

Title: Health Services Safety Investigations Body (HSSIB) IA No: 3136 RPC Reference No: Lead department or agency: Department of Health and Social Care Other departments or agencies:	Impact Assessment (IA)			
	Date: 19/07/2022			
	Stage: Final			
	Source of intervention: Domestic			
	Type of measure: Primary legislation			
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Summary: Intervention and Options	RPC Opinion: Not applicable
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Cost of Preferred (or more likely) Option (2022 prices, 2023 present value)

Total Net Present Social Value	Business Net Present Value	Net cost to business per year	Business Impact Target Status
-£51.6m			Not a regulatory provision.

What is the problem under consideration? Why is government action or intervention necessary?

Historically, the quality of local NHS investigations into serious patient safety incidents (in the region of 20,000 investigations per year) has been inconsistent. The Healthcare Safety Investigation Branch (HSIB) was established to allow the wider NHS to learn from mistakes and prevent repetition of the same problems. However, there remains no established, independent body to carry out healthcare safety investigations impartially and with public confidence. Government intervention is necessary to establish the Health Services Safety Investigations Body (HSSIB) and place it on an independent statutory footing, including robust protections of information provided in confidence so that it is held in a 'safe space'. Without legislation neither independence, 'safe space', nor the necessary investigative powers would be guaranteed, and thus avoidable patient safety incidents would continue to occur at higher rates than is acceptable and a high number of stand-alone, expensive inquiries are likely to continue.

What are the policy objectives of the action or intervention and the intended effects?

The policy objective is to establish an independent Non-Departmental Public Body (NDPB), the Health Services Safety Investigations Body (HSSIB) to deliver expert investigations with protected material held in a 'safe space', with the necessary investigatory powers, thereby improving the quality of patient safety investigations and also supporting improvements in the quality and effectiveness of local safety investigations. The intended effects are: improved public confidence in investigations arising from both the independence of the HSSIB and the provision of a 'safe space' to safeguard protected material from disclosure; to make recommendations that improve patient safety across the NHS and the independent sector; to encourage a culture of learning and safety improvement throughout the NHS and the independent sector and to drive greater consistency in the quality investigations.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: Do nothing: The HSIB, established by the Department of Health and Social Care by Directions as a branch of NHS Improvement in April 2017, continues to operate under its current arrangements.

Option 2: A new independent body, the Health Services Safety Investigations Body (HSSIB) is established. This is the preferred option, as only with primary legislation can an independent NDPB be established that has the same ability to protect material as other industry regulators by providing for a statutory prohibition on disclosure of material collected and held in a 'safe space' during the course of an investigation and beyond. This is the only option that ensures the independence of patient safety investigations and the associated benefits of this.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: 2024/25

Is this measure likely to impact on international trade and investment?	No			
Are any of these organisations in scope?	Micro No	Small Yes	Medium Yes	Large Yes
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)	Traded:		Non-traded:	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:  Date: 19/07/2022

Summary: Analysis & Evidence

Policy Option 1

Description: Do Nothing: The Healthcare Safety Investigation Branch (HSIB) established by the Department of Health and Social Care in Directions as a branch of NHS Improvement in April 2017, continues to operate under its current arrangements.

FULL ECONOMIC ASSESSMENT

Price Base Year 2022	PV Base Year 2023	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)			
			Low: Optional	High: Optional	Best Estimate: 0	
COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Cost (Present Value)	
Low	Optional		Optional		Optional	
High	Optional		Optional		Optional	
Best Estimate	0		0		0	
Description and scale of key monetised costs by 'main affected groups' The HSIB continues to operate as it does at the moment. (N.B. Due to the NHS England and Improvement merger, the Trust Development Authority will be abolished and the HSIB will soon be operating as part of NHS England.) In line with impact assessment guidance this do nothing option has zero costs and benefits as impacts are assessed as marginal changes against the 'do nothing' baseline.						
Other key non-monetised costs by 'main affected groups'						
BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Benefit (Present Value)	
Low	Optional		Optional		Optional	
High	Optional		Optional		Optional	
Best Estimate	0		0		0	
Description and scale of key monetised benefits by 'main affected groups' In line with impact assessment guidance the do nothing option has zero costs or benefits as impacts are assessed as marginal changes against the do nothing baseline.						
Other key non-monetised benefits by 'main affected groups'						
Key assumptions/sensitivities/risks					Discount rate (%)	3.5
In line with impact assessment guidance the do nothing option has zero costs or benefits as impacts are assessed as marginal changes against the do nothing baseline. This do nothing option would not provide investigators of patient safety incidents with the same investigatory powers as other industry regulators and would not provide for a statutory prohibition on disclosure of material collected and held in a 'safe space'. It would also fail to ensure the independence of investigations and so the associated benefits of this would not be achieved.						

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 0	Benefits: 0	Net: 0	

Summary: Analysis & Evidence

Policy Option 2

Description: Establish an independent Health Service Safety Investigations Body (HSSIB).

FULL ECONOMIC ASSESSMENT

Price Base Year 2022	PV Base Year 2023	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)			
			Low: Optional	High: Optional	Best Estimate: -£51.6m	
COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Cost (Present Value)	
Low	Optional		Optional		Optional	
High	Optional		Optional		Optional	
Best Estimate					£51.6m	
Description and scale of key monetised costs by 'main affected groups'						
<p>The cost of the HSSIB is estimated to be £1.55m per annum/year higher than the do nothing option of the HSIB continuing under its current arrangements (noting the move to NHS England as outlined on page 2). Broadly, this relates to the addition of non-executive directors to the board and higher corporate costs, including enhanced financial reporting and accountability.</p> <p>The incremental running costs for an independent HSSIB of £1.55m per annum/year will be met from the existing DHSC budget, so we need to account for the opportunity cost of redirecting resources to this use. We do this by assuming that funding at the margin generates Quality Adjusted Life Years (QALYs) per £15,000 of resources and that each QALY is valued by society at £60,000. This implies that the opportunity cost of £1.55m per annum/year of diverted spending is £6.2m. This gives a present value of cost over the 10-year appraisal period of £51.6m.</p>						
Other key non-monetised costs by 'main affected groups'						
<p>Legal costs incurred by the HSSIB in defending applications to the High Court for disclosure of protected material held in a 'safe space', and associated costs incurred by the courts and those bringing applications. Likewise, legal costs incurred by the HSSIB, the courts and defendants in relation to the HSSIB's powers. Possible legal costs in establishing new exemptions to 'safe space' provision if the Secretary of State exercises their regulation-making power. Possible additional costs of no longer being hosted by and sharing certain services with NHSEI. Reduced initial investigations to cover costs of transition to NDPB.</p>						
BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Benefit (Present Value)	
Low	Optional		Optional		Optional	
High	Optional		Optional		Optional	
Best Estimate	-		-		-	
Description and scale of key monetised benefits by 'main affected groups'						
<p>There are no monetised benefits.</p>						
Other key non-monetised benefits by 'main affected groups'						
<p>Increased public and staff confidence in the independence of investigations for patient safety incidents and associated recommendations. Greater efficiency of investigations relating to the additional powers that will be granted to the HSSIB when compared with the HSIB. The HSSIB's remit will be extended to cover healthcare provided in and by the independent sector, improving patient safety in this sector and the NHS.</p>						
Key assumptions/sensitivities/risks					Discount rate (%)	3.5
<p>The HSSIB will carry out a similar number of investigations as the HSIB and will take over their existing budget. The HSSIB will appoint a Chief Executive and Non-Executive Directors as an independent body.</p>						

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	Benefits:	Net:	

