving safety”?

Would the draft Bill adequately protect from disclosure information given to the HSSIB?

**Accreditation**

Will the public have confidence in trusts carrying out their own ‘safe space’ investigations, and will this build public confidence in the NHS safety investigations system more generally?

Are the accreditation provisions in the draft Bill satisfactory?

Will the HSSIB be able to maintain standards of investigation?

**Reporting**

Will the HSSIB be able to effect change and ensure its recommendations are acted upon?

Would there be adequate safeguards for people referred to in HSSIB reports?
### Appendix 3: Schedule of technical drafting / legal points

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<tr>
<th>Clause</th>
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<th>Question</th>
<th>Department of Health and Social Care response</th>
<th>Committee conclusion or recommendation</th>
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<td>2</td>
<td>(2) The function … is exercisable for the purpose of addressing risks to the safety of patients by facilitating the improvement of systems and practice in the provision of NHS services.</td>
<td>Could the drafting of the purpose of the HSSIB be made clearer? Compare, for example, the objective of the Air Accidents Investigation Branch (AAIB): “the prevention of accidents and incidents” (Civil Aviation (Investigation of Air Accidents and Incidents) Regulations 2018, Reg 8).</td>
<td>The Department will review the drafting of these clauses to consider whether the purpose of the HSSIB could be made clearer.</td>
<td>Clarify and simplify the drafting of the HSSIB’s function.</td>
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<td>2 &amp; 3</td>
<td>2(6)(a) references to qualifying incidents are to incidents that have (or may have) implications for the safety of patients and which meet the criteria determined under section 3(1)(a) … 3(1) The HSSIB must determine … the criteria to be used by it for determining which qualifying incidents it investigates.</td>
<td>The definition of “qualifying incidents” is circular.</td>
<td>The Department considers that HSSIB should have the flexibility to set the criteria to be used to determine which incidents it will investigate, providing those incidents have or may have implications for the safety of patients. The drafting of this clause will be reviewed to ensure that it fully meets that policy aim. In particular, we will review the definition of “qualifying incident” to ensure that it is not circular.</td>
<td>Remove the circularity in drafting of qualifying incidents.</td>
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<td>5</td>
<td>(6) The following persons fall within this subsection … (c) persons providing NHS services … and their officers (in the case of bodies corporate) (d) persons providing services to— (i) an NHS foundation trust… (ii) persons falling within paragraph (c) and their officers (in the case of bodies corporate).</td>
<td>Has “and their officers (in the case of bodies corporate)” the effect the Government intends at paragraphs (c) and (d)? Are the words emphasised (left) intended to apply only to the subject of subparagraph (d)(iii), or rather to the “persons providing services” in paragraph (d)? As currently drafted, subparagraph (d)(iii), read literally, means only that a person providing services to persons providing NHS services and their officers would be within the subsection. Presumably, the intention is to encompass the officers of persons providing services to an NHS foundation trust, etc, in which case the emphasised words should form a “sandwich” continuation, after subparagraph (iii). Even with the emphasised words moved to form a sandwich continuation, a person providing services to officers of persons providing NHS services and their officers in paragraph (c). Is that really the intention?</td>
<td>The purpose of the clause is to capture subcontractors (such as cleaning services) of NHS foundation trusts, NHS trusts and other persons providing NHS services (such as GPs, dentists, community pharmacists etc.). Where the subcontractor is a corporate body the officers of that body should be captured. The Department will review the drafting of this clause to ensure it has the intended effect.</td>
<td>Correct the drafting of those against whom power to enter premises is exercisable.</td>
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<td>6</td>
<td>(4) The Chief Investigator may apply to a justice of the peace for a warrant … if… (5) An application under subsection (4) must… (7) A warrant granted on an application under subsection (4) authorises…</td>
<td>What criteria must a justice of the peace apply when deciding whether to grant a warrant? Why is this not set out in the legislation? The Justice of the Peace would need to be persuaded by the reasons set out in the application and consider that it is proportionate to issue the warrant. In practice we would expect that a warrant would only be granted if access is necessary for the purpose of the investigation, a notice has been issued in accordance with subsection (2) and the body or person to which the notice was given has not complied with the notice by the date specified.</td>
<td>See Chapter 6 (para 261).</td>
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<td>7 &amp; 9</td>
<td>7(1) ... to obtain any information, documents, equipment or other items from a person falling within subsection (12) ... 7(12) The following persons fall within this subsection— (a) an NHS foundation trust, an NHS trust or any other person providing NHS services; (b) any person providing services to a person falling within paragraph (a);</td>
<td>Is paragraph (b) of clauses 7(12) and 9(10) intended to include staff employed by an NHS trust? If so, why are employees of NHS bodies treated separately in cl 5(6)(e)?</td>
<td>These clauses are intended to capture NHS bodies only. They are not intended to capture any individuals including staff employed by an NHS trust. The information will be held and owned by the NHS body rather than the individual so it is the body that will be required to provide the information. It is also the body that can be penalised if the information is not provided. Certain individuals can be interviewed in private in accordance with clause 5(3)(d) and (6). It is expected that the NHS bodies listed will encourage their employees to co-operate with HSSIB. Clause 12(a) is intended to capture any body providing NHS services such as trusts, foundation trust, GP practices, and community pharmacists. It is not intended to capture individual employees or offices of those bodies. Clause 12(b) is intended to capture sub-contractors such as cleaning companies who provide services to NHS bodies but not individual employees of those sub-contractors. This is in contrast to clause 5 which is intended to capture individuals and therefore includes references to the officers and employees of various NHS bodies etc. The Department will review the drafting to ensure it meets the policy intention.</td>
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Please explain what classes of individual are intended to fall within clauses 7(12) and 9(10), with reference to the paragraphs of those subsections. These clauses are not intended to capture individuals.
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<td>9</td>
<td>(4) A penalty notice must … (f) explain the right to apply for an appeal under section 12.</td>
<td>A person does not apply for an appeal. Paragraph (f) should read “explain the right to appeal under section 12”. Do you agree?</td>
<td>The Department agrees and will consider amending the Bill accordingly.</td>
<td>Remove inaccurate wording relating to the explanation in penalty notices about the right to appeal.</td>
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| 12     | (2) An appeal under subsection (1) must be made only on one or both of the following grounds—  
