

| Title: Health Service Safety Investigations Bill IA No: 3136 RPC Reference No: Lead department or agency: Department of Health Other departments or agencies: | Impact Assessment (IA) | | | |
|--|---|--|--|--|
| | Date: 12/06/2017 | | | |
| | Stage: Final | | | |
| | Source of intervention: Domestic | | | |
| | Type of measure: Primary legislation | | | |
| | Contact for enquiries: | | | |

| | |
|--|------------------------------------|
| Summary: Intervention and Options | RPC Opinion: Not applicable |
|--|------------------------------------|

| Cost of Preferred (or more likely) Option | | | | |
|---|----------------------------|---|-------------------|-------------------------------|
| Total Net Present Value | Business Net Present Value | Net cost to business per year (EANDCB in 2014 prices) | One-In, Three-Out | Business Impact Target Status |
| -£0.23m (plus unquantified benefits) | | | Not in scope | Not a regulatory provision |

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

The problem under consideration is: the quality of NHS investigations into patient safety incidents (24,000/year) is inconsistent with no mechanism to systematically learn from mistakes and prevent repetition of the same problems; there is no established, independent body to carry out investigations impartially and with public confidence; as a result, Government has commissioned many independent inquiries at significant cost. Government intervention is necessary to put the current HSIB (established in Directions) onto a statutory independent footing, including powers of safe space (information provided in confidence). In addition, accreditation would allow NHS Trusts to assume equivalent investigation powers in the future. Without legislation neither independence, safe space or accreditation would be possible, and thus further stand alone, expensive inquiries are likely to continue.

What are the policy objectives and the intended effects?

The policy objective is to establish an independent Non Departmental Public Body (NDPB), the Health Service Safety Investigations Body (HSSIB) to deliver expert investigations with 'safe space' powers, improve the quality of the NHS' own investigations, and to enable NHS Trusts to carry out equivalent investigations to the same standard. The intended effects are: improved public confidence in investigations arising from both the independence of HSSIB and the provision of safe space for holding of confidential information; to make recommendations that improve patient safety, encourage a culture of learning and safety improvement throughout the NHS; drive greater consistency in the quality of NHS investigations, including the ability for the NHS, subject to accreditation, to carry out its own safe space investigations; and as a result of this increased capacity, reduce the need for further expensive public inquiries.

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

Option 1: Do nothing

Option 2: A new independent body. The preferred option is option 2, as only with primary legislation can an independent NDPB be established, alongside the safe space powers that other industry regulators have, including the prohibition of the release of material generated by HSSIB during the course of its investigation. The Department of Health has already established HSSIB in directions as a Branch of NHS Improvement. However this does not guarantee the independence of investigations. NHSI is the overseer of NHS Trusts, so HSSIB is effectively investigating another part of its own organisation; safe space powers are weaker than for other regulators with no protection of information; and the directions do not include powers of accreditation. So without legislation the policy objective cannot be delivered.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: 2022/23

| | | | | | |
|---|--|-------------|--------------|---------------|--------------|
| Does implementation go beyond minimum EU requirements? | | | 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 Chief Economist: Chris Mullin Date: 15 June 2017

Summary: Analysis & Evidence

Policy Option 1

Description: Do Nothing

FULL ECONOMIC ASSESSMENT

| Price Base Year | PV Base Year | Time Period Years | 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'

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 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. The do nothing option would fail to generate sufficient learning to prevent future patient safety incidents and harm or improvements in local investigations. | | |

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: Independent Healthcare Safety Investigation Branch (HSIB)

FULL ECONOMIC ASSESSMENT

| Price Base Year 2016 | PV Base Year 2017/18 | Time Period Years 10 | Net Benefit (Present Value (PV)) (£m) | | |
|-------------------------|-------------------------|-------------------------|---------------------------------------|----------------|------------------------|
| | | | Low: Optional | High: Optional | Best Estimate: -£0.23m |

| 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 | | | | £38.4m |

Description and scale of key monetised costs by 'main affected groups'
Key costs will be those involved in the operation of HSSIB and to NHS providers and the public involved in HSSIB investigations. There may be legal costs associated with applications to obtain warrants to gain entry or in appeals should NHS providers or other organisations not cooperate with an investigation or provide the required information, leading to the imposition of a fine by HSSIB which could be appealed against. Costs of an appeal would fall on HSSIB and the NHS body appealing against the fine. There will also be costs associated with individuals or organisations applying to the High Court for disclosure of material generated by HSSIB during the course of an investigation.

Other key non-monetised costs by 'main affected groups'
Costs to NHS providers to implement recommendations to address patient safety incidents and improve local investigations. In addition, costs to NHS Trusts and FTs applying for accreditation and meeting and maintaining standards.

| 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 | | | | £38.2m |

Description and scale of key monetised benefits by 'main affected groups'
HSSIB investigations will improve the experience and well being of those patients, families, carers and staff directly involved in its investigations, in part by providing reassurance that incidents will be investigated thoroughly and impartially, and mitigating the stress caused by poor investigations. HSSIB investigations are also expected to prevent and reduce the demand for future costly national public inquiries like Mid Staffordshire and Morecambe Bay, diverting valuable NHS resources which could otherwise be used for frontline service delivery.

Other key non-monetised benefits by 'main affected groups'
Increased public and staff confidence in the independence, impartiality and rigour of investigations for patient safety incidents in the NHS. Improved investigation capability is expected to remove inefficient practices and the learning from patient safety incidents will ultimately reduce harm to patients in the future.

| | | |
|-------------------------------------|-------------------|-----|
| Key assumptions/sensitivities/risks | Discount rate (%) | 3.5 |
|-------------------------------------|-------------------|-----|

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 the 14th leading cause of the global disease burden. In some OECD countries, the burden of patient harm is similar to that of chronic disease such as multiple sclerosis and some types of cancer.³
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 adverse patient events. This is similar to other high risk sectors such as air, automotive, and the oil industry, where investment decisions are being made on 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 incidents⁴ do happen, it is important that lessons are learned to prevent the same safety incident occurring again or elsewhere. When a serious incident occurs or a loved one dies in care, knowing how and why the incident occurred is the very least a family should expect.
5. A patient safety incident can have an impact on the patient at various levels:
 - Low: any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm to one or more persons;
 - Medium: any unexpected or unintended incident that resulted in further treatment, possibly surgical intervention, cancelling of treatment, or transfer to another area, and which caused short term harm to one or more persons;
 - Severe: any unexpected or unintended incident that caused permanent or long term harm to one or more persons;
 - Death: any unexpected or unintended incident that caused the death to one or more persons.
6. The NHS 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.⁵
7. There is evidence that families have had to go to great lengths themselves to get answers to their questions and were subjected to poor treatment from across the healthcare system. Patients, families and carers often have poor experiences of investigations and are not always treated with kindness, respect and honesty.⁶ Those working in healthcare have a moral responsibility and a legal duty⁷ to be open and honest with patients, families and carers.
8. The policy to establish a Healthcare Safety Investigation Branch (HSIB) 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', and the Morecambe Bay Investigation (July 2015)”. It aligns with DH’s commitment to establish the NHS as the world 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*”.

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

² The National Reporting learning System defines ‘harm’ as injury, suffering, disability or death.

³ Slawomirski, Aaraen and Klazinga, The Economics of Patient Safety, OECD, March 2017

⁴ 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.

⁵ Macrae and Vincent, Learning from failure: the need for independent safety investigation in healthcare, Journal of the Royal Society of Medicine, November 2016

⁶ Learning, candour and accountability, CQC, December 2016

⁷ The Duty of Candour, Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

9. Directions were given to the NHS Trust Development Authority to establish HSIB as a branch of the Special Health Authority and operate from 1 April 2017. Since then, the Department of Health (DH) has been granted drafting authority to prepare a new bill to set up a new independent body and enable it to discharge its investigative functions without interference or influence by any other body.
10. This Impact Assessment considers the cost and benefits of centrally run patient safety investigations and the additional costs and benefits related to setting up a new independent body.
11. 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

12. There were 1.76 million incidents reported to the National Reporting and Learning System in 2015:

- Nearly 24,000 serious incidents reported and investigated in 2016⁸;
- Around 8,000 avoidable hospital deaths in the NHS every year⁹;
- 442 recorded “never events” (such as wrong site surgery) during 2015-16.¹⁰

The NHS Litigation Authority’s latest estimate of expenditure on claims for clinical negligence is nearly £1.4 billion in 2015/16.¹¹

13. Additionally, since around 2000 there have been an increasing number of large scale national public inquiries costing the NHS millions and diverting valuable NHS resources from frontline services. For instance, the cost of the Francis Inquiry into the Mid Staffordshire NHS Foundation Trust was £19.7 million.¹²
14. Across the healthcare system, there is limited capacity to investigate effectively 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 further distress on top of the harm caused by the events themselves.
15. Investigations into patient safety incidents are often delayed, protracted, and of variable or poor quality. 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.
16. 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.
17. A recent review¹³ of the way NHS trusts review and investigate the deaths of patients found:
 - Most NHS trusts report they follow the Serious Incident Framework¹⁴ when carrying out investigations. Despite this, the quality of investigation is variable and staff are applying the

⁸ Strategic Executive Information System (STEIS)

⁹ Based on Hogan and Black, Avoidability of hospital deaths and association with hospital-wide mortality ratios: retrospective case record review and regression analysis, BMJ, 2015

¹⁰ Never Events data summary 2015/16, NHS England

¹¹ 2015-16 NHS LA Annual report and accounts

¹² [Link to The Mid Staffordshire NHS Foundation Trust Public Inquiry report](#)

¹³ Learning, candour and accountability, CQC, December 2016

¹⁴ [Link to the Serious Incident Framework web page](#)

methods identified in the framework inconsistently, thereby acting as a barrier to identify 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.