Evidence Base

Policy Background

1. Patient harm^{1,2} is estimated to be among the top 10 leading causes of the global disease burden, and internationally, as many as 40% of people experience harm after accessing primary or ambulatory care.³ In some Organisation for Economic Cooperation and Development (OECD) countries, the burden of patient harm is similar to that of chronic diseases such as multiple sclerosis and some types of cancer.⁴
2. The fundamental case for improving patient safety is a moral and ethical one. Patient harm exerts a burden on individuals, their families, carers, and wider society. Maximising patient safety is therefore a fundamental responsibility of individual healthcare providers and healthcare systems.
3. Investing in the prevention of patient harm creates long term value through the reduction of the costs incurred to address patient safety incidents. This is similar to other high-risk industry sectors including air, automotive, rail, maritime and oil, where investment decisions are being made by balancing costs of preventing errors with the costs incurred by the errors.
4. Every day, millions of people are treated safely and successfully in the NHS. However, when patient safety incidents⁵ do happen, it is important that lessons are learned to prevent the same safety incident occurring again. When a serious incident occurs, knowing how and why the incident occurred is the very least a patient and their family should expect.
5. Within the NHS, a patient safety incident is defined⁶ as any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare. Harm is categorised into 5 'levels' of increasing severity. This is primarily done to aid consistent reporting of incidents and subsequent management of and response to risks. The 5 levels of physical harm are defined as:

i) No harm

This has two sub-categories:

- No harm (impact prevented) – Any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm. This may be locally termed a 'near miss'.
- No harm (impact not prevented) - Any patient safety incident where no harm occurred.

ii) Low harm

- Any unexpected or unintended incident that caused minimal harm to one or more persons requiring extra observation or minor treatment.

iii) Moderate harm

- Any unexpected or unintended incident that resulted in a moderate increase in treatment, possible surgical intervention, cancelling of treatment, or transfer to another area, and which caused significant but not permanent harm, to one or more persons.

iv) Severe harm

- Any unexpected or unintended incident that appears to have resulted in permanent harm to one or more persons.

v) Death

- Any unexpected or unintended incident that directly resulted in the death of one or more persons.

¹ Patient harm is any unintended and unnecessary harm resulting from, or contributed by, healthcare; OECD (2017)

² The National Reporting and Learning System defines 'harm' as injury, suffering, disability or death.

³ Aarssen, A., L. Slawomirski and N. Klazinga (2018), "The economics of patient safety in primary and ambulatory care: Flying blind", OECD Health Working Papers, No. 106, OECD Publishing, Paris, <https://doi.org/10.1787/baf425ad-en>

⁴ Slawomirski, Aarssen and Klazinga, The Economics of Patient Safety, OECD, March 2017

⁵ A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care.

⁶ Seven Steps to Patient Safety, the National Archives, July 2004

6. Since it was established in 2003, the National Reporting and Learning System (NRLS) has improved our understanding of the types of incidents occurring in the NHS. However, this has not addressed the need for improvements in understanding why these incidents occur and what can be done to learn from them and prevent them in the future.
7. It has been highlighted that ‘The NHS currently has no consistent approach to investigating and learning from safety issues. There is a smorgasbord of approaches to investigate and address systemic safety issues at various levels of the healthcare system with little apparent consistency, logic or strategy underlying their design or execution’.⁷
8. There is evidence that patients, families and carers have had to go to great lengths to get answers to their questions and have not always been treated with kindness, respect and honesty.⁸ Those working in healthcare have a moral responsibility and a statutory duty⁹ to be open and honest.
9. The policy to establish an independent body to investigate patient safety incidents was first set out in ‘Learning not blaming: The government response to the Freedom to Speak Up consultation’, the Public Administration Select Committee report ‘Investigating Clinical Incidents in the NHS’,¹⁰ and the Morecambe Bay Investigation (July 2015). It aligns with the Department of Health and Social Care’s (DHSC) commitment to establish the NHS as the world’s largest learning system and in turn, deliver the Government’s manifesto commitment for Health to “*Ensure English hospitals and GP surgeries are the safest in the world*”.
10. In April 2016, the then Secretary of State, gave Directions to the NHS Trust Development Authority to establish the Healthcare Safety Investigation Branch (HSIB) as a branch of the Special Health Authority (now operating as NHS Improvement). HSIB has been operating since 1 April 2017. It was an important first step, but it lacks independence and the necessary powers to make its investigations fully effective.
11. The DHSC therefore published the Health Service Safety Investigations (HSSI) Bill in draft in September 2017, to address this issue in three ways:
 - **It establishes a new independent non-departmental public body** - the Health Service Safety Investigations Body (HSSIB) - to take on many of the functions of HSIB and discharge its investigative functions without interference or influence by any other body. The independence of the new body’s investigations from the NHS and Government will help give the public full confidence in its investigation processes and its ability to deliver impartial conclusions and recommendations.
 - **It establishes ‘safe space’ protections**, prohibiting the disclosure of information held in connection with an investigation, apart from in tightly limited circumstances, as set out in the legislation. The safe space provisions encourage all participants, such as NHS staff, to be completely candid in the information that they share. This will enable more thorough investigations and the development of meaningful recommendations.
 - **It provides for appropriate powers, including enforcement via criminal sanctions, so that it can discharge its investigative function.** These include powers of entry and inspection which would allow investigators to enter and inspect premises, and by notice require individuals, NHS bodies, independent healthcare providers and private companies e.g. manufacturers of medical devices, to provide information and answer questions.
12. The draft Bill was scrutinised by a Joint Committee in summer 2018 and a revised Health Service Safety Investigations Bill was introduced in October 2019 but fell when the general election was called. Further amendments were made to the HSSIB clauses in response to both the Joint

⁷ Macrae and Vincent, Learning from failure: the need for independent safety investigation in healthcare, Journal of the Royal Society of Medicine, November 2016

⁸ Learning, candour and accountability, CQC, December 2016

⁹ The Duty of Candour, Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

¹⁰ Learning not blaming: the government response to the Freedom to Speak Up consultation, the Public Administration Select Committee report ‘Investigating Clinical Incidents in the NHS, and the Morecambe Bay Investigation, July 2015

Committee's recommendations and to comments made during the second reading of the Bill in October 2019. In particular, the Bill was updated to:

- Extend the HSSIB's remit to cover **independently funded healthcare** and all aspects of the health care pathway relating to a patient safety incident.
- Grant the **Secretary of State power of direction**, to require the HSSIB to investigate a particular qualifying incident or groups of qualifying incidents.
- Grant the **Secretary of State a new regulation making power to set out additional circumstances when the prohibition on disclosure (safe space) does not apply**.

When the HSSI Bill fell in October 2019, the Government committed to finding a new legislative vehicle for the HSSIB reforms. They were included in the Health and Care Act 2022 which was introduced on 6 July 2021. The then-Bill was updated to:

- Reflect the fact that **the exemption allowing senior coroners to access protected material held by the HSSIB was removed** during the passage of the Bill.
13. This impact assessment therefore updates that published in October 2019¹¹, to reflect these changes. The evidence base for this impact assessment is structured as follows:
- Section A: Problem identification and rationale for government intervention
 - Section B: Policy objectives and intended effects
 - Section C: Description of the options
 - Section D: Costs and benefits assessment
 - Section E: Conclusions and Summary
 - Section F: Summary of specific impact tests

Section A: Problem Identification and rationale for government intervention

Problem Identification

14. Between April 2019 to March 2020, over 2.2 million patient safety incidents in England were reported to the NRLS. This is 10.3% more than from April 2018 to March 2019, continuing the upward trend.¹²
15. Furthermore, NHS Resolution's Annual Report and Accounts show that there were 11,682 new clinical negligence claims and reported incidents in 2019/20 (compared to 10,684 in 2018/19) and expenditure on clinical claims amounted to over £2.3 billion.¹³
16. Where there have been failures to address serious patient safety concerns through early intervention, large-scale national public inquiries costing the NHS millions and diverting valuable NHS resources from frontline services have had to be initiated. For example, the cost of the Francis Inquiry into the Mid Staffordshire NHS Foundation Trust was £19.7 million¹⁴ (see Annex B).
17. Across the healthcare system, there is limited capacity to effectively investigate the common, system-wide causes of patient safety incidents that can recur across different settings, or to address them consistently. There is a fragmentation of responsibility for rigorous investigation, both within individual organisations and across the healthcare system. Patients, families and the public are too often let down by poor investigations, and the result is significant additional distress on top of the harm caused by the events themselves.
18. Investigations into patient safety incidents are often delayed, protracted, and of variable quality.¹⁵ They frequently fail to capture all relevant information and may unhelpfully conflate efforts to learn and improve with attempts to determine liability and allocate blame.