|        | (a) that the person is not liable to the imposition of a penalty under section 9;  
|        | (b) that the amount of the penalty is too high.                                                                                                                                                       | Is it the intention to prevent a person from appealing to the First-tier Tribunal (FTT) where the decision to impose a penalty was irrational (or other public law grounds)?  
|        |                                                                                                                                                                                                 | Subsection (2)(a) offers a ground of appeal only where a person was not “liable” to imposition of a penalty under clause 9.                                                                                                                                 | This clause does not prevent a person from bringing a judicial review claim to review the lawfulness of a decision by the Chief Investigator on public law grounds where the powers of the Tribunal do not apply. The application would be made to the Administrative Court rather than the FTT.  
|        |                                                                                                                                                                                                 | The Department considers that a person could challenge whether they are “liable” to the imposition of a penalty on public law grounds. For example, they could say that they aren’t liable because of a public law error, such as an irrational decision by the Chief Investigator.  
|        |                                                                                                                                                                                                 | The Department will give further consideration to whether the grounds of appeal to the FTT should be broader, for example to allow an appeal against the decision to impose the penalty.                                                                                                                                 | See Chapter 6 (para 253). |
|        |                                                                                                                                                                                                 | On what basis is the FTT to assess whether the penalty is too high? Is the appeal to be by way of complete rehearing?                                                                                                                                               | Any sanctions will be against health bodies and providers of NHS services (most commonly NHS Trusts or NHS foundations Trusts) rather than individuals. The NHS bodies will be aware of the sanction and the maximum penalty that can be imposed and would have the right to appeal.  
|        |                                                                                                                                                                                                 | Insofar as a penalty notice can be given to an individual, it is not clear the Bill will be compliant with human rights legislation unless there is the broadest of appellate jurisdictions in relation to fines.  
|        |                                                                                                                                                                                                 | The Department expects that the FTT would consider the application and evidence before it and apply proportionality test to determine whether a penalty was too high. The FTT would be able to take human rights considerations into account when determining an appeal under clause 12.  
|        |                                                                                                                                                                                                 | The appeal allows decisions to be reviewed and then remade or remitted.  
|        |                                                                                                                                                                                                 | Further question:  
|        |                                                                                                                                                                                                 | What is the purpose of allowing the FTT to remit the decision to the Chief Investigator? How does this go beyond asking the investigator to mark their own homework?                                                                                                                                 | Further response:  
|        |                                                                                                                                                                                                 | Our intention here was for the FTT to have the option of remitting a decision to the Chief Investigator to be able to input/apply [the CI’s] expertise – this is broadly echoed in similar provisions for Monitor, but we take the point about marking own homework and we are reviewing this clause to ensure it is necessary.  
|        |                                                                                                                                                                                                 | We recommend the power to remit be re-drafted or omitted.  
|        |                                                                                                                                                                                                 | The clause as drafted does not provide a power to remit the decision to give a penalty notice, but—unusually, and for no obvious reason—gives a power to remit the appeal decision itself.  
<p>|        |                                                                                                                                                                                                 | As to the available grounds of appeal, see Chapter 6 (para 253). |</p>
<table>
<thead>
<tr>
<th>Clause</th>
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<th>Question</th>
<th>Department of Health and Social Care response</th>
<th>Committee conclusion or recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>(1) The HSSIB must publish guidance explaining the effect of sections 5 to 13.</td>
<td>What status and effect is the guidance intended to have?</td>
<td>The guidance is intended to explain the effect of clauses 5 to 13. This will include HSSIB’s powers to inspect premises and documents, the issuing of notices requiring the production of information, documents or equipment, the powers to enforce such notices including the power to impose a penalty of up £20,000, the duty to report non-compliance to the Secretary of State and the procedures to appeal against these decisions. The guidance is intended to advise and inform the reader so that they understand the process fully. Although there is no statutory requirement for any particular person to have regard to it, there will still be a public law duty to have regard to it.</td>
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<td>Clause</td>
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<td>Question</td>
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<tr>
<td>28</td>
<td></td>
<td>What is the intended sanction for an individual (e.g. employee of HSSIB) who causes a body to breach clause 28 by disclosing information? Is it simply those penalties provided by the Data Protection Act 1998 (s 55)/ GDPR / Data Protection Bill (cl 166)?</td>
<td></td>
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</tbody>
</table>

