Department of Health & Social Care

The Government response to the Report of the Joint Committee on the Draft Health Service Safety Investigations Bill

Published December 2018

The Government response to the Report of the Joint Committee on the Draft Health Service Safety Investigations Bill

Presented to Parliament

by the Secretary of State for Health and Social Care

by Command of Her Majesty

Cm number: 9737

This publication is available at www.gov.uk/government/publications

Any enquiries regarding this publication should be sent to us at:

Acute Care & Workforce/Acute Care & Quality/Quality, Patient Safety and Investigations
www.gov.uk/dhsc

ISBN:978-1-5286-0890-9

CCS1118031708 11/18

Printed on paper containing 75% recycled fibre content minimum

Printed in the UK by the APS Group on behalf of the Controller of Her Majesty's Stationery Office

Contents

Foreword

Caroline Dinenage MP, Minister of State for Care

The NHS is committed to delivering the highest level of health care in the world. Part of this means learning from failures in care, such as those that came to light at Mid-Staffordshire Foundation Trust, Morecambe Bay Foundation Trust and Gosport War Memorial Hospital. These tragedies more than ever highlighted the importance of having consistent, effective, learning-oriented investigations of incidents where things have gone wrong.

A key part of our response was to establish a new national investigation branch in April 2016, with an explicit focus on learning from healthcare safety incidents. The Healthcare Safety Investigation Branch (HSIB) has already launched 26 investigations and published a range of reports into serious safety incidents with a focus on providing learning across the whole health system.

This ground-breaking approach moves away from a culture of blame to a culture of learning, and has demonstrated a commitment to fully involving patients and families in investigations. At the same time, the “safe space” approach to investigations, based on similar models in aviation, has allowed the Branch to establish the underlying system causes of safety incidents.

The Government published a draft Health Services Safety Investigations Bill in September 2017 which set out legislative provisions to establish a new, fully independent body to investigate healthcare safety incidents in the NHS in England.

Our planned legislation will cement this progress and deliver an independent health service safety investigations body. This will be the first of its kind in the world, with the right powers and duties to conduct these crucial system-wide learning investigations effectively. We believe this is the right way to ensure that the safety gains we have made so far continue, and are supported by a healthcare culture where safety and high-quality investigations are everybody’s business.

The Committee has made a significant contribution to this work. I would like to personally thank each Committee Member, for their diligence and time in scrutinising this draft Bill in

order to ensure we achieve the very best in investigating patient safety, with particular thanks to Sir Bernard Jenkin MP as Chair.

We will continue to work with system partners and stakeholders in revising the draft Bill in line with this response, and will bring forward this legislation when parliamentary time allows.

Caroline Dinenage MP

Minister of State for Care, Department of Health and Social Care

1. Introduction

1.1 The Joint Committee's report *Draft Health Service Safety Investigations Bill: A new capability for investigation patient safety incidents*[1], was published on 2 August 2018, setting out a number of recommendations. The Joint Committee ("the Committee") was appointed by the House of Commons on 17 April 2018 and the House of Lords on 15 May 2018. It scrutinised the draft Health Service Safety Investigations Bill ("the Bill") by considering written and oral evidence from a range of contributors, including the Minister of State for Care, Caroline Dinenage MP.

1.2 The Government welcomes the Committee's report and the considered, evidence-based approach the Chair and Members of the Committee have taken in scrutinising the Bill. The Government would like to thank Sir Bernard Jenkin MP for his role in chairing the Committee. We are pleased with the support that the Committee has given to the over-arching aim of the draft Bill which is to establish an independent body to investigate patient safety incidents, for the purpose of supporting system-wide safety improvement and learning.