¹¹ <https://publications.parliament.uk/pa/bills/lbill/2019-2019/0004/20004-IA.pdf>

¹² <https://www.england.nhs.uk/wp-content/uploads/2020/03/NAPSIR-commentary-Sept-2020-FINAL.pdf>

¹³ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/901085/nhs-resolution-2019-20-annual-report-and-accounts.pdf

¹⁴ <http://webarchive.nationalarchives.gov.uk/20150407084003/http://www.midstaffspublicinquiry.com/inquiry-costs>

¹⁵ Learning, candour and accountability, CQC, December 2016

19. Within individual healthcare organisations, safety investigations are often poorly resourced, with limited access to the required expertise and skills and insufficient allocation of time to undertake a meaningful investigation.¹⁶
20. A review by the Care Quality Commission of the way NHS trusts review and investigate the deaths of patients published in 2016¹⁷ found:
 - Most NHS trusts report that they follow the Serious Incident Framework¹⁸ when carrying out investigations. Despite this, the quality of investigations is variable and staff are applying the methods identified in the framework inconsistently, thereby acting as a barrier to identifying opportunities for learning.
 - Specialised training and support is not universally provided to staff completing investigations. Many staff completing reviews and investigations do not have protected time in which to carry out investigations. This reduces consistency in approach.
 - There are significant issues with the timeliness of investigations and confusion about the standards and timelines stated in guidance, affecting the robustness of investigations.
 - A multi-agency approach to investigation is restricted by a lack of clarity on identifying the responsible agency for leading investigations. Organisations work in isolation, missing opportunities for identifying improvements in services and commissioning.
21. The report highlighted that where investigations have taken place, there are no consistent systems in place to make sure the recommendations are acted on or learning is being shared with others who could support the improvements needed. Robust mechanisms to disseminate learning from investigations or benchmarking beyond a single trust do not exist. This means that mistakes may be repeated.
22. The same report also highlighted that many families and organisations external to the NHS raised concerns about the independence of investigations carried out within the NHS and there was limited engagement with patients and families in those investigations. For example, the report of the Gosport independent panel noted in respect of the nature of communication with families, including complaints, that in a few cases there were well-recorded discussions of treatment plans for individuals. However, for the most part, the records show snippets of brief exchanges characterised by ambiguous phrases reflecting the underlying attitude: the families were marginalised by the professional staff.¹⁹

Rationale for government intervention

23. Patient harm imparts a high financial cost. The available evidence suggests that 15% of hospital expenditure and activity in OECD countries can be attributed to treating safety failures. Patient harm impacts on the broader economy through lost capacity and productivity of patients and their families and carers. It is estimated that the aggregate costs amount to trillions of dollars each year globally. In the political economy, the cost of safety failures includes loss of trust in health systems, in governments and in social institutions.²⁰
24. NHS providers do not usually enact or share the learning from patient safety incidents and so government intervention is required to provide this coordination.
25. 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. This requires a new, single, independent and accountable investigative body to undertake investigations into the most serious and avoidable incidents, provide national leadership, to serve as a resource of skills and expertise

¹⁶ PASC Investigating Clinical incidents in the NHS, March 2015
<https://publications.parliament.uk/pa/cm201415/cmselect/cmpubadm/886/886.pdf>

¹⁷ Learning, candour and accountability, , December 2016

¹⁸ <https://www.england.nhs.uk/patientsafety/serious-incident/>

¹⁹ Gosport War Memorial Hospital – The Report of the Gosport Independent Panel, June 2018

²⁰ Slawomirski, Aaraaen and Klazinga, The Economics of Patient Safety, OECD, March 2017

for the improved conduct of patient safety incident investigations locally, and to act as a catalyst to promote a just and open culture across the whole health system.

26. The Parliamentary and Health Service Ombudsman have reported that in their assessment of the quality of NHS investigations, 40% were not adequate at finding out what had happened.²¹ They highlighted several barriers that prevent a good investigation from taking place and from learning opportunities being shared. For example, staff involved in investigations may be uncomfortable with speaking openly and could possibly hold back information for fear of blame and litigation. In addition, NHS staff leading investigations often do not have the time or skills or necessary support to uncover the underlying causes of the incident. Organisational and cultural barriers could therefore prevent thorough investigation and learning.
27. The NHS typically has more information about a patient's care and related safety incidents, than the patient, families or carers. However, poor investigative practices mean that the NHS often fails to identify all the information it could have about an incident, in addition to a lack of protocols for sharing the information with patients, families or carers. Where the NHS fails to manage this information asymmetry, patients, families or carers do not receive full information about the incident, causing further distress on top of the harm caused, as the NHS is perceived as withholding information from them. This market failure prevents patients and their families holding the NHS to account, creating an imbalance of power which frustrates families.

Alternatives to legislation and options

28. Several alternatives to legislation were carefully considered but none of these were judged to deliver the desired policy objectives and intended effects as set out below:
 - Information provision for service users: Given the existing evidence suggests a lot of variation in investigation practice across NHS organisations and the limited learning and sharing from patient safety incidents it is difficult to identify what information shared to patients could help improve local investigatory practices or learning and sharing.
 - Information/guidance to service providers: Guidance exists on reporting patient safety incidents, alerts and learning. Nonetheless, existing evidence illustrates that the quality of investigations for patient safety is variable and staff are applying the methods identified in the framework inconsistently. We do not consider further guidance, which is not related to an evidence base of established effective investigative processes which we expect the HSSIB to develop, will deliver a consistent approach in investigation practices or promote the necessary learning.
 - Financial incentives: Use of financial incentives to encourage more openness and ensure investigations are properly resourced would not necessarily deliver a comprehensive or consistent approach in investigation practices or promote learning across the NHS.
 - Competition: The existence of information asymmetries across the NHS limits the ability of market forces to encourage providers to improve investigation practices and share learning from patient safety incidents.

Section B: Policy objectives and intended effects

29. The primary purpose of an independent safety investigation body is to identify the full facts of the patient safety incident which will generate richer learning to support improvements in patient safety and ultimately reduce harm to patients in the future. A safety investigation should be conducted in such a way as to determine what has happened, how it happened and why it happened, in order to make recommendations to prevent similar events from happening again. The HSSIB will also conduct its investigations and report its findings in such a way that patients, families, carers and staff are reassured that the full facts of a patient safety incident have been impartially considered.
30. Shortcomings to investigating and learning from patient safety incidents have been highlighted by the reports of the Ockenden review of maternity services at Shrewsbury and Telford Hospital NHS Trust, the Mid Staffordshire Inquiry, the Morecambe Bay Investigation, the Public Administration Select Committee report 'Investigating Clinical incidents in the NHS', to name a few. The latter made specific recommendations on the need to establish an independent, learning-focused patient

²¹ PHSO, Learning from mistakes, July 2016

safety investigation body that would investigate the most serious patient safety issues and promote a just and learning culture across the healthcare system.

31. The HSSIB will conduct investigations into risks that affect the safety of patients. The purpose of these investigations is to improve safety across the healthcare system by determining the systemic causes of serious safety issues and to identify system-wide learning to make safety recommendations that are intended to reduce risks to patients. An independent body is expected to be objective and impartial, and not to be compromised in how it conducts investigations or how it reports on its findings and makes recommendations. Providing a statutory prohibition on disclosure will help interview participants to be more candid which in turn will produce recommendations that more effectively support patient safety improvement. Alongside which it will support improvement in the quality and effectiveness of local safety investigations.
32. There are three main functions of an independent HSSIB:
 - Health services safety investigations: The HSSIB will undertake up to 30 investigations per annum operating under the legal provisions of safe space which prohibit the release of protected material.
 - Undertake programmes of work to support improvement in the quality and effectiveness of local safety investigations
 - Encourage development of skills: The HSSIB will disseminate its learning from patient safety incidents across the healthcare system to prevent similar incidents from occurring.
33. The HSSIB will employ rigorous expert safety investigations processes analogous with those in aviation, rail and marine sectors to routinely identify and address safety issues that span the healthcare system.