Clause 28 prohibits disclosure by HSSIB or an accredited trust and references to HSSIB or the trust includes any of its investigators or other employees. The Department expects these bodies to have procedures in place to ensure that the information they hold is kept secure and not unlawfully disclosed.

There is no specific sanction in the Bill in relation to an individual who discloses information held by HSSIB or an accredited trust in breach of this clause.

It may be possible for any person who is affected by any breach to seek an injunction or damages (depending on the context and consequences of the disclosure).

Any employee who causes a breach would be in breach of their contract of employment.

An individual who breaches this provision may have committed a criminal offence. Section 170(1) of the DPA 2018 makes it an offence for a person who knowingly or recklessly obtains, discloses or procures the disclosure of personal data without the consent of the data controller.

The Department considers that these are sufficient deterrents.
<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>30 &amp; 33</td>
<td>30(4) The Court may make an order ... only if it determines that the interests of justice served ... outweigh any adverse impact (a) on future investigations under Part 2 or 3 by deterring persons from participating in them...</td>
<td>Should not the balancing exercise in clauses 30(4) and 33(5) also include any adverse impact on current investigations?</td>
<td>The Department agrees that the balancing exercise should include consideration of any adverse impact on current and future investigations and will consider amending the Bill accordingly.</td>
<td>Re-draft to ensure the balancing exercise takes into account the adverse impact on current, as well as future, investigations</td>
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<td></td>
<td>Is it the intention that information should not be accessible under any right to information such as Art 15 of the GDPR? Do the proposed functions of the HSSIB fall within any of the exemptions in Schedule 2 (or elsewhere) of the Data Protection Bill?</td>
<td>HSSIB will be required to process personal data in accordance with data protection legislation. The Department considers that HSSIB’s proposed functions would fall within the exemption in paragraph 7 of Schedule 2 to the Data Protection Act 2018. In particular HSIB’s functions include (a) protecting the public against dishonesty, malpractice or other seriously improper conduct or unfitness or incompetence and (b) protecting persons other than those at work against risk to health or safety arising out of or in connection with the action of persons at work. Therefore the listed GDPR provisions including Article 15 would not apply to personal data for the purpose of discharging those functions. This will mean that information held in connection with an investigation will not be disclosed, including in response to any data subject access requests made by individuals.</td>
<td>See Chapter 3 (para 138).</td>
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<tr>
<td>Clause</td>
<td>Text</td>
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<tr>
<td>31</td>
<td>(7) Before it publishes a report the HSSIB or the accredited trust must send a draft of the report to every person who participated in the investigation.</td>
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</tbody>
</table>

**Question**

Why is no draft report to be sent to someone whose reputation could be damaged by the report, though they didn’t participate?