18. The report highlighted 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.
19. 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.

Rationale for government intervention

20. 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. This is likely to be a conservative figure. Patient harm is felt in the broader economy through lost capacity and productivity of patients and their carers. It is estimated that the aggregate costs amount to trillions of dollars each year. In the political economy, the cost of safety failures includes loss of trust in the health systems, in governments and in social institutions.¹⁵
21. Market forces fail to coordinate the actions of the many NHS providers to achieve the optimal allocation of resources, leading to suboptimal outcomes and inefficient use of resources. NHS providers do not usually enact or share the learning from patient safety incidents and this requires the government to intervene to provide this coordination.
22. 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 strengthened investigative capacity locally in most of the NHS, supported by a new, single, independent and accountable investigative body to provide national leadership, to serve as a resource of skills and expertise for the conduct of patient safety incident investigations, and to act as a catalyst to promote a just and open culture across the whole health system.
23. Evidence suggests 40% of investigations were not adequate at finding out what had happened.¹⁶ There are a number of barriers that prevent a good investigation taking place and learning opportunities shared. Staff involved in investigations may be uncomfortable with speaking openly and could possibly hold back information for fear of blame and litigation. NHS staff leading investigations do not have the time or skills or necessary support to uncover the root cause of what led to the incident. Organisational and cultural barriers could prevent thorough investigation and learning.
24. The NHS typically has more information about a patient's care and related safety incidents, than the patient, families or carers have. However, poor investigative practices mean that the NHS 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 of the root cause of the incident, causing further distress on top of the harm caused, as the NHS is perceived at withholding information from them. This market failure prevents patients and their families holding the NHS to

¹⁵ Slawomirski, Auraen and Klazinga, The Economics of Patient Safety, OECD, March 2017

¹⁶ PHSO, Learning from mistakes, July 2016

account, creating an imbalance of power which frustrates families, and limits the NHS from becoming a world leading learning organisation.

Alternatives to legislation and options

25. Alternatives to legislation were judged not 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: There is considerable patient safety guidance 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 believe further guidance, which is not related to an evidence base of established effective investigative processes as we expect HSSIB to conduct, 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

26. The primary purpose of an independent safety investigation body is to 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 it from happening again. The independent safety investigation body will also 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.
27. Shortcomings in the current approach to investigating and learning from patient safety incidents have been highlighted by the reports of the Mid Staffordshire Inquiry, the Morecambe Bay Investigation, and the Public Administration Select Committee report “Investigating Clinical incidents in the NHS”. The latter made specific recommendations on the need to establish an independent, learning-focused patient safety investigation body that would investigate the most serious patient safety issues, and promote a just and learning culture across the healthcare system.
28. HSSIB will conduct major safety investigations into the most serious risks that affect the safety of patients receiving NHS funded care in England. 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 generate richer information regarding the patient safety incidents which will identify the root cause of the incidents and improve the shared learning amongst NHS provider organisations.
29. There are three main functions of an independent HSIB:
- Health Service Safety Investigations: HSSIB will undertake up to 30 investigations per annum operating under the legal provisions of safe space which prohibit the release of material held by the independent body in connection with the investigation.
 - Providing advice, guidance and training: HSSIB will provide advice, advice and training to NHS providers to improve local investigation practices.
 - Encourage development of skills: HSSIB will spread its learning from patient safety incidents across the NHS to prevent similar incidents from occurring.

30. 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.
31. In addition to the three principle functions, HSSIB will also have the function of accrediting NHS Trusts and NHS Foundation Trusts (FTs) to undertake investigations of safety incidents in NHS services, under the same non-disclosure prohibitions as HSSIB.

Section C: Description of options

Option 1: Do nothing

32. A Healthcare Safety Investigations Branch (HSIB) was established under NHS Trust Development Authority Directions 2016 and hosted by NHS Improvement (the umbrella body of TDA and Monitor). HSIB became operational on 1 April 2017, with a budget of £3.8 million. As this branch is only just being established, this IA considers the policy for establishing a central body to undertake patient safety investigations as well as the costs associated with creating a new independent body. Typically, under the 'do nothing' scenario the costs of the existing branch would not be considered as part of the option appraisal but we are examining the impact of additional investigations and an independent body.
33. HSIB is expected to undertake up to 30 investigations in this budget. It is not clear at this stage what shape or form these investigations will take place and the patient safety incidents they will investigate but it is likely they will focus on serious incidents in the NHS. HSIB is expected to focus on commonly experienced patient safety incidents, where systemic rather than locally specific causes are more likely to be responsible. As such, we assume that HSIB investigative work will be additional activity, building on rather than substituting for local investigations.
34. Although the establishment of HSIB as part of NHS Improvement will generate 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 it needs to discharge its functions fully and effectively.
35. HSIB operating as part of NHS Improvement which oversees the operation of NHS Trusts, NHS Foundation Trusts as well as independent providers that provide NHS-funded care generates a potential conflict of interest which risks undermining confidence in HSIB's investigations and findings by the public and NHS staff.
36. Under the 'do nothing' scenario, we would retain the current patient safety framework with the NHS investigating safety incidents locally. Individual trusts conduct large numbers of investigations into serious incidents, sometimes with the assistance of external advisers. These investigations can lead to important local safety improvements. However, the scope of these investigations is necessarily focused on a specific trust. With occasional exceptions, local investigations rarely encompass the wider systemic factors that can contribute to serious failures of care, such as ambiguous regulatory requirements or inappropriate commissioning.¹⁷
37. There is a lot of variation in the practice and the quality of investigations across England. Investigations are often delayed, protracted, and of variable or poor quality. There is a fragmentation of responsibility for rigorous investigation, both within individual organisations and across the healthcare system. 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.
38. The failure to learn from incidents means patients, families and the public are too often let down by poor investigations, and the result is significant further distress on top of the harm caused by the events themselves.

Option 2: A new independent body

39. This option would establish a new independent Non Departmental Public Body (NDPB) known as the Health Services Safety Investigations Body (HSSIB). Subject to parliamentary clearances, we expect the new body to be fully operational on an independent statutory footing in the next financial year.

¹⁷ Macrae and Vincent, Learning from failure: the need for independent safety investigation in healthcare, Journal of the Royal Society of Medicine, November 2016

40. Independence is essential to generate public confidence in safety investigation processes in the NHS 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.¹⁸
41. Whilst welcoming the establishment of HSIB, the Public Administration and Constitutional Affairs Committee, as well as health experts and patient and family advocates have argued that for HSIB to be truly effective it needs to be completely independent of the NHS and to have powers similar to those of the Air Accident Investigation Branch (AAIB).
42. The Public Administration and Constitutional Affairs Committee (formerly PASC) also has a clear public position that HSIB should have its independence put on a statutory footing. "...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."¹⁹
43. Although the new independent body will investigate a limited number of safety incidents from their own investigation, their independence is likely to uncover richer information about the patient safety incidents and improve the 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. The independent body will also develop a system of accreditation for NHS trusts and foundation trusts so that in the future they will be able to conduct patient safety investigations to the same standards as HSSIB.
44. This is the preferred option as it is the only way to guarantee the independence and autonomy of an investigation body which 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 without interference from the healthcare system. In addition, establishment of an independent body is necessary in order for the new body to 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 the investigation.