Statutory Powers and Criminal Sanctions

34. Similar to national safety investigation bodies in other sectors, the non-compliance with the HSSIB's powers of entry, inspection and seizure may result in criminal sanctions. It should be noted that the HSIB does not have these powers. The HSSIB provisions in the Act include six new criminal offences; three relating to the HSSIB's investigations:
 - i. intentionally obstructing an investigator in the exercise of their powers in clause 117 (entry, inspection and seizure);
 - ii. failing without reasonable excuse to comply with a notice given under clause 118 (to require the provision of information or attendance at an interview);
 - iii. providing information to the HSSIB which the person knows or suspects is false or misleading in a material way;

and three relating to unlawful disclosure of protected material:

- iv. breaching the prohibition in clause 121(1) by the HSSIB (or connected individual) knowingly, or recklessly disclosing protected material, where the person making the disclosure knows or suspects the disclosure is prohibited;
- v. breaching the prohibition in clause 121(5) by an individual who was previously connected with the HSSIB knowingly or recklessly disclosing what was protected material, whilst knowing or suspecting that the disclosure is prohibited;
- vi. a person not connected with the HSSIB, who is in receipt of protected material per cl 123(3), knowingly or recklessly disclosing protected material to another person without reasonable excuse, knowing or suspecting that it is protected material.

A person who commits any of these offences is liable on summary conviction to a fine. The Act makes provisions for offences by bodies corporate and by partnerships, as well as individuals. For example, where a senior individual (an officer) in an organisation e.g. a director, manager, secretary or other similar officer or any person acting in a similar capacity committed an offence,

the offence may also be committed by the body corporate, as well as the individual (cl 130). Similarly, an offence may be committed as an individual, as well as a partnership if certain criteria are fulfilled (cl 131(5)). Fines imposed on a partnership must be paid out from the partnership assets. We expect that offences would mostly apply to individuals.

Section C: Description of options

Option 1: Do nothing

35. The 'Do nothing' option (option 1) is for the HSIB to continue to operate under direction from NHS Improvement (or NHS England once the NHS England and NHS Improvement merger has taken place). The HSIB's national investigations can include any patient safety concern that occurred as a result of NHS-funded care in England after 1 April 2017.
36. As of May 2022, the HSIB had launched 122 National Investigations for scoping. Of these: 23 cases did not progress to full investigation as they did not meet the investigation criteria; 10 cases are in the scoping stage; and 89 have progressed to full investigation. The HSIB has published 66 reports. The length of time an investigation takes varies as it depends on the type and complexity of the case, but on average it has taken approximately 10 months to complete a National Investigation.²² The number of investigations undertaken each year by HSIB is expected to stabilise at 30 (with its allocated budget), and this is taken as the baseline for our analysis for the HSSIB.
37. The HSIB consider the requirement to investigate potential incidents or issues based on wide sources of information including that provided by healthcare organisations and their own research and analysis of NHS patient safety systems.
38. The HSIB decide what to investigate based on the scale of risk and harm, the impact on individuals involved and on public confidence in the healthcare system, as well as the potential for learning to prevent future harm. The HSIB welcomes information about patient safety concerns from the public but they do not replace local investigations and cannot investigate on behalf of families, staff, organisations or regulators.
39. Although the establishment of the HSIB has begun generating some learning from patient safety incidents and may improve the quality of patient safety investigations in the NHS to prevent future healthcare harm, it does not, however, give the investigative body the legal independence and separation from the NHS, investigatory powers, safe space protections and the creation of offences it needs to discharge its functions fully and effectively. We agree with the Joint Committee's recommendation²³ on 'Independence of judgement' that HSSIB should decide its own priorities objectively in respect of what it investigates and its independence of judgement in such decisions is reflected in the Health and Care Act 2022.
40. The HSIB operates as part of NHS Improvement which oversees the operation of NHS Trusts and NHS Foundation Trusts as well as independent providers that provide NHS-funded care. This presents a potential conflict of interest which risks undermining confidence in the HSIB's investigations and findings by the public and NHS staff. With the merger of NHSEI in the Act this potential conflict of interest would increase further.
41. The HSIB has no statutory 'safe space' to protect information gathered during its investigation from disclosure. This limits the degree of confidence that staff, patients and families may have in the HSIB and may limit their willingness to share information about what happened candidly. This means that the HSIB can only operate at a sub-optimal level without the necessary powers of entry, inspection and seizure to conduct investigations and protect material in a 'safe space'.
42. The HSIB has no ability to investigate safety incidents that are not NHS-funded. In 2018, the CQC reported that as at 2 January 2018, 41% of independent acute hospitals required improvement for safety and 1% were inadequate.²⁴ There is a large crossover of staff providing care commissioned

³⁸ Management information provided to DHSC

²³ The Government Response to the Report of the Joint Committee on the Draft Health Services Safety Investigations Bill, Dec 2018

²⁴ CQC: *The state of care in independent acute hospitals*, available at <https://www.cqc.org.uk/publications/major-report/state-care-independent-acute-hospitals>

by the NHS and privately, and recent concerns about the provision of breast implants and vaginal mesh have significantly affected privately funded patients. A number of organisations, including the Independent Healthcare Providers Network, support the extension of these investigations to cover healthcare not funded by the NHS²⁵.

Option 2: A new independent body

43. This option would establish a new independent Non-Departmental Public Body (NDPB) known as the Health Services Safety Investigations Body (HSSIB). We expect the new body to be fully operational on an independent statutory footing from April 2023. This will take over the HSIB's national investigation function.
44. Independence is essential to generate public confidence in safety investigation processes and to deliver impartial conclusions and recommendations. The evidence suggests a patient safety investigator must be entirely independent of all regulatory, commissioning, operational and political activities of the healthcare system it investigates. A safety investigator must be able to impartially investigate all areas of the healthcare system, it must be free from conflicts of interest and it must be entirely separated from any regulatory or performance management functions. It must also not become involved in the design or implementation of safety improvements, to ensure it is never put in the position of investigating failures that it may itself have contributed to in the past. A safety investigator derives a great deal of its authority, legitimacy, trustworthiness and influence from its independence.²⁶ The Joint Committee set up for pre-legislative scrutiny of the draft HSSI Bill heard from witnesses that to win the confidence of patients, healthcare professionals and other bodies with responsibility for patient safety, the HSSIB had to be, and be seen to be, independent of existing healthcare structures.²⁷
45. Whilst welcoming the establishment of the HSIB, the Public Administration and Constitutional Affairs Committee, as well as health experts and patient and family advocates have argued that for a patient safety investigation body to be truly effective it needs to be completely independent of the NHS and to have powers similar to those of the Air Accidents Investigation Branch (AAIB).
46. The Public Administration and Constitutional Affairs Committee also has a clear public position that the HSIB should have its independence put on a statutory footing which would be achieved by establishing the HSSIB: "...there should be primary legislation to provide that HSIB shall be established as a separate body, independent from the rest of the NHS, in order that it can conduct – and be seen to conduct – fully independent investigations. As part of NHS Improvement HSIB will be vulnerable to improper influence and is likely to find itself in the impossible position of having to include the body of which it is a part in its own investigations. We cannot accept the decision to dilute a core principle of the new Investigation Branch, and believe that there is a clear consensus across the sector that the proposed arrangements are an intolerable compromise."²⁸
47. The Expert Advisory Group for the HSIB similarly recommend that "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."²⁹
48. Although the new independent body will investigate a limited number of safety incidents through their own investigations, their independence is likely to uncover richer information about patient safety incidents and improve learning and sharing across the NHS. Additionally, an independent body can set standards to carry out robust quality investigations in a more authoritative manner which NHS providers will be encouraged to follow. This is the preferred option as the only way to guarantee the independence and autonomy of an investigation body is to set it up as a fully independent body. This is necessary to secure the confidence of patients, the public and NHS staff that investigations into patient safety incidents will be carried out fairly and with full cooperation but without interference from the healthcare system.
49. Investigations will need to obtain the full facts about safety incidents. Clinicians will need to be confident that they will not be blamed to enable them to speak honestly. The Joint Committee