This contrasts with the approach with AAIB reports, where a notice of the proposed analysis of facts and conclusions must be served.

**Department of Health and Social Care response**

The Department expects that in most cases anyone whose reputation could be damaged by the report would have participated in the investigation.

HSSIB will have a common law duty to ensure that any person who will be criticised in the public report has a fair opportunity to respond to the criticism before the report is published. This could be during the investigation stage.

The Department will review this clause 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.

**Committee conclusion or recommendation**

Re-draft to require the HSSIB to share a draft report with anyone whose reputation could be damaged by the report.

**Question**

Why is no express requirement of confidentiality placed on recipients of draft reports?

This contrasts with the approach in relation to AAIB reports.

**Department of Health and Social Care response**

The Department’s view is that any draft report would contain confidential information and would be shared in circumstances importing an obligation of confidence. Therefore the HSSIB would be able to a claim for breach of confidence if there is an unauthorised use of the report or the information it contains.

HSSIB will be expected to explain to consultees that the draft report is provided in confidence.

**Committee conclusion or recommendation**

Make it an offence to disclose information contained in a draft report sent pursuant to clause 31(7)–(9).
<table>
<thead>
<tr>
<th>Clause</th>
<th>Text</th>
<th>Question</th>
<th>Department of Health and Social Care response</th>
<th>Committee conclusion or recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>(9)</td>
<td>If a person’s comments on a draft report are not to be taken into account in the report published under subsection (1) the HSSIB or the accredited trust must give the person an explanation of its reasons.</td>
<td>Is the intended effect of this subsection that the HSSIB or accredited trust should be free not to consider a person’s comments, rather than consider them but reject them? In contrast, the investigator-in-charge of an AAIB investigation must consider any representations made and make such changes as the investigator thinks fit.</td>
<td>The Department intends that HSSIB should consider any comments it receives in response to a draft report that are received before the deadline in the notice. HSSIB may amend the report in light of those comments if it considers it appropriate to do so. If the comments are not reflected in the final report, HSSIB must give the person an explanation of its reasons. The Department considers that the clause as drafted requires HSSIB to consider the comments as it must do so in order to determine whether or not to take them into account in the published report. However, we will consider whether the Bill should be amended to place an explicit obligation on HSSIB to consider any representations made to it.</td>
<td></td>
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<tr>
<td>33</td>
<td>(1) Subject to subsection (3), the following are not admissible in any proceedings falling within subsection (2)— (a) a report under section 31 or 32, or (b) a draft of such a report sent to any person under section 31(7).</td>
<td>Is it the Government’s intention that details of evidence given by an HSSIB investigator at an inquest should be admissible in other proceedings? If those details are admissible, might the bar on admissibility of reports lose much of its force? See paragraph 94 of the judgment in Hoyle v Rogers [2014] EWCA Civ 257.</td>
<td>Clause 33 only deals with the admissibility of reports and not the status of evidence given by an HSSIB investigator at an inquest. Whether or not a transcript of evidence is admissible in other proceedings will depend on the usual rules of evidence. We will consider this further and would invite the Committee’s views.</td>
<td>Protect any evidence given by an HSSIB investigator to a Coroner’s inquest from being admissible in other proceedings without an order of the High Court, which is to conduct the same balancing exercise as in clauses 30 and 33. See Chapter 3 (para 134).</td>
</tr>
</tbody>
</table>
Appendix 4: Responsibilities and processes following a healthcare incident

(From NHS Providers’ supplementary written evidence)

Following an incident, trusts have multiple responsibilities to discharge, and a number of parallel processes will be undertaken […] To give a brief overview:

