PHSO review: Quality of NHS complaints investigations

First Report of Session 2016–17
House of Commons
Public Administration and Constitutional Affairs Committee

PHSO review: Quality of NHS complaints investigations

First Report of Session 2016–17

Report, together with formal minutes relating to the report

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The Public Administration and Constitutional Affairs Committee

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Summary

In December 2015 the Parliamentary and Health Service Ombudsman (PHSO) published a *Review into the quality of NHS complaints investigations where serious or avoidable harm has been alleged* highlighting concerns about the ability of NHS organisations to conduct effective clinical investigations. Following a review of 150 NHS investigations in which avoidable harm or death had been alleged, PHSO found that “NHS Trusts are not always identifying patient safety incidents and are sometimes failing to recognise serious incidents” and that the quality of investigations is “inconsistent, often failing to get to the heart of what has gone wrong and to ensure lessons are learnt.”

The Public Administration and Constitutional Affairs Committee (PACAC) subsequently conducted a short inquiry into the issues identified in the PHSO report. This built on the work of PACAC’s predecessor committee, the Public Administration Select Committee (PASC), which recommended in March 2015 that the Government create an independent and transparent national clinical investigations function, modelled on the Air Accidents Investigation Branch, which would create a ‘safe space’ for people directly involved in the most serious patient safety incidents - as patients, clinicians, or family members - to speak honestly and openly in the interests of learning from mistakes. The Government subsequently accepted this recommendation in its July 2015 response *Learning not Blaming* and set up an Expert Advisory Group to produce more detailed proposals for the new Investigation Branch. The EAG’s final report was published on 12 May 2016.¹

During the course of our inquiry both the Department of Health and NHS England responded positively and constructively to the PHSO’s report. Both acknowledged that NHS England currently lacks a broad and deep high quality clinical investigations capability and that it does not deal with complaints effectively. The establishment of a national clinical investigations function, the Healthcare Safety Investigation Branch (HSIB), is a critical step towards improving how NHS organisations handle clinical investigations, although its remit does not include complaints handling.

However, for HSIB to succeed it must be underpinned by primary legislation, providing for its independence and creating the crucial ‘safe space’ in which doctors and patients, as well as their families and carers, can provide full and candid contributions to patient safety investigations, without fear of punitive sanctions. HSIB must also take full responsibility for setting national standards and establishing appropriate accreditation and training for local investigators. This is essential if HSIB is to drive up the quality of clinical investigations at a local level, where, given its own limited capacity, the vast majority of investigations will continue to take place. The Committee’s recommendations on HSIB fit closely with those made by the EAG in its final report. There is a clear consensus that the Government must do more to ensure HSIB’s independence and effectiveness in reducing risks to patient safety, but there is still a long way to go to realise the Secretary of State for Health’s ambition of creating “the world’s largest learning organisation”.

## 1 Introduction

1. The Parliamentary and Health Service Ombudsman (PHSO) as part of its role makes final decisions on NHS complaints in England, and from time to time reports to Parliament on wider themes emerging from its casework. It is a function of the Public Administration and Constitutional Affairs Committee (PACAC) to examine these reports and to use their findings to hold Government to account. The post of Parliamentary and Health Service Ombudsman is currently held by Dame Julie Mellor DBE, who was appointed in 2012. She is supported in this role by casework and corporate staff at the PHSO.

2. This Report focuses on the issues arising from the PHSO’s December 2015 Review into the quality of NHS complaints investigations where serious or avoidable harm has been alleged which examined 150 NHS complaints investigations where avoidable harm or death was alleged. It highlighted a significant variation in the quality of investigations, and that the process of investigating was neither consistent nor of a sufficiently high quality. The review also found that staff need to be better supported in their investigatory role and that there were missed opportunities for learning at all levels of the NHS.²

3. Since the “Mid Staffs inquiry”, the public inquiry led by Sir Robert Francis into the role of the commissioning, supervisory and regulatory bodies in the monitoring of Mid Staffordshire Foundation NHS Trust, reported in February 2013³ a series of reports and inquiries have identified systemic failures across the NHS in clinical investigations and complaints handling. For example, a review of unexpected deaths at Southern Health Trust between April 2011 and March 2015 found evidence of delayed and poorly undertaken investigations,⁴ whilst an NHS England review of maternity services found that there needed to be “much greater consistency in the standard of local investigations”.⁵

4. PACAC’s predecessor committee, the Public Administration Select Committee (PASC), made a number of recommendations in its March 2015 report Investigating clinical incidents in the NHS, including establishing an Independent Patient Safety Investigation Service (IPSIS), which was brought into existence on 1 April 2016 as the Healthcare Safety Investigation Branch (HSIB).⁶ However, given this new body’s limited capacity, its creation alone will not solve this complex, systemic problem. This Report therefore sets out the wider implications of the PHSO’s review, and assesses what further actions the Government must take to achieve the transition “from a blame culture to a learning culture.”⁷ Whilst the Committee welcomes the creation of HSIB and other commitments made by the Secretary of State for Health, we remain deeply concerned that HSIB currently lacks the necessary legislative underpinning to provide for its independence and for the reality of the ‘safe space’ which is so essential for it to achieve its objectives.