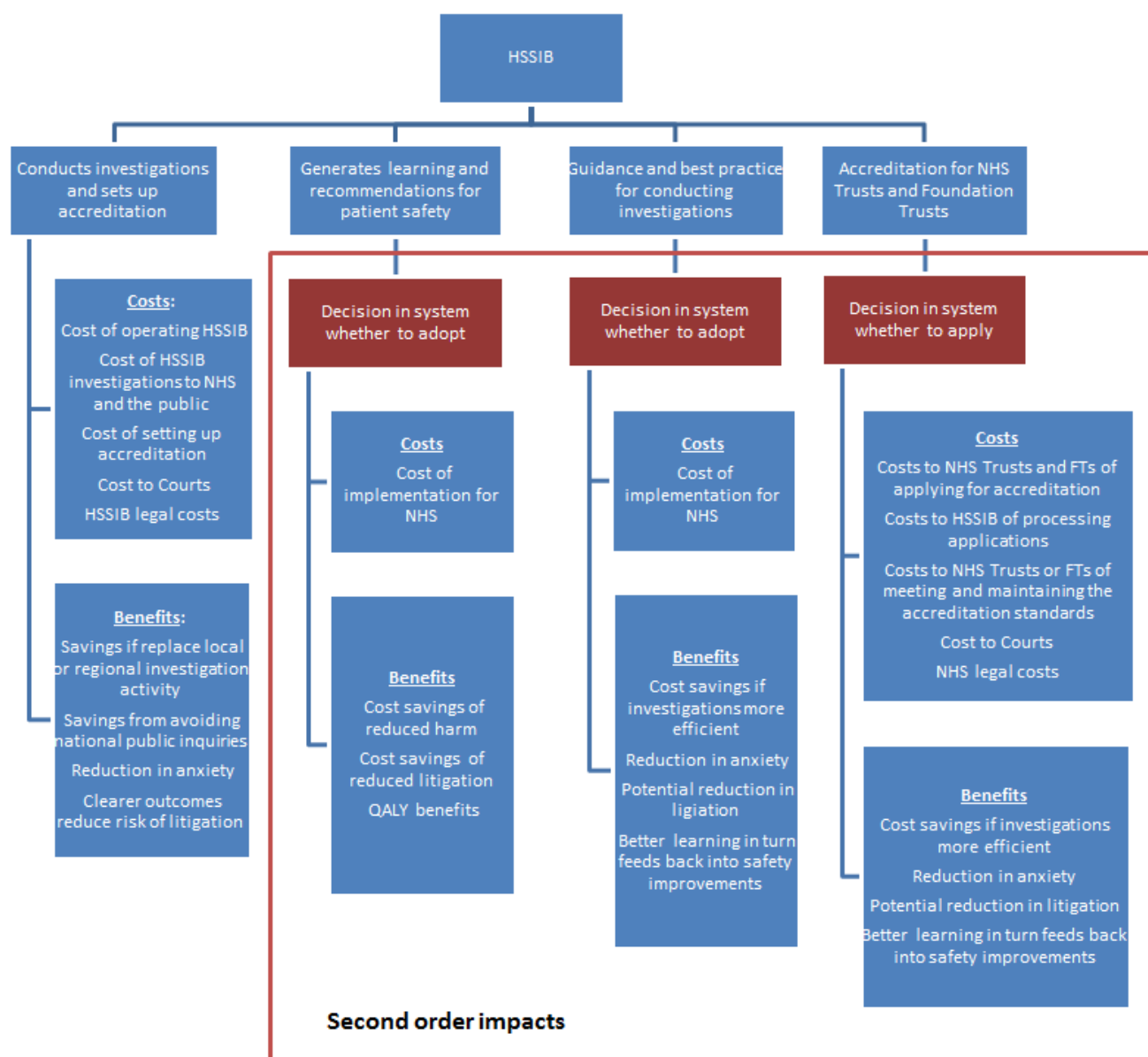
Section D: Costs and benefits assessment

45. The setup of an independent body will have two types of effects for the NHS. We have categorised these effects into first-order and second-order effects. The first-order effects relate directly to the activity undertaken by the new body, namely investigations, setting up accreditation and accrediting NHS Trusts or FTs. The new HSSIB body will make recommendations to address patient safety, develop guidance and provide advice for local investigations and also develop criteria for accreditation for NHS Trusts and FTs to undertake investigations similar to HSSIB standards.
46. However, it will be for other parts of the system, namely NHS providers, to respond to the recommendations and implement them and to decide whether or not to seek HSSIB accreditation. Since these impacts depend on the decisions of others, they are categorised as second-order effects as illustrated in the diagram below.

¹⁸ Macrae and Vincent, Investigating for Improvement: Designing an Independent Patient Safety Investigator for Healthcare, October 2015

¹⁹ Paragraph 47, Investigating clinical incidents in the NHS, Public Administration Select Committee, 2015

47. This IA focuses on the first-order effects and discusses the second-order effects only in so far as to offset the first-order effects but does not discuss them in detail.



Costs

Operating HSSIB

48. HSIB as a branch of NHS Improvement has a budget of **£3.8 million per annum**. Setting up a new independent body with executive team functions will cost approximately **£300,000** per annum, taking the total budget to **£4.1 million per annum**. It is expected that HSSIB will undertake up to 30 investigations per annum. It is not clear at this stage what shape or form these investigations will take and the safety incidents they will investigate but it is likely they will focus on serious incidents in the NHS. The new body is expected to focus on commonly experienced incidents, where systemic rather than locally specific causes are more likely to be responsible. As such, we assume the investigation work will be additional activity, building on (rather than substituting for) local investigations.
49. The extent to which the cost to HSSIB of carrying out investigations represents a net increase in investigative costs across the NHS as a whole depends on the extent to which HSSIB investigations will substitute for investigation activity currently undertaken elsewhere, whether at a national or regional level. This is not something that is known with certainty at this stage. For the purpose of this IA, however, our expectation is that most HSSIB investigations substitute for a particular type of

national investigation (see paragraph 82-91 on reduced incidence of large scale national investigations and public inquiries).

50. We expect HSSIB to review up to 4 individual patient's cases for each of the investigations it undertakes. The process under which these investigations will be conducted, including the obtaining of any associated information, will be dependent on the terms of reference of each investigation. All the individual cases will have been subjected to the existing arrangements that require a local investigation.
51. The HSSIB has purposely been designed to be small and narrow in focus, similar to other accident safety investigation bodies. We do not expect to extend the powers or responsibilities of HSSIB in future years and therefore assume their budget will remain the same in real terms.

HSSIB accreditation set up costs

52. One of the functions of HSSIB is to develop a system of accreditation for NHS Trusts and FTs so that in the future they will be able to conduct investigations into safety incidents which meet qualifying criteria published by HSSIB, which benefit from the prohibition on disclosure of certain information provided within a 'safe space'. Qualifying incidents will be those which appear to involve risks to the safety of patients and which fall within the criteria determined by HSSIB.
53. Once HSSIB is established as an NDPB and carried out a sufficient number of investigations, HSSIB will develop its criteria for accreditation. It is possible a research pilot exercise to test how accreditation could be implemented would be conducted with two hospital trusts. The research pilot is likely to require an experienced investigator to work with the trust and experience first-hand how local investigations are conducted, whilst providing support and training where necessary. The intention is that by observing first-hand how a trust actually conducts investigations, along with reviewing investigation reports, a real assessment of the trust's capability can be completed. This approach will also help to raise and inform investigation standards locally.
54. A full evaluation of the pilots would be carried out by an independent research organisation and the evaluation findings will be used to determine the accreditation model and potential costs to determine the best value for money approach. The estimated cost to run the pilot is:
- £90k to second an experienced person;
 - £25k to evaluate the pilots and write a comprehensive report.
55. In terms of the second-order impacts, our expectation is that accredited bodies will carry out a minimum of one investigation at year and the number of accredited bodies will, be very small. We do not yet know how many NHS Trusts or NHS FTs will seek to become accredited but, applications are only likely to come from the top performing Trusts such as those rated 'outstanding' by Care Quality Commission (CQC), of which there are only five. Given additional funding will not be made available to accredited Trusts to undertake investigations, it is unlikely that their volume of investigation activity will be high, perhaps no more than four to five cases a year.
56. We do not expect the number of accredited NHS Trusts or FTs to be very large and there is no expectation that all NHS Trusts or even the majority of NHS Trusts will be accredited. We do expect the number of accredited Trusts to grow over time, although we envisage there being no more than 10-20 such accredited Trusts in the system at most.
57. However, until HSSIB is established and publishes criteria for accrediting NHS Trusts or FTs, we cannot say with certainty how many trusts might a) pass the bar for accreditation b) what the costs of doing so might be and c) how many trusts this is likely to attract to apply for accreditation beyond the top five performing trusts rated 'outstanding' by CQC. A further assessment of the impact of accreditation will be published following consultation by HSSIB on its criteria for accreditation. As these are classified as second-order costs, we have not estimated the impact in this IA.

HSSIB Investigations

58. There are approximately 250 NHS secondary care providers that are likely to be the main focus of an HSSIB investigation and subjected to the standards HSSIB will determine in respect of locally conducted investigations. 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.

59. NHS providers will need to partake in the HSSIB investigations as appropriate. We would expect staff involved in the patient safety incidents under investigation to participate in HSSIB interviews and be open and transparent about the actions and processes that led to the patient safety incident in question occurring.
60. It is difficult to quantify the costs involved with this activity as each incident will be different and will require different levels of staff involvement to determine the root cause. If we assume a typical HSSIB investigation would require a maximum of 5 staff interviews (a consultant, doctor, nurse, other healthcare professional and NHS manager) per patient safety incident, and approximately an hour per interview that would amount to 600 staff hours based on HSSIB reviewing 4 individual patient safety cases per each of the 30 investigations.
61. Based on average unit costs per NHS staff, we estimate the direct costs of participating in 30 HSSIB investigations for NHS providers could be between **£26,880 to £32,160 per annum**.

| | Consultant Medical | Doctor (FY2) | Nurse (band 5) | Clinical support (band 3) | NHS manager (band 8b)* |
|---------------------------------------|-----------------------|-----------------|-------------------|------------------------------|---------------------------|
| Cost per working hour | £104 | £29 | £35 | £27 | £29 |
| <i>costs including qualifications</i> | £135 | £42 | | | |

Source: Unit costs of Health & Social Care 2016, PSSRU

* <https://www.healthcareers.nhs.uk/about/careers-nhs/nhs-pay-and-benefits/agenda-change-pay-rates>²⁰

62. We would also expect HSSIB to speak to patients, family or carers to fully understand the safety incident and provide the relevant context. The NHS underestimates the role families and carers can play in helping to fully understand what happened to the patient. They offer a vital perspective because they see the whole pathway of care that their relative experiences.²¹ If we assume an HSSIB investigation would require a maximum of 2 interviews with the patient, family member or carer per patient safety incident, and approximately an hour per interview, that would amount to 240 hours based on HSSIB reviewing 4 individual patient safety cases per each of their 30 investigations.
63. Based on 2016 national weekly earnings (£539) and working hours (39.2), using an average hourly wage of £14, we estimate the costs to the public of participating in HSSIB investigations could amount to **£3,300 per annum**.²²

Court Costs

64. There are potential costs to the courts arising from HSSIB investigations and operating 'safe space' investigations in healthcare.