<table>
<thead>
<tr>
<th>Instigated by patients, families, staff; undertaken by or involving the trust</th>
<th>Processes undertaken by the trust</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complaints—raised by patients or those representing their interests, which trusts must resolve within six months</td>
<td>Trust investigation—complying with the Serious Incident Framework (see next section), and completing investigations within 60 days</td>
</tr>
<tr>
<td>Concerns raised by staff—investigated by the line manager or freedom to speak up guardian</td>
<td>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>
<td>Legal action—taken by patients or their 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>
<td></td>
</tr>
</tbody>
</table>
### 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 (e.g. 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 |
Appendix 5: List of abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AAIB</td>
<td>Air Accidents Investigation Branch</td>
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<tr>
<td>AvMA</td>
<td>Action against Medical Accidents</td>
</tr>
<tr>
<td>APIL</td>
<td>Association of Personal Injury Lawyers</td>
</tr>
<tr>
<td>BMA</td>
<td>British Medical Association</td>
</tr>
<tr>
<td>CHFG</td>
<td>Clinical Human Factors Group</td>
</tr>
<tr>
<td>CQC</td>
<td>Care Quality Commission</td>
</tr>
<tr>
<td>DHSC</td>
<td>Department for Health and Social Care</td>
</tr>
<tr>
<td>FOI</td>
<td>Freedom of information</td>
</tr>
<tr>
<td>GMC</td>
<td>General Medical Council</td>
</tr>
<tr>
<td>GPPhC</td>
<td>General Pharmaceutical Council</td>
</tr>
<tr>
<td>HSCE</td>
<td>Health Service Commissioner for England</td>
</tr>
<tr>
<td>ISCAS</td>
<td>Independent Sector Complaints Adjudication Service</td>
</tr>
<tr>
<td>MDDUS</td>
<td>Medical and Dental Defence Union of Scotland</td>
</tr>
<tr>
<td>MDU</td>
<td>Medical Defence Union</td>
</tr>
<tr>
<td>MOU</td>
<td>Memorandum of Understanding</td>
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<tr>
<td>NMA</td>
<td>News Media Association</td>
</tr>
<tr>
<td>NMC</td>
<td>Nursing &amp; Midwifery Council</td>
</tr>
<tr>
<td>NRLS</td>
<td>National Reporting and Learning System</td>
</tr>
<tr>
<td>PACAC</td>
<td>Public Administration and Constitutional Affairs Committee (House of Commons)</td>
</tr>
<tr>
<td>PASC</td>
<td>Public Administration Select Committee (House of Commons)</td>
</tr>
<tr>
<td>PCA</td>
<td>Parliamentary Commissioner for Administration</td>
</tr>
<tr>
<td>PHSO</td>
<td>Parliamentary and Health Service Ombudsman</td>
</tr>
<tr>
<td>PSA</td>
<td>Professional Standards Authority for Health and Social Care</td>
</tr>
<tr>
<td>RCoA</td>
<td>Royal College of Anaesthetists</td>
</tr>
<tr>
<td>RCM</td>
<td>Royal College of Midwives</td>
</tr>
<tr>
<td>RCN</td>
<td>Royal College of Nursing</td>
</tr>
<tr>
<td>RCOG</td>
<td>Royal College of Obstetricians and Gynaecologists</td>
</tr>
<tr>
<td>RCP</td>
<td>Royal College of Physicians</td>
</tr>
<tr>
<td>RCS</td>
<td>Royal College of Surgeons of England</td>
</tr>
<tr>
<td>StEIS</td>
<td>Strategic Executive Information System</td>
</tr>
</tbody>
</table>
Formal minutes

Tuesday 24 July 2018

Members present:

Sir Bernard Jenkin, in the Chair
Baroness Chisholm of Owlpen  Mr David Jones
Baroness Eaton  Dr Philippa Whitford
Lord Kirkwood of Kirkhope
Baroness Watkins of Tavistock

Draft Report (Draft Health Service Safety Investigations Bill: A new capability for investigating patient safety incidents), proposed by the Chair, brought up and read.

Ordered, That the Chair’s draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 286 read and agreed to.

Appendices 1 to 5 agreed to.

Summary agreed to.

Resolved, That the Report be the Report of the Committee to both Houses.

Ordered, That Lord Elder make the Report to the House of Lords and the Chair make the Report to the House of Commons.

Ordered, That embargoed copies of the Report be made available (Standing Order No. 134 of the House of Commons).
Witnesses

The following witnesses gave evidence. Transcripts can be viewed on the publications page of the Committee’s website.