Background

1.3 In April 2016, the Healthcare Safety Investigation Branch (HSIB)[2] was set up to investigate up to 30 serious patient safety incidents in England a year, with a focus on system learning. The HSIB has now completed a number of these investigations and made significant recommendations for the healthcare system (including national bodies) on the safety learning they have uncovered.[3]

1.4 The Government published the draft Health Service Safety Investigations Bill in September 2017. The Bill proposes to establish the Health Service Safety Investigations Body (HSSIB)[4], as an independent body to investigate patient

---

[1] The Committee's report is available online at: https://www.parliament.uk/business/committees/committees-a-z/joint-select/draft-health-service-safety-investigations-bill/hssib-17-19/publications/.

[2] HSIB was set up under Secretary of State Directions given to the NHS Trust Development Authority (TDA) – the special health authority that operates alongside Monitor under the umbrella organisation NHS Improvement (NHSI). The Directions are available online at: https://www.gov.uk/government/publications/nhs-trust-development-authority-directions-2016.

[3] Published HSIB reports of completed investigations, and details of ongoing investigations are available online at: https://www.hsib.org.uk/.

[4] HSSIB is referred to throughout this response as "the new body".

safety incidents in healthcare in England with the legislative powers it needs to conduct effective investigations as an independent investigator in its own right.

1.5 The draft Bill also provides for the creation of a 'safe space' in investigations to ensure that information provided to the new body (HSSIB) in connection with an investigation will only be disclosed in certain limited circumstances or by Order of the High Court.

1.6 The 'safe space' approach is designed to encourage NHS staff and others to contribute fully and frankly to investigations so that they can get quickly to the heart of what has gone wrong and make recommendations for the wider system. The focus of the new body will be on investigating incidents that have the potential to maximise learning throughout the healthcare system.

1.7 In April 2018, the former Secretary of State gave further Directions[5] to require the current Investigation Branch (HSIB) to investigate approximately 1000 maternity cases per year as part of the National Maternity Safety Strategy. These investigations are carried out instead of internal trust investigations and do not operate with 'safe space' principles. Their purpose is to provide high quality, standardised investigations of maternity incidents to uncover the learning from them and provide patients and families with a full account of what happened.

[5] National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2018, available online at: https://www.gov.uk/government/publications/nhs-trust-development-authority-hsib-maternity-investigations-directions-2018.

2. Responses to the recommendations

2.1 The Government has given serious consideration to all the Committee's recommendations and accepts many of them in full, including the recommendation to remove accreditation of Trusts to carry out 'safe space' investigations from the Bill.

2.2 The Government also accepts in principle a further group of recommendations, principally around the arrangements for safe space and the powers of the new body, but considers that further detailed work will need to be done to ensure the revised Bill achieves our policy intent taking into account the views of the Committee on these issues.

2.3 The Government has not accepted a small number of the Committee's recommendations, including the Committee's recommendation to exclude the current maternity investigations programme from the Bill. The reasons for this are set out below.

2.4 In addressing all the recommendations, the Government remains committed to ensuring that the NHS continues to be at the forefront of improving patient safety and is able to move towards a more open, learning culture, especially where things go wrong.

2.5 In this Government response, individual responses to the 31 recommendations in the Committee's report are grouped under the following broad themes:

- Accreditation;
- Maternity investigations;
- Remit of the new body;
- 'Safe space';
- Investigative powers; and
- Independence, monitoring and review.

2.6 The Committee's recommendations have been numbered and ordered accordingly. Annex A of this response lists the recommendations in their original sequence, for ease of reference.

Accreditation

The Committee recommendations:

1. a. 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.

b. 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.

2.7 We recognise the strong views of the Committee and contributors to the scrutiny process on the issue of accreditation and the extension of 'safe space' investigations to local Trusts. We agree with the Committee's recommendation and will remove accreditation provisions from the Bill altogether.

2.8 The underlying policy intent behind our proposals on accreditation was always to improve local safety investigations and spread a just culture of learning within the NHS. We, therefore, also agree that the new body's role should include promoting better standards for local safety investigations and improving their quality and effectiveness through advice, guidance and training. We will take this into account in revising the Bill.

2.9 We will also explore measures more globally, as part of the long term national strategy on patient safety by the Secretary of State for Health and Social Care, to improve the quality of local investigations and reduce variation throughout the healthcare system. Finally, we commit to reviewing the capacity of the new body in future years, in light of this recommendation.