Applications to access HSSIB 'safe space' information

65. The Bill provides an exception to the prohibition on disclosure of information held by HSSIB (or subsequently an accredited NHS Trust) in connection with an investigation conducted within a 'safe space'. An application may be made to the High Court for disclosure of this information. The High court will incur costs in considering these disclosure applications and there may be legal costs to HSSIB (or subsequently an accredited NHS Trust) should they choose to make representations against disclosure of the information.
66. Applications to the High Court to obtain information which is prohibited from disclosure (safe space) in other sectors which operate a similar investigation model including Air, Rail and Marine accident investigations were initially few and far between, though the numbers have increased as litigation becomes more prevalent.
67. Litigation in healthcare is a more frequent occurrence than in other areas of accident investigation. It is likely that lawyers representing patients involved in safety incidents or NHS staff involved in a

²⁰ Using the annual salary for band 8b, we have calculated an hourly wage assuming 7.25 working hours per day.

²¹ Learning, candour and accountability, CQC, December 2016

²² Annual Survey of Hours and Earnings: 2016 provisional results, ONS

patient safety incident that has been investigated by HSSIB, will 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. Initially we may expect interested organisations to test the scope of this exception from the prohibition on disclosure of information held in connection with investigations to challenge when the Courts might deem disclosure to be in the interests of justice. Given, HSSIB will be reviewing up to 4 patient safety cases per investigation and 30 HSSIB investigations a year; we estimate there could be between 60-120 disclosure applications for information held by HSSIB per year. But this is likely to fall over time as the high court defines and clarifies the parameters to access HSSIB 'safe space' investigation information and disclosure applications for HSSIB investigations are expected to reach a steady state of around 20 applications per annum.

Applications for HSSIB enforcement and appeals

69. The proposal is that HSSIB will be able to impose a fine as a sanction for repeated failure to comply with requests for certain information from NHS providers and the public. Once a fine is imposed, the recipient of the fine would have a right to appeal to the First Tier Tribunal. HSSIB would if necessary be able to seek enforcement of payment of the fine via the County Court.
70. Fines would be imposed on the rare occasions where the HSSIB considers there is particular information, documents or records required, or an explanation of events that is key to an investigation but has been unable to persuade the NHS organisations to supply the said information or explanation. We anticipate there would be very few, if any, cases per year. Our expectation is that HSSIB will only ever impose a fine in extremis. In most cases we would expect NHS Improvement to ensure that HSSIB's requests are complied with before there is any need for HSSIB to impose a fine. At most we would expect to see no more than one or two instances of HSSIB imposing a fine on a provider of NHS services in a single year, if at all.
71. It is also our expectation that providers of NHS services, their staff, patients and the public will want to cooperate with HSSIB as the intent of the investigations is to identify the root cause and not apportion blame and will foster learning, with HSSIB making recommendations for improvements in patient safety. We therefore think there will be no or minimal costs to both the First Tribunal and County Courts.
72. In conclusion, across both types of applications, the total costs to the courts of HSSIB activity is **£104,550**. Justice impact test forms were submitted to Ministry of Justice (MOJ) and the costs to the courts were agreed and approved.

HSSIB Legal costs

73. 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 HSSIB will reduce the funding left over to undertake investigations and improve local investigative practice (whether through accreditation or otherwise).
74. The probability of HSSIB taking NHS providers or the public to court to impose a fine is very unlikely. But, HSSIB may choose to make representations against disclosure of information 'safe space'. Feedback from a panel of solicitors suggests that defending an average application for disclosure could cost between £2,000 to £3,000 per case, with claimants' costs up to £5,000. If the application is successful, then the claimant's legal fees will also have to be covered and so the total cost would increase to around £7,000-£10,000.
75. Based on the estimated number of disclosure applications for HSSIB information described above, HSSIB legal fees could reach a maximum cost (including covering claimant's legal fees) of **£1.2 million per annum**.
76. However, it is important to understand that this is considered to be a maximum. For such a large proportion of HSSIB's budget to be accounted for in defending applications for disclosure of information each of the assumed 4 cases per HSSIB investigation, for all of HSSIB's 30 annual investigations would need to result in an application for disclosure of information and the High Court would need to find in favour of applicants in every such instance.

77. Such a high propensity to make applications, alongside such a high rate of success, would significantly impact HSSIB's ability to conduct high quality investigations to such an extent that the continued existence of HSSIB (and their 'safe space' powers in particular) is likely to need to be reviewed.

NHS Legal costs

78. If NHS providers appeal the HSSIB fine then they will incur legal costs. However, it is very unlikely that fines will be imposed and thus appealed.

Cost Summary

79. The costs above are summarised in the table below:

| Cost Summary | | | Year 0 2017/18 | Year 1 2018/19 | Year 2 2019/20 | Year 3 2020/21 | Year 4 2021/22 | Year 5 2022/23 | Year 6 2024/25 | Year 7 2025/26 | Year 8 2026/27 | Year 9 2027/28 | Year 10 2028/29 | Total | |
|----------------------------|----------------|---|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|--------------------|-------------|----------|
| Description of costs: | HSSIB | Total Cost | £3,800,000 | £4,215,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £44,915,000 | |
| | | HSSIB Budget | £3,800,000 | £3,800,000 | £3,800,000 | £3,800,000 | £3,800,000 | £3,800,000 | £3,800,000 | £3,800,000 | £3,800,000 | £3,800,000 | £3,800,000 | | |
| | | NDPB executive team function | 0 | £300,000 | £300,000 | £300,000 | £300,000 | £300,000 | £300,000 | £300,000 | £300,000 | £300,000 | £300,000 | | |
| | | Setting up accreditation | 0 | £115,000 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | | |
| | | Number of investigations | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | | |
| | | HSSIB legal costs | 0 | £1.2-£0.24m | £0.9-£0.18m | £0.6-£0.12m | £0.2-£0.04m | £0.2-£0.04m | £0.2-£0.04m | £0.2-£0.04m | £0.2-£0.04m | £0.2-£0.04m | £0.2-£0.04m | | |
| | Patient/Public | Total Cost | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £36,300 |
| | | Public participation in HSIB investigations | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | |
| | NHS | Total Cost | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £353,760 |
| | | NHS staff participation in HSIB investigations | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | |
| | | HSSIB fines | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | | |
| | MOJ | Total Cost | £0 | £30,600 | £22,950 | £15,300 | £5,100 | £5,100 | £5,100 | £5,100 | £5,100 | £5,100 | £5,100 | £5,100 | £104,550 |
| | | High Court costs (£255 per case review) | 0 | £30,600 | £22,950 | £15,300 | £5,100 | £5,100 | £5,100 | £5,100 | £5,100 | £5,100 | £5,100 | £5,100 | |
| | | Applications for disclosure: HSSIB investigations | 0 | 120-60 | 90-30 | 60-20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | |
| | | First tier/County courts costs | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | |
| | | Applications for HSSIB fines and appeals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Total Costs (undiscounted) | | | £3,835,460 | £4,281,060 | £4,158,410 | £4,150,760 | £4,140,560 | £4,140,560 | £4,140,560 | £4,140,560 | £4,140,560 | £4,140,560 | £4,140,560 | £45,409,610 | |
| Discount adjustment | | | 1 | 0.97 | 0.93 | 0.90 | 0.87 | 0.84 | 0.81 | 0.79 | 0.76 | 0.73 | 0.71 | | |
| Total costs (discounted) | | | £3,835,460 | £4,136,290 | £3,881,920 | £3,743,748 | £3,608,259 | £3,486,240 | £3,368,348 | £3,254,443 | £3,144,389 | £3,038,057 | £2,935,321 | £38,432,475 | |

80. The additional costs associated with HSSIB as an independent body are those related to the NDPB executive team function and the cost to the courts which amount to an additional £3.1m over the 10 year period.

Benefits

81. It is expected that independent HSSIB investigations will have multiple benefits to both service users and providers. We focus on the first-order effects related directly to HSSIB investigations on improving the experience of those involved in investigations, reducing the risk of litigation and savings from avoiding national public inquiries. As in the discussion of costs above, we assume that each HSSIB investigation involves the review of 4 individual incidents, which will already have been the subject of a local investigation.