5. We are grateful to all those who provided evidence to us. In particular we would like to thank Ben Gummer MP, Parliamentary Under Secretary of State for Care Quality,

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² PHSO, Review into the quality of NHS complaints investigations where serious or avoidable harm has been alleged (2015).
³ Sir Robert Francis, Mid Staffordshire NHS Foundation Trust Public Inquiry (2013).
⁶ Throughout this Report the body formerly known as IPSIS has been referred to by its new name of HSIB.
⁷ Secretary of State for Health, “From a blame culture to a learning culture”, transcript of speech given to Global Patient Safety Summit at Lancaster House, 3 March 2016.
Clinical investigations in NHS England

6. The PHSO is the final stage for NHS complaints in England. Complainants can refer their case to the PHSO if they are unhappy with how their formal complaint has been dealt with. Roughly 80% of the complaints received by the PHSO are about NHS care and treatment, with many of these involving avoidable harm. In 2013–14 the PHSO assessed 6,093 complaints about the NHS and accepted 3,075 for investigation.

7. Individuals wishing to make a complaint about NHS services in England should initially attempt (where appropriate) to resolve their complaint informally with the service provider (e.g. the relevant GP, hospital or trust). If it is not appropriate to raise a concern informally or where informal resolution has failed, the complainant has the right to raise a formal complaint with either the service provider or with the organisation that commissioned the service (e.g. a Clinical Commissioning Group or NHS England). The organisation being complained about should discuss the complainants’ expectations and desired outcome, as well as the relevant timescales and an agreed action plan for handling the complaint.8

8. In January 2015 the Health Select Committee published a report on Complaints and raising concerns, which found that the system for handling complaints was still too variable:

Too many complaints are mishandled with people encountering poor communication or at worst, a defensive and complicated system which results in a complete breakdown in trust and a failure to improve patient safety.9

9. In March 2015, PASC published its report on Investigating clinical incidents in the NHS, highlighting the need for better investigation of the thousands of serious incidents and avoidable deaths in the NHS every year. As part of a “whole system approach” to tackling these problems, the report advocated the setting up of an Independent Patient Safety Service, whose “sole objective [ … ] should be to prevent incidents and to improve patient safety, and not to apportion blame or liability.”10 In particular PASC recommended that to be effective the new body must:

- offer a safe space: strong protections to patients, their families, clinicians and staff, so they can talk freely about what has gone wrong without fear of punitive reprisals;
- be independent of providers, commissioners and regulators, and so able to investigate whether and how the system as a whole was instrumental in contributing to clinical failure;

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• have the power to publish its reports and to disseminate its findings and recommendations, in the interests of transparency and accountability and to drive learning and improvement.\textsuperscript{11}

10. On 16 July the Government published its response to PASC’s report, entitled \textit{Learning not Blaming}. Its response acknowledged the variable quality of local patient safety investigations and “concurred that there should be a capability at national level to offer support and guidance to NHS organisations on investigations, and to carry out certain investigations itself.”\textsuperscript{12} Following PASC’s recommendations, the Government confirmed its intention “to establish a new Independent Patient Safety Investigation Service which through a combination of exemplary practice and structured support to others, could make a decisive difference to the NHS, promoting a culture of learning and a more supportive relationship with patients, families and staff.”\textsuperscript{13}

11. The Government set up an Expert Advisory Group to advise the Department of Health on the purpose, role and operation of the new body,\textsuperscript{14} which has subsequently been renamed HSIB. Prior to the EAG publishing its findings, the Secretary of State for Health published \textit{Directions} on 1 April 2016, creating HSIB and laying down some of its basic functions. In particular the \textit{Directions} detailed the role of the Chief Investigator and his responsibility to ensure that HSIB is “established and in a position to commence its activities … no later than 1 April 2017.”\textsuperscript{15} In its written evidence the Department of Health indicated that HSIB would conduct around 30 investigations a year, with an annual budget of £3.6 million.\textsuperscript{16}