²⁵ House of Lords Hansard, Health Service Safety Investigation Bill, 2nd Reading, 29 October 2019

²⁶ Macrae and Vincent, Investigating for Improvement: Designing an Independent Patient Safety Investigator for Healthcare, October 2015

²⁷ Joint Committee on Health Services Safety Investigations Bill Report

²⁸ Paragraph 47, Investigating clinical incidents in the NHS, Public Administration Select Committee, 2015

²⁹ Report of the Expert Advisory Group, Healthcare Safety Investigation Branch, May 2016

observes that, “The experience in other safety critical industries is that ‘safe space’ investigations will encourage professionals to be more open with investigators, but only time will tell how effective this will be in the healthcare sector. The ‘safe space’ approach is based on a better understanding of what people feel when they are under scrutiny. It also supports patients who do not want their information shared more widely. Although initially only introduced on a limited scale, this approach is an innovation for the healthcare sector which presents great possibility for positive evolution of the attitudes and behaviour people have tended to adopt towards patient safety incident investigations.”³⁰ It notes that HSIB will need to be an independent body to avoid such conflicts of interest and to operate the “safe space” effectively.

50. The Expert Advisory Group also recommends that, “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.”³¹
51. Even with an established “safe space”, some witnesses or establishments might still wish not to participate fully in investigations, preventing the investigation from establishing the full facts. The Joint Committee states “We recommend that the Government should... reserve to HSSIB the power to issue a summons to compel individuals to answer its questions”³². The Expert Advisory Group also recommends that “hiding or interfering with evidence is unacceptable, and should be made an offence.”³³
52. Similarly, institutions might be reluctant to disclose some information relevant to an investigation. In these circumstances, the Joint Committee believes that the HSSIB should have right of entry to be able to obtain this. “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.”³⁴

Section D: Costs and benefits assessment

53. The preferred policy option is to establish the HSSIB as an independent patient safety investigation body (Option 2). In our assessment of this policy option we also provide an estimate of the current costs of the investigations currently carried out by HSIB to provide context for the incremental cost of the HSSIB’s establishment as an independent body.

Costs

Option 1 – Do nothing

54. Option 1 represents the current arrangements for the HSIB fulfilling its existing responsibilities, and so has an implementation cost of zero. Annex B provides some further information on the operating costs of the HSIB for contextual purposes. The HSIB has a budget of **£3.952 million per annum** (updated from £3.8 million per annum to include inflation/uplifts since the 2019 IA was published) and this funding is expected to continue.³⁵

Option 2 – A new independent body

Monetised costs

Core budget

55. With the exception of additional powers that have been granted to the HSSIB within the Health and Care Act 2022, we can assume that the HSSIB will operate in a very similar way to the HSIB (when undertaking national investigations) and therefore require largely the same budget to meet its

³⁰ Joint Committee on Health Services Safety Investigations Bill Report

³¹ Report of the Expert Advisory Group, Healthcare Safety Investigation Branch, May 2016

³² Joint Committee on Health Services Safety Investigations Bill Report

³³ Report of the Expert Advisory Group, Healthcare Safety Investigation Branch, May 2016

³⁴ Joint Committee on Health Services Safety Investigations Bill Report

³⁵ Information supplied by HSIB in March 2021.

responsibilities.

56. The key difference in costs when comparing the HSSIB with the HSIB is associated with the HSSIB operating as an independent body with a board (which currently does not exist and will need to be set up) and corporate services that are currently shared with NHSEI and the maternity investigation programme.
57. This has been estimated by HSIB to cost approximately **£1.55 million per annum** and includes:
 - ~ £550k to set up the Board (Chair and NEDs); and
 - ~ £1m in pay and non-pay operating costs (e.g. pay for the CEO, executive directors, and corporate services team; non-pay including additional travel and subsistence, training and development, IT equipment for an expanded board; and costs relating to the running of corporate services, such as additional financial and audit reporting, comms, and an IT system for investigations (currently serving both national and maternity investigations)).
58. This figure is higher than the original estimate included in the IA published in October 2019 (£527k per annum) because it has been updated to include operating costs and the costs for corporate services currently shared with NHSEI.
59. The HSSIB has purposely been designed to be small and narrow in focus, similar to other accident safety investigation bodies. However, in response to the Joint Committee's recommendations and representations made during Second reading of the HSSI Bill in October 2019, the government has decided to:
 - Extend the HSSIB's remit to cover independently funded healthcare and all aspects of the health care pathway relating to a patient safety incident.
 - Grant the Secretary of State power of direction to require the HSSIB to investigate a qualifying incident or groups of qualifying incidents.
 - Grant the Secretary of State a new regulation making power to set out additional circumstances when the prohibition on disclosure (safe space) does not apply.
60. As mentioned above, the Health and Care Act was then updated to reflect the fact that **the exemption allowing senior coroners to access protected material held by the HSSIB was removed** during the Act's passage.
61. Extending the remit to include the independent sector and areas identified by the Secretary of State will have no additional impact on the projected number of investigations, offences or costs to the courts associated with the new body.
62. Note that the HSIB is currently undertaking a programme to investigate all maternity cases that meet certain criteria, replacing investigations by local trusts. While the HSSIB may conduct thematic investigations relating to maternity, they will not be undertaking maternity investigations as the HSIB does, under the provision of a separate maternity investigations programme budget. These costs are therefore not considered in this IA.

Non-monetised costs

Impact on healthcare staff and patients

63. HSSIB investigations would be expected to follow a very similar, if not identical, format to HSIB investigations, and, where appropriate, private hospitals will also be expected to participate. We do not expect there to be any significant differences in the total costs to healthcare staff and patients and other members of the public in participating in HSSIB vs HSIB investigations.

Impact on independent health care provider (IHP) sector

64. The overall cost burden of independently funded healthcare investigations on the IHP sector is expected to be negligible. We estimate that the proportion of the UK market value of healthcare

that is independently funded is between 6.5% and 9.1%³⁶. On this basis, investigations triggered by a reference incident relating to independently funded healthcare are likely to be around 6.5% to 9.1% of the 30 carried out each year. Using previous calculations of costs to NHS providers per investigation (i.e. based on the assumption that the time burden placed on staff by an HSSIB investigation and the opportunity cost of that time is broadly similar in both the NHS and the independent sector), we estimate that per annum costs to the IHP sector would be unlikely to exceed approximately £1,600 to £2,000 in total³⁷.

Applications to access HSSIB 'safe space' information

65. The Act allows applications to be made to the High Court to seek disclosure of protected material held by the HSSIB within a 'safe space'. The High Court will incur costs in considering these disclosure applications and there may be legal costs to the HSSIB should they choose to make representations against the disclosure of the information.
66. Applications to the High Court to obtain information which is prohibited from disclosure (protected material) in other sectors which operate a similar investigation model including air, rail and marine accident investigations have been few and far between, though the numbers have increased slightly as litigation becomes more prevalent.
67. Litigation in healthcare is a more frequent occurrence than in other areas of accident investigation. It is therefore possible that lawyers representing patients or NHS staff involved in safety incidents that have been investigated by the HSSIB may make applications for disclosure of 'safe space' information hoping to uncover material of benefit to their clients.
68. It is difficult to know how many disclosure applications the High Court will have to consider, although we expect there to be a maximum of five per annum. Initially we may expect interested organisations to test the Court's interpretation of the balancing exercise which they must engage in, to ascertain when the Courts might deem disclosure to be in the interests of justice.
69. The impact of the Secretary of State adding to the list of 'safe space' exemptions on the number of disclosure requests is unknown.