Replacing local investigations

82. It is possible that, in understanding the underlying causes of a specific type of incident in more detail, HSSIB will take on the investigation of local incidents referred to it within a theme they happen to be investigating at a particular point in time. This will require discussion and agreement between the HSSIB and the local NHS, as any such activity undertaken by HSSIB will have to support the local NHS in meeting its duties to investigate safety incidents. Where some HSSIB investigations substitute for local investigations, this will free up resources in those providers who no longer have to undertake the investigations themselves. However, with respect to local investigations, we assume HSSIB investigations do not substitute for any investigations undertaken at local level.

Preventing national investigations/public inquiries

83. The NHS is dependent on one-off independent or public inquiries to learn from the most serious of system-wide failures. But these inquiries are rare, costly, conducted years after the events occurred and have no capacity to drive the organisational change necessary to implement their recommendations.¹
84. Inquiries can have considerable impact and provide much needed public explanation after terrible events. However, each one starts afresh and determines its own unique approach rather than building on systematic and established methods of safety investigation. Inquiry teams are short-lived and are dissolved once the report is complete. Public inquiries appear to spend 90% of the time examining what happened and 10% of the time considering the future.²
85. There is a strong case that by introducing a HSSIB function that performs robust independent investigations into serious incidents and shares learning to improve standards, public inquiries will be avoided in the future. Since 2000, there have been 6 large scale national investigations, costing the NHS over £63 million. For further detail, see Annex B.
86. Since 2000, successive Governments have increased the amount of oversight and scrutiny of the NHS. In addition, it is important to note that both the Mid Staffs and Morecambe Bay inquiries, whilst very recent reports, were inquiries/investigations into failings in NHS Trusts which predate the current regulatory and oversight model operated by CQC which has been in operation since April 2014-15.
87. The failings at Mid Staffs and Morecambe Bay occurred over a number of years, because the system was lacking in its ability to identify problems early and provide the public with clarity as to where serious problems lie.
88. Since 2014, CQC has been placing poorly performing NHS trusts into 'special measures' where NHS Improvement works to help those trusts to improve their performance and capability to the point where CQC assesses them as being sufficiently well performing as to no longer need to be in special measures. CQC's ratings and the special measures system, provide the public with clarity about where problems are in the NHS.
89. HSSIB's role in the system is to help the NHS understand why problems (specifically patient safety incidents) occur and what action the NHS can take to resolve those problems. HSSIB is being established with the capability and expertise required to secure public confidence that it can get to the facts of a matter and, working in concert with the wider system, get to the facts sooner so that problems do not go on for years unchecked. In addition, should the need for a national investigation

¹ Macrae and Vincent, Learning from failure: the need for independent safety investigation in healthcare, Journal of the Royal Society of Medicine, November 2016

² Macrae and Vincent, Learning from failure: the need for independent safety investigation in healthcare, Journal of the Royal Society of Medicine, November 2016

or inquiry arise in future, it is expected that HSSIB would be seen as being the national independent body best placed to conduct a thorough investigation to get to the facts.

90. HSSIB, and the wider system of oversight and accountability, is intended to mitigate against future failings in NHS care. The system is intended to catch problems early, intervene where there is a need to urgently safeguard patients from harm and then HSSIB's role is to provide understanding of why problems occur. This system cannot mitigate against historical concerns being brought to light and there being a political desire to investigate those concerns. It is anticipated that HSSIB would be seen as the best choice for investigating historical patient safety concerns but that might not be appropriate in every case, depending on the nature and scale of the concerns.
91. Based on the existing number and cost of inquiries, preventing all national investigations would save the NHS an average of **£4.1 million** per annum on national led inquiries, although in the discussion of Value for Money below, a less optimistic assumption about the potential of HSSIB to prevent expenditure on national inquiries is presented.³

Improved experience and satisfaction (reduced anxiety)

92. It is widely recognised that patients, families and carers want to be told about a patient safety incident and, when such an incident arises, it is fully investigated to prevent similar incidents from occurring again. There is evidence to suggest that families and carers often have poor experiences of investigation and are not consistently treated with respect, sensitivity and honesty.
93. The extent to which families and carers are involved in any reviews or investigations undertaken varies considerably. Families are not always informed or kept up to date about investigations, something that often causes further distress and undermines trust in the process of investigation.⁴
94. Since the currently poor degree of involvement of families and carers in investigations is something that has been highlighted (at least in the case of investigations into deaths), we postulate that any improvement in the investigation of patient safety incidents undertaken by HSSIB could involve HSSIB re-contacting and involving the affected parties of past local investigations. Improving the outcome of these investigations and by consolidating the learning from across a number of related incidents or by applying their expertise in investigations to better identify the root causes of these incidents, will reduce the degree of distress and anxiety experienced by the main affected parties.
95. However, since the local cases that HSSIB will review in their investigation will already have happened, so too will any anxiety and distress caused to patients, their family and staff as the result of an initially poor quality local investigation. Therefore, HSSIB's impact is likely to be in terms of relieving anxiety and distress associated with a perceived unsatisfactory outcome of a past investigation rather than anything to do with the process of investigation. Since the level and duration of anxiety and distress associated with the outcome of an investigation is not known, it has not been possible to quantify the impact that HSSIB is likely to have.

Litigation

96. While the costs of conducting an investigation may appear prohibitive, the costs of legal claims to the NHS are much higher. The NHS Litigation Authority's Annual Report shows there were 10,965 clinical claims in 2015/16 and expenditure on clinical claims amounted to nearly £1.4 billion (see *illustrations below*).
97. The clinical claim expenditure reflects expenditure on new claims as well as ongoing expenditure relating to past claims e.g. ongoing payment of compensation. It is therefore not possible to estimate the average cost per claim from these figures.
98. Evidence suggests an important motivation for medical negligence claims is to gain more information about mistakes in their care or due to a perceived lack of apology by the provider.⁵ There is also evidence showing that an expert report is associated with an increased chance of resolution.⁶ We expect an independent investigation report that clearly sets out the root cause leading to the patient safety incident is likely to have a similar effect.

³ Calculated by converting past inquiries into 2016 prices and spread over 18 years.

⁴ Learning, candour and accountability, CQC, December 2016

⁵ Scottish Government, Medical Negligence Claiming in Scotland, June 2012

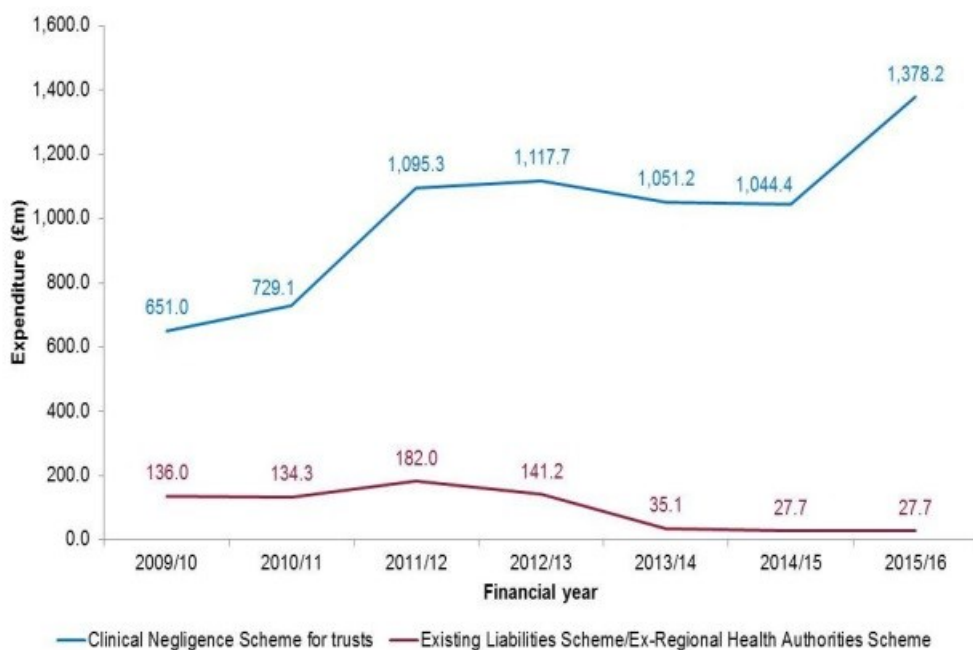
⁶ Fenn and Rickman, Time and the selection hypothesis, September 2016

The number of new clinical and non-clinical claims reported



Source: NHS LA Annual Report

Expenditure on clinical claims



Source: NHS LA Annual Report

99. Due to the difficulty of estimating average cost per new claims, we are unable to quantify the benefits related to the reduced risk of litigation claims. However, given HSSIB is only investigating a very small proportion of incidents, the impact is likely to be negligible.