12. \textit{Complaints and raising concerns}, \textit{Investigating clinical incidents in the NHS} and \textit{Learning not Blaming} fit into a wide body of literature highlighting failings in how the NHS in England deals with both clinical investigations and with complaints. In February 2013, the final report of the Mid Staffordshire NHS Foundation Trust Public Inquiry (otherwise known as the \textit{Francis report}) was published.\textsuperscript{17} The report found that there was a negative culture of dealing with complaints at the trust in question, with concerns being downplayed and patients and families not being listened to. It also found that there were inadequate processes for dealing with complaints and serious untoward incidents and that the board failed to get a grip on its accountability and governance structure throughout the period under review.\textsuperscript{18}

13. Following the publication of \textit{Learning not Blaming}, two further reports have stressed the urgency of reform. In December 2015 an independent review into unexpected deaths at South Health Trust of people with a learning disability or mental health problem between 2011 and 2015 (the \textit{Mazars report}) found evidence of delayed and poorly undertaken investigations locally, describing “a lack of leadership, focus and sufficient time spent in the trust on carefully reporting and investigating unexpected deaths.” Of
the 1,454 deaths of patients whilst under the care of Southern Health between April 2011 and March 2015, 722 were unexpected. Only 272 (37%) of these unexpected deaths were considered to be untoward and fully investigated as a Critical Incident Review (CIR) by the trust; subsequently only 195 (27%) of these incidents were then classified as Serious Incidents Requiring Investigation (SIRIs) and deemed to meet the criteria for reporting to the Strategic Executive Information System (StEIS), the national system for capturing the details of all Serious Incidents. The report raised concerns about the trust’s ability to identify serious incidents and criticised it for providing untimely and poor quality reports. Concerns were also raised about the trust’s ability to engage and communicate with the families of deceased parents: 64% of investigations into an unexpected death did not involve the family concerned.\textsuperscript{19}


\begin{quote}
There needs to be much greater consistency in the standard of local investigations of perinatal mortality, neonatal mortality, maternal death and serious morbidity. The new Health Safety Investigation Branch (HSIB) should set a common, national standard for high quality serious incident investigations.\textsuperscript{20}
\end{quote}

The report went on to intersect with PASC’s recommendations by concluding that in order to improve the effectiveness of investigations, the threat of individual clinicians being branded as negligent should be reduced.\textsuperscript{21}

15. The EAG published its final report on 12 May 2016, making 13 recommendations for how to improve the quality of clinical investigations across the NHS in England. 10 of these recommendations were aimed at HSIB and made proposals for how to: guarantee its independence; ensure that its aim is “not to apportion blame or liability”; allow patients, families and staff to “be active participants in the process of investigation”; use the new Investigation Branch to drive “system-wide” improvements; and create a “just culture” of “trust, honesty and fairness” across all safety investigations. The EAG’s final 3 recommendations addressed “further actions required across the healthcare system” and proposed the creation of “a Just Culture Task Force” to “determine the appropriate policies, practices and institutional arrangements that are required to move the healthcare system firmly towards a just culture of safety”, along with “a coordinated programme of capacity building and improvement of safety investigation [ … ] across the healthcare system”, and that a process should be introduced “to address unresolved cases”.\textsuperscript{22} On presenting the final report, Mike Durkin, Chair of the EAG and National Director of Patient Safety at NHS England said:

\begin{quote}
This report provides the foundation for a Healthcare Safety Investigation Branch that will deliver high quality investigations; that finds the best way to listen to staff, patients and families - involving them fully and properly;
\end{quote}

\textsuperscript{19} Mazars, \textit{Independent review of deaths of people with a Learning Disability or Mental Health problem in contact with Southern Health NHS Foundation Trust April 2011 to March 2015} (2015).


\textsuperscript{21} \textit{Ibid}.

that serves as an exemplar to the wider healthcare system; and that promotes
a culture of learning and improvement - not blame and defensiveness - to
support lessons to be learnt and adopted across the NHS.23

PHSO report

16. PHSO’s Review into the quality of NHS complaints investigations where serious or avoidable harm has been alleged highlighted concerns about the ability of NHS organisations to conduct effective investigations where it is alleged that someone may have been harmed, or died, avoidably. It found that “NHS Trusts are not always identifying patient safety incidents and are sometimes failing to recognise serious incidents” and that the quality of investigations is “inconsistent, often failing to get to the heart of what has gone wrong and to ensure lessons are learnt.” The process included: reviewing 150 NHS investigations in which avoidable harm or death was alleged; speaking to six Trusts about the challenges of such investigations and opportunities to improve the system; surveying more than 170 NHS complaints managers to provide additional insight; and testing the findings through an advisory group. For the purposes of its investigation the PHSO defined avoidable harm as "everything from minor to moderate harm, to unexpected or avoidable death and incidents that may cause widespread public concern resulting in a loss of confidence in healthcare services."24