Applications for HSSIB enforcement

70. As outlined above, the Health and Care Act 2022 provides the HSSIB with a number of powers of entry, inspection and seizure. This includes the power of entry to enable the HSSIB to enter premises without the need for a warrant and the power to compel individuals to attend for interview. It will be a criminal offence for any person or organisation to intentionally obstruct an investigator in the exercise of their powers of entry, inspection and seizure conferred by the Act, or fail without reasonable excuse to comply with a notice issued by an investigator. The HSSIB may seek to impose criminal sanctions on rare occasions where it requires specific information, documents or records, or an explanation of events that is key to an investigation but has been unable to persuade the relevant individual or organisation to supply the information or explanation. It is also a criminal offence to knowingly provide a false or misleading statement or to willingly disclose material the individual believes to be protected. We anticipate that there will be very few, if any, cases per year. We therefore expect to see no more than one instance of a case being heard in a single year. Since this cost is uncertain, but in any event is expected to be small, it has not been included in the headline quantified costs of this proposal.
71. It is also our expectation that providers of NHS services, their staff, patients and the public will want to cooperate with the HSSIB as the intent of the investigations is not to apportion blame but instead to generate and foster a culture of learning, with the HSSIB making recommendations for improvements in patient safety. The fact that any information provided to the HSSIB in the course of an investigation will be held in a 'safe space' should further encourage such cooperation. We therefore think that there will be no or minimal costs to the relevant courts related to HSSIB's enhanced powers of enforcement.

³⁶ Based on the UK market value of acute healthcare, mental health hospitals and primary care broken down by source of funding in the Laing & Buisson UK Healthcare market review (30th edition, 2018), we estimate an IHP share of 6.5%. This rises to 9.1% if dentistry is included.

³⁷ This cost estimate is limited to the costs to HIPs of independently funded care only. This is likely to be an overestimate as it assumes that all staff involved in an investigation triggered by an incident in an independently funded healthcare setting will be employed by independently funded healthcare providers and this is unlikely to be the case given the HSSIB's focus on wider system learning.

HSSIB Legal costs

72. Legal costs incurred by HSSIB will need to be met from within their overall annual budget – i.e. no additional funding will be provided to meet these costs. In effect this means that any legal fees incurred by the HSSIB will reduce the funding left over to undertake investigations and support improvements in local investigative practices.
73. The probability of a case against healthcare providers or the public being heard in court is very low. However, the HSSIB may choose to make representations against an application or the disclosure of protected material.
74. Based on the estimate that up to five applications for disclosure of protected material held by the HSSIB could be made per year, the HSSIB's legal fees could reach a cost (including covering a claimant's legal fees) of approximately *£50,000 per annum*. (This figure is based on feedback from a panel of solicitors prior to the 2019 IA being published).

Coroners' Legal costs

75. We acknowledge that coroners may, in some cases, have cause to apply for access to protected material. Given that not all investigations will relate to a death, and that not all of these deaths would be referred to a coroner, we anticipate this volume to be low, with claimants' costs of up to *£5,000 per case*³⁸ (based on estimates from the 2019 IA). A separate JIT is being drafted with updated estimates about access to protected material by coroners, given amendments to the Act. We anticipate about one of the estimated five applications to access protected material per year to be from a coroner.

Summary of costs

76. We estimate that the incremental running costs for establishing the HSSIB as an independent NDPB will be approximately **£1.55m**. (This does not include the HSSIB's legal costs which are assumed to be met from the existing the HSIB annual budget. Nor does it include the additional potential costs mentioned above as they are uncertain or expected to be small.)
77. As this cost will be met from the DHSC budget, we need to account for the opportunity cost of redirecting resources to this use. We do this by assuming that funding at the margin generates Quality Adjusted Life Years (QALYs) per £15,000 of resources and that each QALY is valued by society at £60,000. This implies that the opportunity cost of £1.55m per annum/year of diverted spending is **£6.2m**. This gives a present value of cost over the 10-year appraisal period of **£51.6m**.

Benefits

78. The HSSIB is expected to improve the quality of locally conducted investigations and, through its own high quality investigations and better-conducted local investigations, to reduce the incidence of future harm in the NHS, through an improved process of capturing and acting on learning (although the extent to which this happens will largely depend on the actions of other organisations in the system rather than the HSSIB itself).
79. While these benefits cannot be quantified, it is anticipated that they should outweigh the monetary costs incurred by HSSIB investigations, avoid costs associated with correcting or compensating for harmful incidents, and generate health gains, anticipated to be sufficient to offset the costs associated with making any necessary improvements in investigative practice and/or safety. As set out previously, expenditure on clinical negligence claims amounted to over £2.3 billion in 2019/20. If the lessons generated from HSSIB investigations could reduce patient safety incidents and in turn clinical negligence claims by just 0.3%, this would level out the £6.2 million per annum investment.
80. Unlike the HSIB, the preferred option will guarantee the creation of a patient safety investigation body that is truly independent, and can deliver impartial conclusions and recommendations that the general public, the NHS and other relevant organisations can have full confidence in. It is only by establishing an independent body to conduct them that patient safety investigations will be able to

³⁸ Incurred by the coroner only if the application for access is denied

operate under the legal provisions of safe space which prohibit the release of any information, record, document or other item held by the independent body in connection with an investigation.

81. Furthermore, the Health and Care Act will provides the HSSIB with the necessary investigatory powers that the HSIB does not have. This is expected to improve compliance with investigations and therefore make them more efficient. Having greater access to all relevant information will ensure a proper understanding of events leading to the incident and appropriate recommendations to improve patient safety.
82. These independent investigations, which are seen to have greater access to all relevant information and are able to draw conclusions free from any external influence will give the public greater assurance that lessons have been learnt from the truth behind the incident, reducing the likelihood of litigation being brought against the NHS and the need for future public inquiries.

Value for money

83. The incremental costs of establishing the HSSIB as an independent investigation body are reasonable in comparison with the HSIB's current spend (£3.952 million per annum). The creation of a statutory safe space will ensure that witnesses can be more candid when they give information. Investigators will be able to access more information than the HSIB which will help them to identify changes to improve patient safety.

Risks

Policy risks

84. On 17 October 2016, the Department of Health launched a consultation on proposals to protect material in a 'safe space' in healthcare safety investigations, by creating a legal prohibition on the disclosure of information provided for a HSSIB investigation. In the course of a safety investigation contributions are more likely to be comprehensive and candid if they are made in confidence and used solely for the purpose of identifying improvements in safety. This in turn should help to understand the problem far more quickly and provide for a better and faster way of learning from healthcare harm, preventing incidents from being repeated.
85. There was widespread support for the HSSIB's leadership role in creating a learning culture, and a recognition that the HSSIB's credibility will rest on its ability to do this job well. Over 60% of respondents were in favour of creating a 'safe space' for HSSIB investigations, and many saw this as critical to the effective operation of the HSSIB. Consultation responses have emphasised that local NHS reviews and investigations need to also improve and the HSSIB has a role to play as an exemplar.
86. The first-order costs of the HSSIB defending applications for disclosure of protected material will need to be met from within the HSSIB's annual budget. The greater the propensity for people to apply for disclosure of protected material gathered as part of a 'safe space' investigation and the higher the share of applications that are found in favour of the information being disclosed then the less of the HSSIB's budget will be available to it for conducting its own investigations (and thus, the lower the level of first and/or second-order benefits that are likely to be achieved).