Maternity investigations

The Committee recommendations:

2. 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.

3. 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'.

2.10 We appreciate the Committee's views on the importance of ensuring high quality maternity investigations and note its concerns about the new body conducting investigations into a defined cohort of maternity cases.

2.11 We are also mindful of the Committee's view that the new body's focus should be on high-level, systemic investigations conducted with the benefit of 'safe space' and we agree with this ultimate goal.

2.12 However, as acknowledged in the evidence submitted to the Committee, there is a real need to improve the quality of maternity investigations within the NHS.

2.13 Above all, we want to ensure that the learning and improvements to maternity safety that we believe can be gained from the existing maternity investigations programme can be secured, and sensible arrangements put in place to enable high quality maternity investigations on an ongoing basis.

2.14 We believe the best way to achieve this is to allow the current maternity investigations programme to complete its rollout to all healthcare regions in England and continue for a limited period so that the learning and benefit can be gained from these investigations, whether or not the new body has been established in the meantime.

2.15 We therefore believe there should be provision in the revised Bill to allow the new body to undertake the maternity investigations, and that there should be flexibility in how long the maternity investigations should continue under the new body's remit to allow appropriate lessons to be learnt and to determine where these

investigations might best sit in the future. We will consider how best to achieve this in a revised Bill. This will ensure that the establishment of the new body does not, in itself, bring the programme to a premature end and should allow the benefits of the programme to be fully realised. We do not believe it would be appropriate for the investigation programme to transfer to NHS Improvement, which would not have the expertise or operational independence to carry out these specialised investigations effectively, once the investigative function had transferred to the new body.

2.16 We agree that all national, high-level investigations by the new body should have the protection of 'safe space'. We will ensure the revised Bill continues to reflect this and articulates clearly the distinction between the maternity investigation programme (local investigations of single incidents conducted without 'safe space') and the national high-level investigations to be conducted by the new body.

Remit of the new body

Independently funded healthcare

The Committee recommendations:

4. 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.

5. 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.

2.17 We agree to give further consideration to the Committee's recommendation to extend the remit of the new body to investigate independently funded health care in England and to how this might be funded. We will consult with stakeholders on these two recommendations. We will consider the Committee's recommendations on the title of the Bill and the new body in revising the Bill.

Social care

The Committee recommendation:

6. 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.

2.18 We agree with the Committee that the new body should not be an investigatory body for social care but that it should be empowered to investigate all aspects of the health care pathway relating to a patient safety investigation, including where there are transitions and other interactions of the pathway with social care

provision. We will look at the best way to meet this recommendation in the revised Bill, including how the new body's investigative powers may need to be changed. We will engage with stakeholders to ensure their views are reflected in this process.

Cross-border cooperation

The Committee recommendation:

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

a) enable reciprocal arrangements between HSSIB and the devolved health systems in cases of cross-border care; and

b) allow devolved administrations to choose whether HSSIB's remit should be extended to their territory, if they so wish.

2.19 We are engaging with the devolved administrations on the issues raised in the Committee's recommendations to understand the potential for reciprocity, how the new body could be involved in cross border healthcare pathways, and the new body's role in the context of the existing devolution settlements.

Safe Space

2.20 The Government welcomes the Committee's support for 'safe space' principles. The policy to establish the 'safe space' within the Bill is comparable to similar legal provisions for bodies that investigate air, rail and marine accidents. The success of these investigation branches in using 'safe space' principles to achieve significant safety gains is a founding principle behind establishing 'safe space' for health service investigations within the provisions of this Bill.

Engagement

The Committee recommendations:

8. 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.

9. In the light of the two preceding recommendations [this refers to numbered recommendations 15 & 16 below] *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.*

2.21 We agree with the Committee's recommendation on the need to engage further with patients, families and the public on the role, purpose and value of 'safe space' investigations. We will work with the current investigation Branch, and the new body, as well as with patients and families to ensure a better understanding of these issues.