17. The report found that:

- Serious incidents are not being reliably identified by Trusts - despite 96% of complaints managers stating that there was both a process and trigger to help identify these incidents.
- There is wide variation between, and within, trusts in how patient safety incidents are investigated:
  - 40% of investigations were not adequate to find out what happened, and Trusts did not find failings in 73% of cases where the PHSO found them.
  - In over a third of cases where PHSO found failings, Trusts did not find out the cause of the incident and therefore could not learn from it.
- There is an absence of shared investigatory principles, meaning that how a case is investigated depends on the individual investigator.
- There is no national guidance for patient safety incident investigations, including what general outcomes a good investigation should achieve.25

23 Dr Mike Durkin, Letter from the Chair of the Healthcare Safety Investigation Branch Expert Advisory Group (May 2016).
24 PHSO, Review into the quality of NHS complaints investigations where serious or avoidable harm has been alleged (2015). In their own written evidence (CLI0004) NHS England noted that PHSO’s definition is not consistent with their definition of a patient safety incident: “[The PHSO report] defines patient safety incidents as low or moderate harm incidents. Actually patient safety incidents are defined as any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare. They therefore include no harm/near miss incidents as well as those leading to severe harm and death.”
25 PHSO, Review into the quality of NHS complaints investigations where serious or avoidable harm has been alleged (2015).
18. PHSO’s visits to NHS Trusts revealed substantial cultural barriers to answers being found, including: a lack of openness; staff not having protected time to investigate; and substantial disparities between those leading different levels of investigations (whilst serious incident investigations would often be led by a trained, named investigator, all other investigations were merely led by an ‘appropriate person’). In addition, 25% of complaints managers surveyed by PHSO were unsure that sufficient processes existed to prevent a recurrence of incidents, whilst a further 10% believed that sufficient processes were not in place.26

19. These findings led to PHSO making five general recommendations for how to address these difficulties:

i) HSIB and NHS England should consider how the role of NHS complaints managers and investigators can be better recognised, valued and supported. This includes working with others to develop a national accredited training programme.

ii) HSIB should develop and champion broad principles of a good investigation. The emphasis should be on building capability and capacity at a local level whilst also allowing for flexibility and proportionality.

iii) HSIB should work with others to lead, inspire and share learning from its own investigations in order to improve the capability of the local NHS. This includes demonstrating to organisations how they can take what they have learned from one investigation and apply it not just across divisions within a hospital, but across organisations too.

iv) Trusts should demonstrate to their boards that they have clear objectives both for their organisations and their staff to be open and honest, learn from investigations, and resolve complaints. Boards should be using “My Expectations for raising concerns and complaints” (a document issued jointly by PHSO, the Local Government Ombudsman and Healthwatch setting out the principles by which public bodies should handle complaints) to assess to what extent local complaints services are meeting the needs of people who use the service.27

v) The Department of Health and NHS England should work with HSIB to make clear who has accountability for conducting quality NHS investigations at a national and local level. The different roles of organisations that provide care, commissioners, and regulators including NHS Improvement, should be clearly outlined.28

**Responses to the PHSO report**

20. The Minister for Care Quality acknowledged that the report is “another very helpful contribution to what I think now is a broad-based understanding that the NHS is still not handling complaints as well as it should.”29 In its written evidence the Department of Health also stated that:

26 PHSO, *Review into the quality of NHS complaints investigations where serious or avoidable harm has been alleged* (2015).
28 PHSO, *Review into the quality of NHS complaints investigations where serious or avoidable harm has been alleged* (2015).
29 O2
It has helped to raise the importance of this issue further. Primary responsibility for safe care resides with the provider of that care and Trusts should recognise the importance and value of investigations as a means for learning and continuous improvement in patient safety rather than an end in itself.\textsuperscript{30}

21. NHS England told the Committee that it “welcomes the PHSO’s report as a contribution to our understanding of where the NHS needs to improve its response to things going wrong in healthcare. Undoubtedly local investigations in the NHS need to be better and carried out to a more consistently high standard.” However, it also highlighted a number of areas where it says the report contains “inconsistencies with existing policy and some aspects that would benefit from further clarity”. For example, NHS England took issue with PHSO’s questioning of whether investigations “get to the root cause” of an incident, instead arguing that there may be no one “root cause”,\textsuperscript{31} because “it is nearly always the fault of a system around that individual”,\textsuperscript{32} in fact the Ombudsman conceded in oral evidence that it is “very often … a range of factors” which lead to mistakes being made.\textsuperscript{33}

22. NHS England also questioned the process by which “in 73% of cases [PHSO] found ‘failings’ where providers found none”, noting that “NHS England would probably question everyone’s competence in this field.” It also noted that PHSO’s sample only included “cases where patients were sufficiently dissatisfied to escalate their concerns to the PHSO”,\textsuperscript{34} whilst it did not call into question the validity of the report’s findings on this basis, it did raise doubts over the degree to which these failings could be ascribed to NHS England as a whole.