Value for money

100. Based on the above analysis, we expect the establishment of HSSIB to generate first order benefits that largely offset the estimated first order costs, suggesting the policy is broadly cost neutral.

| Overall Net Present Value | | | Year 0 2017/18 | Year 1 2018/19 | Year 2 2019/20 | Year 3 2020/21 | Year 4 2021/22 | Year 5 2022/23 | Year 6 2024/25 | Year 7 2025/26 | Year 8 2026/27 | Year 9 2027/28 | Year 10 2028/29 | Total | |
|---|----------------|---|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|--------------------|-------------|----------|
| Description of costs: | HSSIB | Total Cost | £3,800,000 | £4,215,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £44,915,000 | |
| | | HSSIB Budget | £3,800,000 | £3,800,000 | £3,800,000 | £3,800,000 | £3,800,000 | £3,800,000 | £3,800,000 | £3,800,000 | £3,800,000 | £3,800,000 | £3,800,000 | | |
| | | NDPB executive team function | 0 | £300,000 | £300,000 | £300,000 | £300,000 | £300,000 | £300,000 | £300,000 | £300,000 | £300,000 | £300,000 | | |
| | | Setting up accreditation | 0 | £115,000 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | | |
| | | Number of investigations | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | | |
| | | HSSIB legal costs | 0 | £1.2-£0.24m | £0.9-£0.18m | £0.6-£0.12m | £0.2-£0.04m | £0.2-£0.04m | £0.2-£0.04m | £0.2-£0.04m | £0.2-£0.04m | £0.2-£0.04m | £0.2-£0.04m | | |
| | Patient/Public | Total Cost | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £36,300 |
| | | Public participation in HSIB investigations | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | £3,300 | |
| | NHS | Total Cost | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £353,760 |
| | | NHS staff participation in HSIB investigations | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | £32,160 | |
| | | HSSIB fines | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | |
| | MOJ | Total Cost | £0 | £30,600 | £22,950 | £15,300 | £5,100 | £5,100 | £5,100 | £5,100 | £5,100 | £5,100 | £5,100 | £5,100 | £104,550 |
| | | High Court costs (£255 per case review) | 0 | £30,600 | £22,950 | £15,300 | £5,100 | £5,100 | £5,100 | £5,100 | £5,100 | £5,100 | £5,100 | £5,100 | |
| | | Applications for disclosure: HSSIB investigations | 0 | 120-60 | 90-30 | 60-20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | |
| | | First tier/County courts costs | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | |
| | | Applications for HSSIB fines and appeals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Total Costs (undiscounted) | | | £3,835,460 | £4,281,060 | £4,158,410 | £4,150,760 | £4,140,560 | £4,140,560 | £4,140,560 | £4,140,560 | £4,140,560 | £4,140,560 | £4,140,560 | £45,409,610 | |
| Discount adjustment | | | 1 | 0.97 | 0.93 | 0.90 | 0.87 | 0.84 | 0.81 | 0.79 | 0.76 | 0.73 | 0.71 | | |
| Total costs (discounted) | | | £3,835,460 | £4,136,290 | £3,881,920 | £3,743,748 | £3,608,259 | £3,486,240 | £3,368,348 | £3,254,443 | £3,144,389 | £3,038,057 | £2,935,321 | £38,432,475 | |
| Description of benefits: | Patient/Public | Improved patient experience and satisfaction of investigation | Unquantified | | | | | | | | | | | £45,100,000 | |
| | NHS Providers | Improved staff experience and satisfaction of investigation | Unquantified | | | | | | | | | | | | |
| | | HSIB replacing local investigations | Unquantified | | | | | | | | | | | | |
| | NHS | Reduced litigation costs | Unquantified | | | | | | | | | | | | |
| Preventing national investigations/public inquiries | | | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | | |
| Total Benefits (undiscounted) | | | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £4,100,000 | £45,100,000 | |
| Discount adjustment | | | 1 | 0.97 | 0.93 | 0.90 | 0.87 | 0.84 | 0.81 | 0.79 | 0.76 | 0.73 | 0.71 | | |
| Total Benefits (discounted) | | | £4,100,000 | £3,961,353 | £3,827,394 | £3,697,965 | £3,572,913 | £3,452,090 | £3,335,353 | £3,222,563 | £3,113,587 | £3,008,297 | £2,906,567 | £38,198,082 | |
| Net Present Value | | | £264,540 | -£174,937 | -£54,526 | -£45,783 | -£35,346 | -£34,150 | -£32,996 | -£31,880 | -£30,802 | -£29,760 | -£28,754 | -£234,393 | |

101. However, given that the sole element of (quantified) benefit is the cost of national/public inquiries avoided, any uncertainty in the realisation of this benefit will have an important impact on the overall value of money of the preferred option. To reflect this, we have included sensitivity analysis in the Risks section below to illustrate the impact of different scenarios for the realisation of this benefit.

Risks

Policy risks

102. On 17 October 2016, the Department of Health launched a consultation on proposals to provide a 'safe space' in healthcare safety investigations, by creating a legal prohibition on the non-disclosure of information submitted to a HSIB investigation or an investigation's led by NHS bodies accredited by HSIB for that purpose. 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 get to the root of the problem far more quickly and provide for a better and faster way of learning from healthcare harm, preventing incidents from being repeated.
103. There was widespread support for HSSIB's leadership role in creating a learning culture, and a recognition that HSSIB's credibility rests on its ability to do this job well. 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 HSSIB. Consultation responses have emphasised that local NHS reviews and investigations need to also improve and HSSIB has a role to play as an exemplar.
104. On extending 'safe space' to NHS organisations, there was general recognition that the standard of some investigations in the NHS was poor and there were reservations about whether this approach would help with the underlying problems with NHS investigations. Patients and staff alike did not yet trust the NHS locally to use 'safe space' fairly or properly and patients saw it as a way to avoid accountability, while staff saw it as a potential way for their employers to force self-incrimination.
105. There is a policy risk of extending 'safe space' investigations to the wider NHS. Respondents felt that the 'safe space' principle should only be extended to local NHS investigations once an organisation had proven that it can be trusted to use 'safe space' procedures appropriately. If the use of 'safe space' were extended to providers of NHS-funded health care, its implementation should come with clear guidance and the development of support for staff.
106. The first-order costs of HSSIB defending applications for disclosure of information and the second-order costs of HSSIB processing applications from organisations seeking accreditation will need to be met from within HSSIB's annual budget. The greater the propensity for people to apply for disclosure of information gathered as part of a 'safe-space' investigation, the higher the share of applications that are found in favour of the information being disclosed and the larger the number of organisations seeking accreditation, the less of 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 is likely to be achieved).

Risk of not realising value for money

107. Given, the sole element of (quantified) first-order benefit is the cost of national/public inquiries avoided, if the central assumption on this is not realised, there is a risk that the policy will not be cost effective. We have limited information on the number and cost of past national public inquiries, as set out in Annex B, but what limited information we do have suggests that the frequency and the unit costs of public inquiries has varied over time. National public inquiries were less frequent between 2000 and 2010 but tended to be more costly. Since 2010, the frequency of public inquiries has increased but they have been less expensive. The table below shows the annual savings from preventing national public inquiries varying the assumptions on the frequency and unit costs of public inquiries based on the above information. For example, our worst case scenario is based on the lower pre 2010 frequency of national inquiries coupled with the lower unit costs of the post 2010 national inquiries, resulting in a smaller benefits/savings of £1.6 million per annum relative to our central case estimate of £4.1 million per annum.

| £m | Frequency | |
|-----------|-----------|-----------|
| Unit cost | Pre-2010 | Post-2010 |
| Pre-2010 | 3.74 | 12.82 |
| Post-2010 | 1.61 | 5.52 |

108. Using the above information, we present a number of scenarios to illustrate the possible average annual cost of national/public inquiries that could be averted. The scenarios in which the pre-2010 frequency is accompanied by the pre-2010 unit cost or the post-2010 frequency is accompanied by the post-2010 unit cost are unsurprisingly similar to the central scenario of £4.1m per year shown in the table in the Value for Money section above. Therefore, we use the other two scenarios – i.e. where pre-2010 frequency is accompanied by the post-2010 unit cost and where the post-2010 frequency is accompanied by the pre-2010 unit cost – to generate alternative worst-case and best-case scenarios respectively.

| £m | Scenarios on realisation of first order benefits | | |
|-----------------------------------|--|--------------|-------------|
| | Worst case | Central case | Best case |
| NPV costs | 38,432,475 | 38,432,475 | 38,432,475 |
| NPV benefits | 15,011,439 | 38,198,082 | 119,399,386 |
| NPV net benefit | - 23,421,036 | - 234,393 | 80,966,911 |
| Net second order benefit required | - 23,421,036 | - 234,393 | 0 |

109. From the table above, we find that there are very slight costs associated with the central estimate but significant costs implications in the worst case scenario where we would need to find significant second order benefits to offset the first order costs of the policy. In the analysis that follows, we take the central estimate and the worst case scenario for the net first order cost of establishing and running HSSIB and show the reasonableness (or otherwise) of generating the level of net second order benefits that would be required to offset the net first order costs.