2.22 We also agree on the importance of being clear about the application of the prohibition on disclosure and will seek to reflect this in public statements. We will consider how this is best represented in the legislation.

Extending the 'safe space'

The Committee recommendation:

10. 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.

2.23 The Committee took detailed evidence on when and how information gathered during HSSIB's investigations should be disclosed and to whom. We agree that the 'safe space' protections should be extended to cover information provided to HSSIB for the purposes of promoting patient safety, whether or not it leads to an investigation. The Government will consider how best to include this in the revised Bill.

Safe space prohibition threshold

The Committee recommendation:

11. 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.

2.24 We agree with the intent of the Committee's recommendation to change the threshold of the prohibition to a definition which focuses on the rationale for disclosure, e.g. "a serious and continuing safety risk". We will explore how this should be reflected in the draft Bill.

Sharing ‘safety benefit’ information

The Committee recommendations:

12. 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.

13 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.

2.25 We agree with the Committee’s intention to provide for a positive avenue for sharing certain information, which, in the view of the new body, will benefit patient safety, and that this should exist alongside the regime of prohibition of disclosure. We will consider how best to achieve this, taking into account the Committee’s suggested approach and the Committee’s other recommendations on the arrangements for ‘safe space’ in the Bill.

Freedom of Information Act

The Committee recommendation

14. 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.

2.26 We agree that information prohibited from disclosure should be exempt from Freedom of Information (FOI) requests. The exemption in section 44(1)(a) of the Freedom of Information Act 2000 exempts information if its disclosure is prohibited by or under any enactment and will apply to material covered by 'safe space'.

The Parliamentary and Health Service Ombudsman

The Committee recommendation

15. 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.

2.27 We recognise the intention of the Committee's recommendation, to provide clarity and certainty with regard to the investigative 'safe space' and to ensure that confidence in 'safe space' investigations is maintained.

2.28 We will engage with the Ombudsman and others to understand further what the impact would be on the Ombudsman's ability to hold public bodies to account and to effectively investigate healthcare matters if it were unable to obtain information held by the new body in 'safe space' without applying for a Court Order.

2.29 It should be noted that, whether or not the Bill expressly prohibits the Ombudsman from accessing 'safe space' information, the Ombudsman will continue to have access to all the information channels it currently uses to effectively progress its own investigations (including information from healthcare providers, patient records etc). As with the current Investigation Branch, the Ombudsman would also have access to all final investigation reports published by the new body.

Coroners

The Committee's recommendations

16. 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.

17. 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'.

2.30 We recognise the intention of these recommendations to provide clarity and certainty with regard to the investigative 'safe space', and to ensure that confidence in 'safe space' investigations is maintained.

2.31 We will engage with the Chief Coroner and others to understand further the impact on coroners' ability to investigate effectively deaths that may be related to healthcare if they are unable to access information held in 'safe space' by the new body established in the Bill.

2.32 It should be noted that coroners will continue to have access to all the information channels they currently use to further their own investigations (including information from healthcare providers and patient records etc). Coroners will also have access to any final investigation reports published by the new body.

2.33 As part of this engagement, we will also consider the question of the use in other proceedings of evidence given to a coroner by the new body.

Investigative Powers

Powers of interview

The Committee recommendations:

18. 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.

19. 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.

2.34 We will consider whether the Bill should include a specific power to enable investigators in the new body to compel witnesses to attend interview and 'if so' in what circumstances. This will be considered in light of the Committee's overall set of recommendations on 'safe space' to ensure that the protections around information are commensurate with the obligations on participants.

2.35 We agree that the new body should have the flexibility to allow witnesses to be accompanied in interviews and we will review arrangements for interviewing witnesses in the context of the Committee's overall set of recommendations on the investigative powers of the new body.

Informing participants prior to commencing investigations

The Committee recommendation:

20. 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.

2.36 We agree that the new body should inform and involve any person who has, or may have been harmed by an incident under investigation.