23. The Patients Association described the report as “superficial” and strongly criticised the work of the PHSO itself in investigating complaints relating to the NHS. However, it welcomed the recommendations “that training and accreditation of investigators should be an immediate priority and detailed criteria for what constitutes a serious incident should be formulated.”\textsuperscript{35}

24. Other campaign groups broadly welcomed the PHSO’s report but still raised substantive concerns about a number of details. Action against Medical Accidents “agree[d] with the main thrust of [the report’s] findings” but was surprised that existing guidance on investigating serious incidents, such as NHS England’s Serious Incident Framework had not been taken into account;\textsuperscript{36} NHS England also drew attention to its publication of the Root Cause Analysis framework for patient safety investigation in the NHS.\textsuperscript{37} A recurring criticism was that “the recommendations in the report are too broad-brush and could have been more detailed”.\textsuperscript{38} This view was shared by the Royal College of Physicians of Edinburgh, who called for “greater clarity regarding recommendations for improving investigations at a local level”, noting that most of PHSO’s recommendations related to HSIB.\textsuperscript{39}

\textsuperscript{30} CLI0008 (Department of Health).
\textsuperscript{31} CLI0004 (NHS England).
\textsuperscript{32} Q6
\textsuperscript{33} Ibid
\textsuperscript{34} CLI0004 (NHS England).
\textsuperscript{35} CLI0010 (Patients Association).
\textsuperscript{36} CLI0003 (Action against Medical Accidents).
\textsuperscript{37} CLI0004 (NHS England).
\textsuperscript{38} CLI0003 (Action against Medical Accidents).
\textsuperscript{39} CLI0001 (Royal College of Physicians of Edinburgh).
25. During the course of our inquiry, the Department of Health and NHS England both gave positive and constructive responses to the PHSO’s report. We commend their honesty in acknowledging that NHS England currently lacks a high quality clinical investigations capability and that it does not deal with complaints effectively. The establishment of HSIB is a critical step towards improving how NHS organisations handle clinical investigations, although its remit does not include complaints handling. However, the Department of Health and NHS England must go further to achieve the transformation “from a blame culture to a learning culture” as quickly as possible. The rest of this Report will assess the proposals that have been made to date and consider what more must be done to deliver the “whole system approach” first called for by PASC in March 2015. In particular we are in agreement with many of the HSIB EAG’s recommendations and believe that there is a consensus across the sector in favour of an independent, transparent and “no blame” Investigation Branch, which Government cannot ignore and must implement in full as a matter of urgency. Despite statements to the contrary, the Secretary of State’s Directions currently fall short of providing this framework.
2 The Healthcare Safety Investigation Branch

Role and remit

26. Upon announcing its intention to create HSIB, the Government described its functions as follows:

A new [HSIB] will conduct independent, expert-led investigations into patient safety incidents. It will be selective about the incidents it investigates to ensure optimum effectiveness, and it will focus on incident types that signal systemic or apparently intractable risks within the local health care system.40

27. In Learning not Blaming the Government set out five high-level principles which would guide HSIB’s work: objectivity, transparency, independence, expertise, and learning for improvement. The Expert Advisory Group was set up to consider the application of these principles, along with the design of the new body.41 The majority of PHSO’s recommendations for how NHS organisations should improve their approach to clinical investigations relate to the new HSIB.