Section E: Conclusions and Summary

Conclusion

87. This impact assessment presents the estimated costs and benefits of establishing the HSSIB as an independent investigative body in comparison to the continued existence of the HSIB in its current form.
88. The incremental costs of operating an independent HSSIB are much smaller than the current costs of the HSIB. The incremental costs relate to certain additional costs associated with operating as an independent body. The incremental benefits, which are difficult to quantify, relate to how much more effective the HSSIB is likely to be having been given additional powers and any improved

cooperation and compliance from individuals and organisations arising from the HSSIB's perceived greater independence.

89. Since the incremental costs are small, it seems likely that the incremental benefits will be large enough to fully offset them.

Section F: Summary of specific impact tests:

Equality Impact Assessment

90. This policy proposal impacts all NHS and independent healthcare providers. The financial costs will not directly impact service users or any group of individuals in particular. There is no evidence that harm or the risk of harm varies significantly across groups protected by equality legislation, nor that the investigations of the HSSIB and other bodies, and their associated findings/learning will favour or disadvantage some groups more than others. The benefits of improved quality of care through improved investigations and improved learning from patient safety incidents will be realised by users of health services equally. This policy will not disproportionately affect any one demographic or social group. In general, the users of healthcare services tend to be people from older age groups, lower income distribution and those with disabilities or long-term conditions. Improved investigations into patient safety incidents, which lead to improved learning and mitigation of risks of future incidents, will therefore benefit older age groups and individuals with disabilities or long-term conditions the most.

Competition

91. In any affected market, would the proposal:

- Directly limit the number or range of suppliers?
No. The proposals do not involve the award of exclusive rights to supply services. Procurement will not be from a single supplier or restricted group of suppliers.
- Indirectly limit the number or range of suppliers?
No. The proposed policy will increase the standards that NHS providers must meet when undertaking an investigation in the NHS.
- Limit the ability of suppliers to compete?
No. This policy is not expected to have any impact on suppliers' ability to compete. The introduction of the HSSIB will strengthen and improve the quality of investigations undertaken in the NHS and affect all NHS providers equally.

This policy proposal does not limit the scope for innovation for the introduction of new products or supply existing products in new ways. It does not limit the sales channels a supplier can use, or the geographic area in which a supplier can operate. It does not limit the suppliers' freedoms to organise their own production processes or their choice of organisational form. It does not substantially restrict the ability of suppliers to advertise their products.
- Reduce suppliers' incentives to compete vigorously?
The proposal does not exempt suppliers from general competition law. It does require providers to be more open and honest in the event of a patient safety incident if they are party to a HSSIB investigation. Whilst this could have an impact on competition, it does not have the impact on the incentives on suppliers to compete vigorously.

Small and Micro Business Assessment

92. How does the proposal affect small businesses, their customers or competitors?

This policy is likely to have greatest impact on NHS providers. NHS trusts are all large organisations with over 250 employees. The HSSIB's focus is likely to be predominantly on

investigating patient safety incidents in NHS trusts but, it can investigate NHS care in other settings such as GP practices, which typically employ less than 250 employees. However, GPs operating under the GP contract are not within scope of the Small and Micro Business Assessment. As set out at paragraph 61 we expect the impact on the independent sector to be negligible.

Legal Aid/Justice Impact

93. The following were considered in the main impact assessment published in October 2019 and an updated Justice Impact Test will be submitted to reflect the changes outlined above.
- Will the proposals create new civil sanctions, fixed penalties or civil orders with criminal sanctions or creating or amending criminal offences? *Yes – a separate Justice Impact Test has been prepared which assesses the impact on the Justice System of the whole package of HSSIB policies.*
 - Any impact on HM Courts services or on Tribunals services through the creation of or an increase in application cases? *Minimal*
 - Create a new right of appeal or route to judicial review? *No*
 - Enforcement mechanisms for civil debts, civil sanctions or criminal penalties? *No*
 - Amendment of Court and/or tribunal rules? *No*
 - Amendment of sentencing or penalty guidelines? *No*
 - Any impact (increase or reduction on costs) on Legal Aid fund? (criminal, civil and family, asylum) *Minimal*
 - Any increase in the number of offenders being committed to custody (including on remand) or probation? *No*
 - Any increase in the length of custodial sentences? Will proposals create a new custodial sentence? *No*
 - Any impact of the proposals on probation services? *No*

Sustainable Development

94. The proposals are not expected to have a wider impact on sustainable development. There will be no impact on climate change, waste management, air quality, landscape appearance, habitat, wildlife, levels of noise exposure or water pollution, abstraction or exposure to flood.

Health Impact

95. Do the proposals have a significant effect on human health by virtue of their effects on certain determinants of health, or a significant demand on health service? (primary care, community services, hospital care, need for medicines, accident or emergency services, social services, health protection and preparedness response)
- The potential impacts on health have been considered above in the cost benefit analysis of this impact assessment (see Section D above).
 - There are no expected health risks in association with, diet, lifestyle, tobacco and alcohol consumption, psycho-social environment, housing conditions, accidents and safety, pollution, exposure to chemicals, infection, geophysical and economic factors, as a result of the proposals.

Rural Proofing

96. Rural proofing is a commitment by Government to ensure domestic policies take account of rural circumstances and needs. It is a mandatory part of the policy process, which means as policies are developed, policy makers should: consider whether their policy is likely to have a different impact in rural areas because of particular circumstances or needs, make proper assessment of those

impacts, if they're likely to be significant, adjust the policy where appropriate, with solutions to meet rural needs and circumstances.

- The proposals will not lead to potentially different impacts for rural areas or people.

Wider Impacts

97. The main purpose of the proposed policy is to incentivise all NHS providers to carry out good quality investigations and to be open and honest with patients where they have suffered serious injury or death, providing the patient with all the necessary facts which led to the incident. This is intended to reduce the level of distress and harm felt by patients in the event of a serious patient safety incident, and improve the culture of healthcare organisations to be more open and transparent.

Economic Impacts

98. The costs and benefits of the proposals on businesses have been considered in the main cost benefit analysis of this impact assessments - see Section D above.

Environmental impacts and sustainable development

99. The proposals have not identified any wider effects on environmental issues including on carbon and greenhouse gas emissions.

Social impacts

100. No impact has been identified in relation to rural issues or the justice system.

Annex A: Reporting incidences and investigations in the NHS

National Reporting and Learning System

The National Reporting and Learning System (NRLS) is a central database of patient safety incident reports.

Serious Incident Framework

A systematic process for responding to serious incidents in NHS-funded care.

Level 1: Concise Internal Investigation

A concise or compact investigation which includes the essentials of a credible investigation. This is suited to less complex incidents that can be managed by individuals or small group at a local level. A level 1 investigation must be completed within 60 working days of the incident being reported to the relevant commissioner.

Level 2: Comprehensive Internal Investigation

A comprehensive investigation used to review complex issues. It should be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable. The standard for completing a level 2 investigation is within 60 working days of the incident being reported to the relevant commissioner.

Level 3: Independent Investigation

Required when the integrity of the investigation is likely to be challenged, or where it will be difficult for an organisation to conduct an objective investigation internally due to the size of the organisation or the capacity/capability of the individuals available and/or the number of organisations involved. The investigator and all members of the investigation team must be independent of the provider. The investigation must be commissioned and carried out entirely independently of the organisation whose actions and processes are being investigated. Level 3 investigations should be completed within 6 months of the date that the investigation is commissioned.

Annex B: Direct costs relating to HSIB investigations

This annex provides information, for contextual purposes, on the costs for HSIB to fulfil its current investigations as part of NHS Improvement. It is largely based on that prepared for the 2019 IA.

HSIB Budget

While operating as a branch of NHS Improvement, the Healthcare Safety Investigation Branch (HSIB) has had a budget of **£3.8 million per annum** and this funding is expected to continue. Actual spend is estimated to be **£3.952 million per annum** (this is based on new information supplied since the previous IA in 2019).