2.37 The draft Bill already places a duty on the new body to publish the process for determining the involvement of patients and their families, and that process must secure that patients and families are involved in investigations, so far as this is reasonable and practicable. We note that it is already the practice of the current

investigative Branch to inform relevant persons of an intent to investigate before an investigation starts.

2.38 As such, we do not believe it is necessary to mandate that the new body inform all parties in advance of every investigation, which may overly constrain the body and delay investigations and learning. We will, however, consider how best this recommendation could be addressed in guidance produced by the new body.

Appropriate sanctions for non-compliance

The Committee recommendations:

21. 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.

22. 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.

2.39 We agree to review the sanctions regime set out in the Bill considering the Committee's overall set of recommendations on 'safe space' and on the investigative powers of the new body. We will consider whether individuals who refuse to comply with the reasonable request of an investigator exercising his or her powers under the Bill should be subject to criminal or civil sanctions.

2.40 We agree that if the civil sanctions regime is retained in the Bill, we will review the arrangements around appeal against a penalty notice set out in clause 12 of the draft Bill.

Powers of entry

The Committee recommendations:

23. 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.

24. 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.

2.41 We will review arrangements for the new body's powers of entry based on the Committee's suggestion and the Home Office Code of Practice on Powers of Entry. We will ensure, as part of our review of the arrangements for the new body's powers of entry, that any warrant provisions in the revised Bill take account of this recommendation.

Independence, monitoring and review

Independence of judgement

The Committee recommendation:

25. 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.

2.42 We recognise and share the Committee's desire to ensure that the new body is independent and seen to be so.

2.43 We agree with the Committee's view that the current provision requiring HSSIB to consider representations from the Secretary of State about investigating an incident do not amount to direction by the Minister. Therefore, we will make this clearer by removing references to the Secretary of State in clause 4(1) of the Bill, and will take this recommendation into account in revising the Bill. We also agree that the new body should decide its own priorities objectively in respect of what it investigates and we will consider how its independence of judgement in such decisions can be further reflected in the revised Bill.

The mutual duty of cooperation

The Committee recommendations:

26. 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.

27. 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.

2.44 We agree that the new body needs to preserve its full independence as it operates alongside other arm's length bodies, inspectors and regulators. However, like other independent arms' length bodies operating in the health sphere, such as

Monitor and the Care Quality Commission, it will also need to work constructively together with other national bodies responsible for healthcare without compromising its unique role and its principles.

2.45 We believe the mutual duty of cooperation on purely logistical issues as set out in the draft Bill is the best way to achieve this, and as with comparable independent arms' length bodies, is an effective way of preserving and promoting independence and sensible cooperation.

2.46 The Committee considered that article 12(3) of Regulation (EU) No 996/2010 could be usefully adapted for the draft Bill in clause 15, to develop Memoranda of Understanding. Currently, the Investigation Branch has agreed, or is in the process of agreeing, Memoranda of Understanding with other bodies such as the Department, NHS Improvement and the Care Quality Commission and we would expect the new body to reach similar agreements with other system bodies. We do not think that legislating for such agreements is necessary.

Power to direct in event of failure

The Committee recommendation:

28. 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.

2.47 The Committee has recommended that clause 18 should be amended so that, in the event of significant organisational failure, the Secretary of State' would not have the power to direct the new body on how to investigate or on the content of its reports or recommendations.

2.48 We agree that the Secretary of State should not have the power to direct the new body on the content of its reports or recommendations and we will ensure this is reflected in a revised Bill. However, if a catastrophic organisational failure were to occur, we believe it may be necessary for the Secretary of State to direct how the new body should investigate, since that would be a core organisational competency which may relate directly to the failure. In our view such a power should be retained in the Bill for use in the very exceptional circumstances invoked in this clause i.e. a significant failure of a public body.

Appointment of Chair and Chief Executive

The Committee recommendations:

29. 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.

2.49 We agree with the Committee's intention and will engage with the Health and Social Care Select Committee on the best way to achieve this, in line with Government guidelines on pre-appointment scrutiny.