28. Much of the evidence submitted to the Committee agreed that HSIB will have a critical role to play in improving the performance of NHS organisations. William Vineall, Director of Quality at the Department of Health, told us that much of what needed to be done related to “the sort of things we want to do through the Healthcare Safety Investigation Branch”.42

29. There is now more clarity about the role of the new body. The Secretary of State for Health issued Directions on 1 April 2016 which brought the new Investigation Branch into existence. These Directions set down the investigatory functions to be fulfilled by the new body:

a) The investigation of incidents or accidents which in the view of the Chief Investigator evidence, or are likely to evidence, risks affecting patient safety;

b) The ascertaining of facts relevant to such risks and analysis of those facts;

c) The identification of improvements or areas for improvement, if any, which may be made in patient safety in -

i) The provision of services as part of the health service, or

ii) The conduct of other functions carried out for purposes of the health service,

and where appropriate, the making of recommendations in relation to such improvements;

42 Q3
d) The publication of reports;

e) Encouraging the development of skills used to investigate local safety incidents in the health service, and to learn from them, including suggesting standards that may be adopted in the conduct of such investigations.43

30. The Directions define “risks affecting patient safety” as “risks resulting in repeated, preventable or common occurrences of safety risks or harm to patients”, “risks indicating a systemic problem with significant impact in more than one setting”, or “those involving new or novel forms of harm or new or novel risks of harm.”44 These criteria will inform the assessment of which risks in particular are worthy of investigation by HSIB, although the Secretary of State said in a speech given to the Global Patient Safety Summit that he had “asked the new organisation to consider focusing initially on maternity and neonatal mortality investigations to give us time to examine and understand its effect before rolling it out to other areas of clinical activity.”45 The Directions also created the new role of Chief Investigator, reporting directly to the Secretary of State, who will have responsibility for establishing HSIB and ensuring that it is capable of commencing operations by no later than 1 April 2017.46 The Department of Health acknowledged in its own evidence, this appointment is critical for HSIB’s future.47 The EAG agreed that “it will be important to appoint the right Chief Investigator to lead the Branch.”48

31. The Directions further emphasised the importance of HSIB creating a “no blame culture” to allow for candid and telling contributions, modelled on the work of the Air Accidents Investigation Branch:

> It is not the function of the Investigation Branch … to identify civil or criminal liability in any matter, nor to apportion blame or otherwise support fault-based legal or regulatory or other formal action against persons whose actions come under consideration as part of its investigations.49

Evidence received by the Committee was very supportive of the proposed ‘safe space’ principle, with the Royal College of Physicians of Edinburgh arguing that if it could be “truly create[d]” it would represent the “single biggest improvement in terms of creating openness and transparency” as “many clinicians remain hugely concerned about personal risk to themselves in a very challenging environment.”50 Creating and sustaining the ‘safe space’ will be a responsibility of the Chief Investigator.

32. The EAG described HSIB’s creation as “a critical step” towards addressing a lack of a high quality clinical investigations function across the NHS in England, and described its role as follows:

> This body must have the authority and capability to conduct systematic safety investigations into the most serious risks and safety issues. It must develop

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43 Department of Health, NHS Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016.
44 Ibid.
45 Rt Hon Jeremy Hunt, Secretary of State for Health, “From a blame culture to a learning culture”, transcript of speech given to Global Patient Safety Summit at Lancaster House, 3 March 2016.
46 Department of Health, NHS Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016.
47 CLI0008 (Department of Health).
49 Department of Health, NHS Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016.
50 CLI0001 (Royal College of Physicians of Edinburgh).
and exemplify best investigation practice, contributing to the creation of a just culture based on learning and improvement. It must conduct thorough and rigorous investigations and reports its findings in detail, making recommendations for the improvement of safety. This will benefit patient safety across the entire healthcare system, far beyond the individual cases or issues examined.\textsuperscript{51}

33. However, concerns were raised by several witnesses regarding HSIB’s capacity to discharge its role. The Department of Health itself noted, “the new investigation function cannot and should not replace the work of local providers to deliver high quality investigations” and that, therefore, “instilling the “right” culture in the NHS is vital.”\textsuperscript{52} The EAG also recognised that “across the healthcare system, there is little capacity to investigate effectively the common, system-wide causes of safety issues” and that “these problems will not all be solved by the creation of a single new investigation body.”\textsuperscript{53} In fact, HSIB will only have a relatively limited capacity:

The Department has been clear that the new function will have the capacity to investigate only a small proportion of the many safety incidents that occur each year, and therefore a key part of its wider role will be to act as an exemplar to providers in how they should conduct their own investigations. A budget of £3.6 million has been allocated in 2016/17 and it is anticipated that the new investigation function will carry out up to 30 investigations each year.\textsuperscript{54}

34. This note of caution was echoed by patient safety campaign groups. Action against Medical Accidents told us that they are “concerned that the PHSO, NHS England and Department of Health may have unrealistic expectations of what [HSIB] can achieve, based on what we understand so far of its proposed budget, capacity and ways of working.”\textsuperscript{55} The Patients Association also expressed reservations:

[HSIB] has a major task. It seems that [HSIB] is only going to undertake a small number of investigations itself, its success will depend on the degree to which there can be a culture and governance changes within individual NHS providers … The PA is concerned about the independence, governance and accountability of [HSIB].\textsuperscript{56}