110. In the central estimate, the policy would generate an **overall net cost of £0.23 million**. To calculate the total economic cost, evidence¹ suggests the NHS can generate Quality Adjusted Life Years (QALYs) at £15,000 and given the value of a QALY is estimated to be worth £60,000, we therefore assume the **economic cost** (including opportunity cost) of HSSIB to be **£0.94 million**. In other words, net second-order benefits of £0.94 million would need to be generated in order for the establishment of HSSIB to produce more benefits than the next best alternative.

111. In the worst case scenario, the policy would generate an **overall net cost of £23.4 million** and the **economic cost** (including opportunity cost) of HSSIB would be **£93.6 million**. In other words, net second-order benefits of £96.3 million would need to be generated in order for the establishment of HSSIB to produce more benefits than the next best alternative.

112. The learning from HSSIB's investigation findings are expected to lead to actions to address patient safety incidents in the NHS, which may incur costs but would also be expected to reduce the incidence (and associated costs) of future harm.

113. While it is not possible to second-guess the actions the NHS will take in response to the findings arising from HSSIB's investigations, in what follows below we provide some context for the reduced harm or improved experience that would be required, net of any associated costs, for the establishment of HSSIB to prove cost-effective; and we show what level of additional spending on safety initiatives would be required to deliver this level of net benefit, depending on the average cost-effectiveness of the safety initiatives adopted by the NHS.

Setting the required level of second-order net benefits in context

¹ [Link to the article "Estimating the NICE cost effectiveness threshold"](#)

114. A Frontier report² estimated the costs of avoidable unsafe care in the NHS to be between £1 billion and £2.5 billion a year. This implies that a net reduction in avoidable harm of between 7.6% and 3% respectively would generate sufficient benefit to offset the costs of HSIB.
115. Let us take the 8,000 deaths per year that are estimated to be preventable. Taking the median life expectancy of these deaths immediately prior to the point of preventable death – 6 months – and multiplying this by the average population Quality of Life (QoL) for the modal age range of preventable deaths (80-89) – 0.71 – gives a total of 2,840 QALYs to be gained from avoiding all preventable deaths. The net annual cost of establishing and running HSSIB (£0.24m or up to £23.4 million) would otherwise generate 63 QALYs or 1,561 QALYs in the worst case scenario at the margin. Therefore, if HSSIB can generate net benefits equivalent to around 2% or 55% reduction in preventable deaths, it will represent a cost effective use of NHS resources – not to mention the net impact that HSSIB might have in delivering other benefits – e.g. from reducing avoidable morbidity as well as avoidable death. This reduction in deaths will offset the first-order costs (HSSIB investigations) but given that costs may be incurred by the NHS (implementing patient safety or investigation practice) to derive the second-order benefits this figure would need to be even higher to offset the gross costs.
116. Another way of assessing the likelihood that HSSIB will deliver net second-order benefits sufficient to offset the opportunity cost of its net first-order costs is to consider the role HSSIB might play in improving the quality of locally conducted investigations, through dissemination of a best practice model of investigation and/or through accrediting organisations.
117. As stated in the discussion of first-order impacts above, when a serious incident occurs and an investigation takes place it is a very intense, stressful and anxious time for all those involved – patients, families, carers and staff. Since the currently poor degree of involvement of families and carers in investigations is something that has been highlighted (at least in the case of investigations into deaths), we postulate that any improvement in the investigation of patient safety incidents undertaken by HSSIB itself will reduce the degree of distress and anxiety experienced by the main affected parties.
118. In order to estimate the degree of anxiety (associated with locally conducted investigations) required to offset the costs of HSSIB, we use the EQ-5D-5L standard scale of health outcomes and associated value sets derived from the stated preferences of a representative sample of the population in England.³ These standard scales comprise the following five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 3 levels: no problems, some problems, and extreme problems.
119. We assume that, for an average HSSIB investigation, there are 4 individuals who are so involved in or directly affected by an investigation that the process of investigation is a significant determinant of their level of anxiety – the patient (unless the incident led to their death), 2 members of close family or carers and 1 member of staff.
120. Furthermore, we assume that the current standard of investigation is poor, so that these individuals experience extreme or severe anxiety (on the 5L scale) for the estimated 3 month duration of an investigation and its immediate aftermath.⁴
121. If a high quality investigation lifts the level of anxiety experienced by those most directly affected by an investigation from extreme/severe to moderate (on the 5L scale), then the proportion of local investigations (24,000) whose quality would need to be improved (net of the costs of making the required improvements) in order to generate sufficient QALYs to substitute for the QALYs foregone from diverting resources to HSSIB would be around 33% in the worst case scenario. This level of benefits would ensure the first-order costs (HSSIB investigations) are offset but given that costs may be incurred by the NHS (implementing patient safety or investigation practice) to derive the second-order benefits an even higher reduction in anxiety would be necessary to offset the gross costs.

What additional second order costs might providers face in seeking to deliver second order benefits?

122. Clearly, the level of any additional expenditure on safety initiatives required to deliver just enough net benefit to offset the first-order costs of establishing HSSIB – equivalent to 63 QALYs or up to

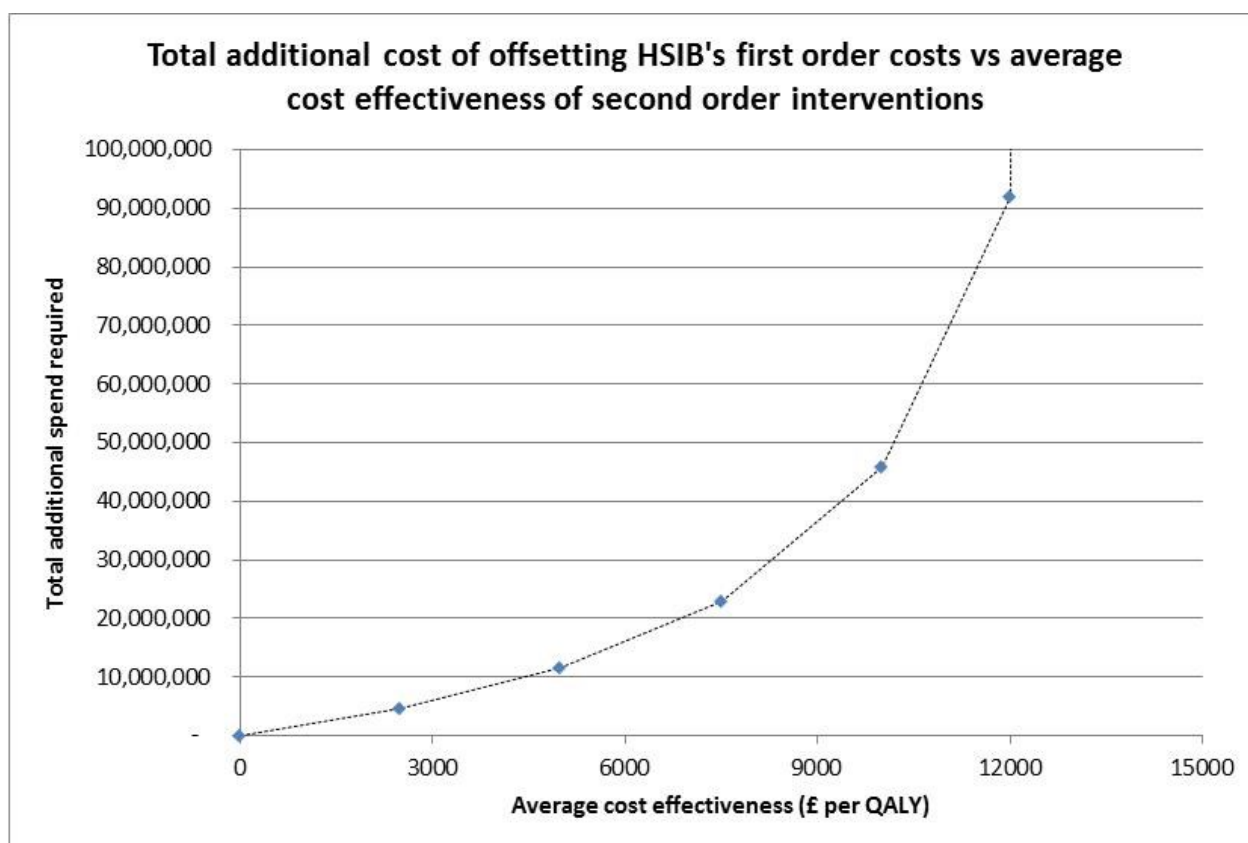
² Frontier Economics, Exploring the costs of unsafe care in the NHS, October 2014

³ EuroQoL and OHE

⁴ Learning, candour and accountability, CQC, December 2016

1,561 QALYs per year in the worst case scenario – will depend on the costs and effectiveness of the safety initiatives undertaken. For example, the higher the costs of the subsequent safety initiatives, then the larger the number of QALYs that will need to be generated to offset both the first-order costs of establishing HSSIB and the costs of the safety initiative. The more cost effective the initiative is, the more likely it is that these QALYs will be generated.