Monitoring and assurance of recommendations

The Committee recommendations:

30. 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.

2.50 We recognise and share the Committee's desire to ensure there is monitoring and assurance of the implementation of the new body's recommendations. We believe this should be a coordinated, whole system effort which can hold all organisations to account, including national organisations. The Care Quality Commission, as the regulator of health and social care providers in England, will have a key role to play but cannot do this alone.

2.51 To achieve this, the National Director for Patient Safety will chair a Programme Board to monitor the system response to the recommendations made by the new body. The Board will include the Care Quality Commission, NHS Improvement, the Department, NHS England and others. The new body will have an advisory role to the Board.

Post-legislative review

The Committee recommendation:

31. 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).

2.52 We agree that this legislation should be reviewed after three years of the new body starting its work and we will ensure this is reflected in a revised Bill.

Technical drafting points

2.53 The Committee has also suggested a number of technical drafting points. These are addressed in turn in the schedule at Annex B of this response.

3. Conclusion

3.1 The Government believes that the establishment of a new independent investigative body represents the best way to bring about meaningful improvements to healthcare safety investigations in England.

3.2 Our vision is for a healthcare system where a just culture of learning is embedded in the way the NHS responds when things go wrong. We believe that the new body set forth in this Bill will not only bring about significant safety gains in its own right, it will spearhead and exemplify the good practice and high quality we want to see in every local patient safety investigation.

3.3 Through the example it will set and the prominent role it will have to nurture and promote high quality, professionalised safety investigations, we believe the new body will have a central role to play in bringing about the culture change in healthcare that Committee Members, contributors and stakeholders alike have said they would like to see.

3.4 We would like to express our thanks to all those who contributed to the Committee inquiry as well as to the Committee Chair, the Members and the Committee Secretariat, who have all given their time, effort and expertise to scrutinising and improving this legislation throughout the pre-legislative scrutiny process.

Annex A - Schedule of Recommendations of the Joint Committee

Recommendations of the Joint Committee (in the order in which they appear in the Committee's report)	Paragraph number in this response	Recommendation number in this response
We recommend that the Department for Health and Social Care and HSSIB [the Health Service Safety Investigation Body, otherwise referred to in this Government response as "the new body"] engage with patients and families, and their advocates or representatives, to ensure that the 'safe space' is widely understood by them.	2.21	8
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.	2.23	10
We recommend that the Government amend clause 29 to permit HSSIB to disclose to police, regulators, and/or trusts: - solely on the grounds that there is a serious and continuing risk to the safety of a patient, or to the public; and, no more than the information necessary to enable the recipient of the information to set in train its own enquiries.	2.24	11a & b
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.	2.27-2.29	15

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.	2.30-2.32	16
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.	2.22	9
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'.	2.33	17
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.**	2.25	12

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.	2.25	13
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.	2.26	14
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. **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.**	2.7-2.9	1a & b
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.	2.10-2.15	2
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'.	2.16	3

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.	2.17	4
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.	2.17	5
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.	2.18	6
To address the uncertainties that will remain around the provision of cross-border services we recommend that the draft Bill should be amended to: **a) enable reciprocal arrangements between HSSIB and the devolved health systems in cases of cross-border care; and** **b) allow devolved administrations to choose whether HSSIB's remit should be extended to their territory, if they so wish.**	2.19	7a) & b)
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.	2.36-2.38	20

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.	2.44-2.45	26
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.	2.46	27
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.	2.34	18
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.	2.35	19
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.	2.39	21
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.	2.40	22
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	2.41	23

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.		
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.	2.41	24 a) & b)
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.	2.50-2.51	30
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.	2.42-2.43	25
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.	2.47-2.48	28
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.	2.49	29
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).	2.52	31
Schedule of technical drafting points made by the Committee	Annex B (below)	N/A

Annex B - Schedule of Government responses to technical drafting points made by the Joint Committee

Clause	Text	Question	Committee conclusion or recommendation	Government response
2	(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.	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).	Clarify and simplify the drafting of the HSSIB's function.	We agree to review the drafting of this clause in light of the Committee's suggestion.
2 & 3	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.	The definition of "qualifying incidents" is circular.	Remove the circularity in drafting of qualifying incidents.	We agree to review the drafting of this clause in light of the Committee's suggestion.