35. The Patients Association raised a number of questions and concerns regarding the powers that HSIB investigators should have, noting that “so often, recommendations are made as a result of a public inquiry, an inquest or a local investigation and absolutely nothing happens.” In particular the group asked what information NHS organisations would be obliged to disclose to HSIB investigators, what powers of redress investigators would have, and whether “adoption and implementation of [HSIB] redress proposals [would] be mandatory upon NHS providers”. It was argued that powers of redress should be tailored “to meet patient / complainant expectations”, ranging from an apology to the

\textsuperscript{52} CLI0008 (Department of Health).
\textsuperscript{54} CLI0008 (Department of Health).
\textsuperscript{55} CLI0003 (Action against Medical Accidents).
\textsuperscript{56} CLI0010 (Patients Association).
creation of a “no fault compensation scheme.” The Government has made clear that HSIB will play no formal role in the NHS complaints handling process. We consider the proposals that have been made for change in this area below.

36. The Committee welcomes the creation of the Healthcare Safety Investigation Branch as a national clinical investigations function. It is right that this body should focus on those risks which pose the greatest threat to patient safety. However, following the publication of the Secretary of State’s Directions, there are still serious questions to be answered regarding how principles will be translated into the design and operations of the new Investigation Branch.

37. The Department of Health must also be very conscious of the limits of what HSIB can achieve with a limited budget and a remit to investigate only 30 cases per year. In this respect it is crucial that HSIB is not only an exemplar of high quality clinical investigations but is also focused on setting national standards and ensuring improvements at a local level - where the vast majority of clinical investigations will continue to take place - is not neglected.

38. We are pleased that the EAG agrees with the Committee on HSIB’s role and remit. Government must now take strong action to show that it is serious about turning the new Investigation Branch into a body of real authority and professional capability.

Independence

39. The Department of Health told the Committee that HSIB will “sit within NHS Improvement and will model the approach of the Air Accidents Investigation Branch.” NHS Improvement is a new body set up on 1 April 2016 combining the roles of Monitor and the NHS Trust Development Authority (TDA), with HSIB sitting within NHS TDA. Mike Durkin told us that this arrangement would only be “for pay and rations.”

40. This proposal has been highly controversial. As early as the October meeting of the EAG the members told the Secretary of State that the Group was “absolutely clear that creating [HSIB] within NHS Improvement or any other DH ALB is not an appropriate solution”. By far the EAG’s preferred option was “for [HSIB] to have its independence set out in primary legislation”:

This is the only way [HSIB] will be able to get the trust and buy-in it needs to ensure its success as an organisation as well as ensure it has the powers it requires to fulfil its principles.

However, the EAG was prepared to accept HSIB being set up as a Special Health Authority using secondary legislation as “a pragmatic but temporary stepping stone”.

41. As was clear from the evidence given to the Committee by the Department of Health, and from the subsequent Directions, the Government has chosen to locate HSIB within

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57 CLI0010 (Patients Association).
58 CLI0008 (Department of Health).
59 Q41
60 Final notes of 6 October EAG meeting.
61 Ibid.
NHS Improvement in the interests of expediency, arguing that no appropriate primary legislative vehicle is currently available. However, the Chair told the Minister for Care Quality, that:

To have HSIB as part of an NHS quango is not implementing this Committee’s recommendation … no other safety board or accident investigation board in any other Government Department doing a similar role is part of the system in that respect.62

42. In response, the Minister replied that “the Air Accidents Investigation Branch is a branch of the Department of Transport” and there is a “Government imperative not to be creating new bodies”63 before going on to claim that HSIB’s oversight arrangement was “even further removed [than that of the AAIB] because it is not a direct branch of a department”.64 At the EAG’s February meeting the Secretary of State conceded that HSIB will be situated within NHS Improvement only on a trial basis and that this will be reviewed within two years.65

43. The Secretary of State’s Directions establishing HSIB included a section on “maintaining the independence of the Investigation Branch”, setting down that the NHS TDA must take “reasonable steps to protect [HSIB’s] independence”, including establishing a permanent group of independent advisors to discuss the independence of the Investigation Branch’s reports, with particular attention given to its activities “in relation to the other activities of the Authority”.66 The job specification for the position of Chief Investigator also includes the claim that “first and foremost, the Chief Investigator will be expected to act independently, and without fear or favour”.67 The EAG concurred that the Chief Investigator must “promote [HSIB’s] independence across the healthcare system” and argued that the new appointee “will not only require the necessary skills, experience and competencies, he or she will need to have credibility with patients, families and staff.”68 The EAG also recommended that “the Chief Investigator should be made answerable to the Secretary of State for Health to provide an additional foundation for his or her independence”, and that the Health Select Committee and PACAC should scrutinize the work of the Chief Investigator.69