123. Going the other way, this relationship also implies that the more cost effective an initiative, the less spend that is required in order to generate sufficient QALYs to offset the first-order costs of establishing HSSIB. The less cost effective an intervention is, the higher the total spend required to generate sufficient QALYs to offset the first-order costs.
124. Given that the latest evidence suggests that cost-effectiveness of NHS spending at the margin is £15,000 per QALY, there is no amount of additional spending on safety initiatives with average cost effectiveness of £15,000 per QALY or above that will generate sufficient additional QALYs than the next best alternative to offset the first-order costs of establishing and running HSSIB. To offset these first-order costs, therefore, the NHS needs to invest in safety initiatives with an average cost effectiveness of less than £15,000 per QALY. The lower the cost per QALY, the lower the additional costs to the NHS will need to be to offset the opportunity costs of establishing and running HSSIB.
125. For example, if the average cost-effectiveness of safety initiatives is £7,500 per QALY, then additional spending of £23.4m is required to generate sufficient net benefit to offset the costs of establishing and running HSSIB.
126. As illustrated in the graph below, as the average cost effectiveness of safety initiatives approaches the estimated marginal cost-effectiveness of NHS spending (£15,000), the required level of additional spending increases. If the average cost-effectiveness of safety initiatives is £12,000 per QALY, the required level of additional spending is £93m per year – equivalent to around £370,000 for each of the roughly 250 NHS providers.



127. Evidence on the cost effectiveness of initiatives that improve quality and safety is limited and mixed. However, there is at least some evidence that a proportion of quality and safety initiatives are cost-saving.^{5,6} If all other initiatives are at least as cost-effective on average than the marginal cost

⁵ [Link to the Health Foundation report "Does improving quality save money?"](#)

⁶ https://ec.europa.eu/health/sites/health/files/systems_performance_assessment/docs/2016_costs_psp_en.pdf

effectiveness of NHS spending, the average of all safety initiatives undertaken in response to HSSIB's findings could plausibly come in under £15,000 per QALY.

128. However, it is important to note that there may be a lag, both in terms of the point at which HSSIB begins an investigation and when NHS providers choose to make resulting improvements in practice and in terms of the point at which the benefits or savings of safety initiatives materialise in relation to when costs are incurred. In practice, this means that net second order benefits equivalent to the recurrent net first order costs of running HSIB may not be generated until towards the latter part of the 10-year time horizon adopted in this Impact Assessment, or beyond.
129. There is considerable uncertainty associated with the question of whether the second-order impacts are likely to generate sufficient net benefits to offset the net first-order costs. As illustrated, we need to find only a small number of second-order benefits to offset the costs in the central case. However, the second-order benefits need to be significantly higher to offset the costs in the worst case scenario.
130. Viewing the transmission of second-order impacts as deriving from a series of sequential steps, there is uncertainty in the extent to which HSSIB are able to identify the underlying causes of incidents they investigate and/or identify/communicate the features of a 'best practice' model for conducting local investigations; there is uncertainty in whether cost-effective measures exist for addressing the underlying causes of incidents identified as the result of HSSIB- or locally-conducted investigations under 'safe space' disclosure prohibitions; there is uncertainty about the extent to which NHS organisations will choose (or be incentivised/compelled) to adopt measures aimed at addressing the underlying causes of incidents identified by HSSIB- or locally-conducted investigations, as well as uncertainty in the additional costs and benefits of any measures that NHS organisations choose to adopt; and there is uncertainty in whether NHS organisations will choose (or be able) to adopt HSSIB's best practice model of investigation for their own investigations and/or decide to apply to be accredited by HSSIB.
131. To mitigate some of the risk and uncertainty, we see HSSIB as a dedicated expert resource trained to undertake root cause analysis to a high standard and also operating with the legal provisions of safe space which prohibit the release of material generated by HSSIB during the course of an investigation. We therefore expect HSSIB to identify the underlying causes of incidents and share learning and 'best practice' so as to improve the quality of local investigations, thus reducing the uncertainty in the early stages of the transmission chain described above.

Section E: Conclusions and Summary

Conclusion

132. HSSIB is expected to improve the quality of investigations in the NHS and, through its own high quality investigations and facilitating better-conducted local investigations through guidance and the accreditation of NHS trusts to undertake 'safe space' investigations, 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 HSSIB itself).
133. The main costs associated with this proposal are the operating costs of HSSIB and costs to NHS providers and the public of partaking in HSIB investigations. We also expect some moderate costs to the Courts from disclosure applications for evidence held by HSSIB from an investigation, appeals against fines imposed by HSSIB on NHS providers and applications for warrants by HSSIB. The main benefits of the proposal are the savings achieved from avoiding large national public inquiries. It has not been possible to quantify the benefits related to HSSIB investigations replacing local or regional investigations activity, improving the experience of those involved in investigations and reducing the risk of litigation.
134. The learning from HSSIB's investigation findings are expected to lead to (second-order) actions to address patient safety incidents in the NHS, which may incur costs but would also be expected to reduce the incidence of future harm. Although, it has not been possible to quantify these benefits, we have illustrated the second-order costs required to deliver these benefits, including a scenario in which the level of first-order benefits is lower than expected.

135. Whether or not the net cost of establishing and running HSSIB is offset by sufficient net second-order benefits – and, therefore, whether or not the establishment of HSSIB provides good value for money - depends crucially on: a) the extent to which HSSIB is successful in identifying the underlying causes of the incidents it investigates and defining a ‘best practice’ model for undertaking local investigations; b) the extent to which HSSIB avoids the need in future for large-scale national/public inquiries, either by helping the NHS to identify and learn from safety incidents before they are allowed to escalate to the point of requiring such a level of subsequent investigation, or by acting as a trusted source for conducting such inquiries in future; and c) the existence and subsequent uptake of cost effective measures at addressing the underlying causes of incidents investigated by either HSSIB or local NHS organisations.
136. Assuming that the first condition holds, measures adopted by NHS organisations to reduce the risk of future harm will need, on average, to generate QALYs at less than £15,000 per QALY - otherwise the costs of doing so would displace more cost-effective spending elsewhere in the NHS. The more cost-effective the safety measures adopted by NHS organisations, the less expenditure on them is required in order to offset any net costs of running and establishing HSIB.
137. Since there is considerable uncertainty in the impacts arising from the establishment of HSSIB, particularly in terms of the quantified first-order benefits and any indirect impacts, the decision on whether to endorse HSSIB ultimately depends on a judgement about how successful HSSIB is likely to be in conducting its work and preventing national public inquiries; and on the extent to which the NHS can be expected to respond by adopting cost-effective ameliorative measures. Under the central case, we have demonstrated that HSSIB imposes very slight costs on the system and the second-order benefits necessary to offset the cost are not substantial, suggesting the policy is cost effective. However, under the worst case scenario (where not many national public inquiries are prevented) then the second-order benefits necessary to offset the costs are very significant.
138. In conclusion, decision-makers must judge firstly, the likelihood of the worst case scenario arising and secondly, the likelihood of the system generating sufficient second-order benefits for this policy to be cost effective. It is worth emphasising, successive Governments have increased the amount of oversight and scrutiny of the NHS in recent times. HSSIB alongside the wider system of oversight and accountability is intended to mitigate against future failings in NHS care occurring such as Mid Staffordshire and Morecombe Bay. The system is intended to catch problems early, intervene where there is a need to urgently safeguard patients from harm and HSSIB plays a critical role in providing the understanding of why patient safety problems occur.

Section F: Summary of specific impact tests:

Equality Impact Assessment

139. This policy proposal impacts all NHS 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 HSSIB and other bodies, and their associated findings/learning will favour or disadvantage 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, most.

Competition

140. 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 HSIB 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 the suppliers from general competition law. It does require providers to be more open and honest with service users in the event of a patient safety incident. Where this information would otherwise not be available, competition is likely to increase as information asymmetries are reduced

Small and Micro Business Assessment

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

This policy is likely to impact NHS secondary care providers. NHS trusts are all large organisations with over 250 employees. HSIB'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.

Legal Aid/Justice Impact

142. The following have been considered in the main impact assessment above and in the Ministry of Justice impact test provided alongside this document:

- 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 HSIB policies.
- Any impact on HM Courts services or on Tribunals services through the creation of or an increase in application cases? */Minimal [Assuming this includes applications for disclosure of safe space material think you have to say minimal rather than no]*
- Create a new right of appeal or route to judicial review? *Yes [In relation to imposition of a fine by HSIB]*
- Enforcement mechanisms for civil debts, civil sanctions or criminal penalties? *Yes for enforcement of HSIB fines as these are civil sanctions*
- 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)
No [Not sure possibly if legal aid is available for disclosure applications when part of a clinical negligence claim?]

- 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

143. 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

144. 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

145. 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

146. 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 incidence. 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

147. 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

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

Social impacts

149. 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. Since the NRLS was set up in 2003, over four million incident reports have been submitted.

Serious Incidence 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: Timeline of National Inquiries

| | | |
|-----------|--|---------|
| 1998-2001 | Bristol Royal Infirmary Public Inquiry | £14.1m |
| 2002-2005 | Shipman Inquiry | £21m |
| 2010-2013 | Francis Inquiry Mid-Staffordshire | £19.7m |
| 2013-2015 | Morecombe Bay Investigation | £1.1m |
| 2014-2016 | Saville Inquiry | £7.4m |
| 2014-2018 | Gosport Investigation Panel | Ongoing |

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