Clause	Text	Question	Committee conclusion or recommendation	Government response
5	(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… (iii) persons falling within paragraph (c) and their officers (in the case of bodies corporate).	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 would be within the subsection (because of “and their officers” in paragraph (c)). Is that really the intention?	Correct the drafting of those against whom power to enter premises is exercisable.	We will review the drafting of this clause in light of the Committee’s comments and the wider recommendations around the powers of entry.

Clause	Text	Question	Committee conclusion or recommendation	Government response
6	(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…	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?	As Committee recommendation 24 in the schedule at Annex A. "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."	(see paragraph 2.41 of the Government response above). "We will review arrangements for the new body's powers of entry based on the Committee's suggestion and the Home Office Code of Practice on Powers of Entry. We agree to ensure, as part of our review of the arrangements for the new body's power of entry, that any warrant provisions in the revised Bill take account of this recommendation."
9	(4) A penalty notice must … (f) explain the right to apply for an appeal under section 12.	A person does not apply for an appeal. Paragraph (f) should read "explain the right to appeal under section 12". Do you agree?	Remove inaccurate wording relating to the explanation in penalty notices about the right to appeal.	We agree and will consider amending the Bill accordingly.

Clause	Text	Question	Committee conclusion or recommendation	Government response
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.	As Committee recommendation in the schedule at Annex A. "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."	(see paragraph 2.41 of the Government response above). "We agree that if the civil sanctions regime is retained in the Bill, we will review the arrangements around appeal against a penalty notice set out in clause 12 of the draft Bill."
-	-	On what basis is the FTT to assess whether the penalty is too high? Is the appeal to be by way of complete rehearing? 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.	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.	(see paragraph 2.41 of the Government response above). "We agree that if the civil sanctions regime is retained in the Bill, we will review the arrangements around appeal against a penalty notice set out in clause 12 of the draft Bill."

Clause	Text	Question	Committee conclusion or recommendation	Government response
			As to the available grounds of appeal, Committee recommendation 22 in the schedule at Annex A refers.	
28		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?	As Committee recommendation in the schedule at Annex A. "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."	(see paragraph 2.26 of the Government response above). "We agree that information prohibited from disclosure should be exempt from Freedom of Information (FOI) requests. The exemption in s.44(1)(a) of the Freedom of Information Act 2000 exempts information if its disclosure is prohibited by or under any enactment and will apply to material covered by 'safe space'."

Clause	Text	Question	Committee conclusion or recommendation	Government response
30 & 33	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…	Should not the balancing exercise in clauses 30(4) and 33(5) also include any adverse impact on current investigations? See, for example, Art 14(3) of the EU Air Accident Investigation Regulation (Regulation (EU) No 996/2010), as it applies to records, and the argument of the AAIB in Hoyle v Rogers [2014] EWCA Civ 257.	Re-draft to ensure the balancing exercise takes into account the adverse impact on current, as well as future, investigations.	We agree and will take this into account in revising the Bill.
31	(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.	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.	Re-draft to require the HSSIB to share a draft report with anyone whose reputation could be damaged by the report.	We 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.
		Why is no express requirement of confidentiality placed on recipients of draft reports? This contrasts with the approach in relation to AAIB reports.	Make it an offence to disclose information in a draft report sent pursuant to clause 31(7)-(9).	We note the Committee's intent around preserving the confidentiality of draft reports when they are shared with recipients and will explore the best way to achieve this in the revised Bill.

Clause	Text	Question	Committee conclusion or recommendation	Government response
33	(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).	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.	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 Committee recommendation in the Schedule at Annex A.	We will consider this issue as part of our engagement with the Chief Coroner and others.

CCS1118031708

ISBN:978-1-5286-0890-9