Wednesday 6 June 2018

Sir David Behan CBE, Chief Executive, Care Quality Commission, and Dr Kathy McLean, Executive Medical Director and Chief Operating Officer, NHS Improvement

Wednesday 13 June 2018

Dame Donna Kinnair, Director of Nursing, Policy and Practice, Royal College of Nursing, Dr Simon Fleming, Trauma and Orthopaedic registrar, and Dr Chaand Nagpaul, Chair of Council, British Medical Association

Niall Dickson, Chief Executive, NHS Confederation, and Chris Hopson, Chief Executive, NHS Providers

Monday 11 June 2018

Harry Cayton, Chief Executive, Professional Standards Authority, Paul Buckley, Director of Strategy and Policy, General Medical Council, Matthew McClelland, Director of Fitness to Practise, and Clare Padley, General Counsel, Nursing and Midwifery Council

Monday 18 June 2018

Imelda Redmond, National Director, Healthwatch England, Peter Walsh, Chief Executive, Action Against Medical Accidents, and Scott Morrish, Patient advocate and father of Sam Morrish

Wednesday 20 June 2018

Professor Brian Toft OBE, Emeritus Professor of Patient Safety, Coventry University, Professor Charles Vincent, Health Foundation Professorial Fellow (Patient Safety), Department of Experimental Psychology, University of Oxford, and Dr Carl Macrae, Nottingham University Business School, University of Nottingham

Dr Michael Devlin, Head of Professional Standards and Liaison, Medical Defence Union, and Matthew McGrath, Partner, DAC Beachcroft LLP (Solicitors)
Published written evidence

The following written evidence was received and can be viewed on the publications page of the Committee’s website.

SIB numbers are generated by the evidence processing system and so may not be complete.

1. Action against Medical Accidents ([SIB0021])
2. Anonymous ([SIB0011])
3. Association of Optometrists ([SIB0020])
4. Association of Personal Injury Lawyers ([SIB0006])
5. British Medical Association (BMA) ([SIB0052])
6. CallConfidential ([SIB0014])
7. Care Quality Commission ([SIB0040])
8. Clinical Human Factors Group ([SIB0017])
9. DAC Beachcroft LLP ([SIB0050])
10. Department of Health and Social Care ([SIB0034])
11. Dr Claire Morrison ([SIB0009])
12. Dr Clare Gerada ([SIB0046])
13. Dr Laurel Spooner ([SIB0027])
14. Dr Roger Fisken ([SIB0001])
15. Equality and Human Rights Commission ([SIB0008])
16. General Medical Council ([SIB0030])
17. General Medical Council ([SIB0047])
18. General Pharmaceutical Council ([SIB0024])
19. ISCAS ([SIB0033])
20. MDDUS ([SIB0041])
21. Medical Defence Union ([SIB0042])
22. Medical Defence Union ([SIB0044])
23. Mills & Reeve LLP ([SIB0022])
24. Mr John Tingle ([SIB0003])
25. Mr Nick Butler ([SIB0005])
26. Mr Simon Fleming ([SIB0026])
27. National Guardian’s Office ([SIB0037])
28. News Media Association ([SIB0012])
29. NHS Confederation ([SIB0051])
30. NHS England National Maternity Review ([SIB0053])
31. NHS Partners Network ([SIB0025])
32. NHS Providers ([SIB0023])
33. NHS Providers ([SIB0045])
34 Nursing and Midwifery Council (SIB0032)
35 Parliamentary and Health Service Ombudsman (SIB0010)
36 Patient Safety Learning (SIB0049)
37 Professor Clare Gerada (SIB0048)
38 Professor Jane Reid (SIB0004)
39 Professor Murray Anderson-Wallace (SIB0036)
40 Royal College of Anaesthetists (SIB0013)
41 Royal College of Midwives (SIB0029)
42 Royal College of Nursing (SIB0038)
43 Royal College of Obstetricians and Gynaecologists (SIB0028)
44 Royal College of Physicians (SIB0019)
45 Royal College of Physicians and Surgeons of Glasgow (SIB0007)
46 Scott Morrish (SIB0035)
47 Susanna Stanford (SIB0016)
48 The Campaign for Freedom of Information (SIB0039)
49 The Doctors’ Association UK (SIB0015)
50 The Patients Association (SIB0043)
51 The Professional Standards Authority for Health and Social Care (SIB0031)
52 The Royal College of Surgeons of England (SIB0018)