In conducting its core investigations, HSIB focus on commonly experienced incidents within NHS-funded care, where systemic rather than locally specific causes are more likely to be responsible. Of those patient safety incidents referred to them³⁹, HSIB decide which to investigate based on 'the scale of risk and harm, the impact on individuals involved and on public confidence in the healthcare system, as well as the potential for learning to prevent future harm'.⁴⁰ As such, the investigation work is additional activity, building on (rather than substituting for) local investigations.

As per the current HSIB process, we expect most HSSIB investigations to be initiated in response to the referral of a specific reference incident. The HSSIB themselves will also be able to identify suitable incidents for investigation. As the nature of these incidents is expected to vary,⁴¹ each investigation may follow its own format and the process under which these investigations will be conducted, including obtaining any associated information, will be dependent on the terms of reference for each investigation. The reference incident on which each investigation will be based will also have been subjected to existing arrangements where it meets the criteria for a local investigation.

HSIB Investigations

There are approximately 250 NHS-funded secondary care providers that are the main focus of HSIB national investigations. However, ambulance services and mental health services are also involved in some investigations.⁴² Different providers might be affected by these investigations in different ways, depending on the incidence of patient harm, the quality of their local investigation practices and their need for improvement.

Providers of NHS-funded healthcare are asked to participate in HSIB investigations as appropriate. More specifically, organisations and staff involved in the reference patient safety incident under investigation will be required to participate in HSIB interviews and be open and transparent about the actions and processes that led to the patient safety incident in question.

It is difficult to accurately quantify the costs to the NHS involved with this activity as reference incidents will vary and as a result, each investigation will require different levels of staff involvement. However, completed HSIB investigations have involved 1-2 hour long interviews with an average of 12 staff at the reference site during the scoping stage.⁴³ NHS staff that HSIB have engaged with as part of their completed investigations range from hospital porters to Medical Directors but predominantly HSIB are engaging with hospital consultants, junior doctors (FY1 – ST6), nurses (at all levels), operating department practitioners, health care assistants and technical support staff.

³⁹ Between April 2018 and March 2019, HSIB received 100 referrals, 31% of which were submitted by members of the public and 34% by NHS staff. As of 31 March 2019, 22 of these referrals had resulted in the launch of an investigation (source: Healthcare Safety Investigation Branch, Corporate Performance Report March 2019 - Official)

⁴⁰ <https://www.hsib.org.uk/about-us/>

⁴¹ As of 31 March 2019, HSIB investigations had been completed on: transfer of critically ill adults; administering a wrong site nerve block; provision of mental health care to adults in the emergency department; transition from child and adolescent to adult mental health services; insertion of an incorrect intraocular lens; implantation of the wrong prostheses during joint replacement surgery; design and safe use of portable oxygen systems; piped supply of medical air and oxygen; neo-natal death

⁴² As of 31 March 2019, HSIB investigations had been completed on: transfer of critically ill adults; administering a wrong site nerve block; provision of mental health care to adults in the emergency department; transition from child and adolescent to adult mental health services; insertion of an incorrect intraocular lens; implantation of the wrong prostheses during joint replacement surgery; design and safe use of portable oxygen systems; piped supply of medical air and oxygen; neo-natal death

⁴³ Of the 9 completed HSIB investigations, 6 involved patient safety incidents in secondary care settings (including acute care and elective surgery), 1 of which also involved ambulance services. Of the remaining 3 investigations, 2 involved mental health services and 1 involved maternity care. Between April 2018 and March 2019, HSIB received 100 referrals, 58% of which related to patient safety incidents in secondary care, 13% in maternity, 13% in primary or community care, 10% in mental health, 2% in ambulance services and 4% in other settings (source: Healthcare Safety Investigation Branch, Corporate Performance Report March 2019 - Official)

⁴³ The number of NHS staff interviewed by HSIB during the scoping stage of different investigations has ranged from 7 to 16 and is dependent on the nature of the investigation (Healthcare Safety Investigation Branch communication – official)

Alongside interviews with staff involved in each reference incident it is assumed that the HSSIB will hold meetings with senior staff at the relevant organisation including for example, the Medical Director, Chief Nurse and/or Head of Patient Safety.

Based on this information and the average unit costs for NHS staff, we estimate the direct costs of participating in an HSSIB investigation for NHS providers could be an average of £639 for interview time with staff involved in the reference incident (see Table 1) plus £162 for 3 hours of meetings with senior staff.⁴⁴ Based on the assumption that the HSSIB will complete 30 investigations per year, costs to NHS providers of their involvement in HSSIB investigations is therefore estimated to be approximately **£24,000 per annum**.

Table 1 – Cost of interviews with NHS staff involved in reference incident

	Consultant medical	Registrar	Doctor (FY2)	Nurse (Band 8a)	Nurse (Band 5)	Clinical support worker (nursing) (Band 2)	Operating department practitioner	Health care assistant
Cost per h	£106	£43	£30	£62	£37	£22	£13	£10
Cost per 1.5h [†]	£159	£65	£45	£93	£56	£33	£20	£15
Average no. interviewed	1	1	2	1	2	2	2	1
Total cost	£159	£65	£90	£93	£111	£66	£40	£15

Source: Unit Costs of Health and Social Care 2017⁴⁵

[†] As HSIB interviews are usually 1-2 hours long we assume an average interview time of 1.5 hours

Alongside HSIB's work to gather information on the reference incident from the relevant NHS provider/s, as part of each investigation HSIB also make reference or observational visits to other trusts and consult relevant experts and professional organisations. There are two ways in which experts are asked to contribute to HSSIB investigations. Firstly, HSIB are able to draw on the expertise of members of their expert advisory board, whose costs are met within the core HSIB budget. In addition, they engage with experts and organisations of relevance for specific investigations on an ad hoc basis.

While fees are not usually charged for ad hoc consultations with experts, there are associated opportunity costs for the senior professionals and organisations that HSIB engage with on this basis. While each investigation varies it is expected that between 6 to 12 different organisations may be consulted in relation to a specific investigation and that the level of ad hoc expert engagement will be wide-ranging and significant.⁴⁶ As this type of engagement is voluntary, if professionals and organisations choose to undertake this work, we assume that they have judged the costs of participating to be outweighed by the benefits.

The HSIB speaks to patients, their families and carers to fully understand the safety incident and provide relevant context. During the first 4 years of operation, 89% of families have engaged with HSIB investigations.⁴⁷ This addresses the claim that the NHS underestimates the role families and carers can play in helping to fully understand what happened to the patient and that they offer a vital perspective because they see the whole pathway of care that their relative experiences.⁴⁸ If we assume an HSIB investigation requires a maximum of 5 interviews with the patient, family member and/or carer per patient safety incident, and approximately two hours per interview, that would amount to an average of 10 hours per HSIB investigation and so 300 hours per annum.

Based on an average of the median hourly wage in the UK of £12.63 for 2017 and 2018,⁴⁹ we estimate the costs to the public of participating in HSIB investigations could amount to approximately **£3,800 per annum**.

⁴⁴ Healthcare Safety Investigation Branch communication - official

⁴⁵ Curtis LA & Burns A. (2017) Unit Costs of Health and Social Care 2017, Personal Social Services Research Unit, University of Kent, Canterbury. ISBN 978-1-911353-04-1

⁴⁶ As part of their completed and ongoing investigations, HSIB have consulted with senior consultants, NHS professional staff at a very senior level, Professors of relevant medical specialties, Royal Colleges, Royal Societies, NHSE and NHI and the MHRA. This level of engagement was often significant – for example, over ~30 hours, HSIB consulted the Royal College of Anaesthetists in relation to their investigation of a wrong site anaesthetic block and this was just one of a number of interactions with different experts and organisations as part of this investigation (Healthcare Safety Investigation Branch communication – official).

⁴⁷ Healthcare Safety Investigation Branch communication – official

⁴⁸ Learning, candour and accountability, CQC, December 2016

⁴⁹ Annual Survey of Hours and Earnings time series of selected estimates, ONS

(<https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/ashe1997to2015selectedestimates>)

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