44. However, the EAG’s final report did not make recommendations for what it described as HSIB’s initial two year “development phase” as the Group “did not wish to suggest that an interim model [of HSIB being located within NHS Improvement and lacking an underpinning in primary legislation] would be an acceptable alternative.” Instead the EAG reiterated its belief that:

HSIB must be, and must be perceived to be, independent in structure and operation, and must be established in primary legislation with stable institutional arrangements to guarantee this.70

62 Q46
63 Q46
64 Q47
65 Final notes of 25 February EAG meeting.
69 Ibid.
70 Ibid.
Without this underpinning in primary legislation HSIB would continue to be at risk of institutional instability, of being perceived as operating in a “threatening or risky way” by those involved in investigations”, and crucially of being perceived as vulnerable to “vested or political interest”.\(^71\)

45. PASC made clear that HSIB must be independent, and the Secretary of State for Health appeared to have accepted this recommendation. Therefore the Government’s decision to locate HSIB within NHS Improvement, instead of making it directly accountable to the Secretary of State, is both disappointing and unacceptable. This appears to be solely to comply with the Government’s general stricture against forming new public bodies, or because Departmental spending is subject to cuts, whilst NHS spending is not.

46. HSIB should be part of the Department of Health, rather than part of the NHS, the organisation which it is being created to investigate. It is the Secretary of State who is ultimately accountable to Parliament for the safety of the NHS in England, not NHS Improvement. Furthermore it is the Secretary of State who is responsible for setting up a public inquiry, should this prove necessary. Therefore, like its parallel bodies who conduct aviation, marine and rail accident investigations, HSIB should report directly to the Secretary of State.

47. However, we agree that Parliament can and should provide additional safeguards and direct oversight so that the Secretary of State is not exposed to any suspicion of untoward ministerial influence. We therefore reiterate the recommendation that 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.

48. The Government must commit in its response to this Report to bringing forward the necessary primary legislation to secure HSIB’s independence as soon as possible. If the Government does not do so then the Committee will call the Secretary of State for Health to give evidence to account for this failure.

49. The first Chief Investigator of HSIB will have considerable responsibilities for establishing the new body, including the developing and publishing of Investigation Principles and creating and sustaining the much discussed ‘safe space’. It is essential that the successful candidate is of the highest calibre and commands public confidence. As the Chief Investigator will play a key role in protecting and safeguarding the public’s rights and interests, it is also vital for the reputation and credibility of HSIB that the post holder is, and is seen to be, independent of Ministers and Government. We are unconvinced by the external commitments that have been made to the Chief Investigator’s independence, and do not believe that the new appointee being made

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directly accountable to the Secretary of State can be said “to provide an additional foundation for his or her independence.” Therefore we believe that a pre-appointment hearing would strengthen public confidence in the new body.

The ‘safe space’ principle

50. In *Investigating clinical incidents in the NHS*, PASC recommended that for the new Investigation Branch “to ensure a safe space for disclosure, witnesses should be given legal immunity for what they say and evidence should be exempt from the Freedom of Information Act.” This principle was consciously modelled on the approach of the Air Accidents Investigation Branch. In evidence submitted to PASC, Keith Conradi, the Chief Inspector of Air Accidents, explained the principle thus:

People [ … ] have learned that, if they actually report these things, when they come to our attention, they are dealt with in a very much no-blame environment. We go to great lengths to ensure that our reports and our investigations do not carry any liability.

51. PASC’s recommendation was accepted by the Government in its response to the PASC report, and set down as one of HSIB’s founding principles for the EAG to implement:

[HSIB] will take a non-punitive approach and its practices and recommendations will be intended for learning and improvement, not to find fault, attribute blame, or hold people to account.

52. The Committee is aware that there has been a difference of opinion between members of the EAG on how HSIB should provide a ‘safe space’, due to concerns that there will be a lack of trust in the new body if there are suspicions that it will prevent patients and their loved ones from accessing information about what happened in their case. The Chair of PACAC addressed a meeting of the EAG on 1 December 2015, outlining PASC’s reasons for making this recommendation, the key justification being that such protection is needed to ensure that patients and staff can feel confident speaking freely about what has gone wrong without punitive reprisals. Our Chair also made the point that the provision of a ‘safe space’ would not protect medical practitioners from proportionate action where negligence is found. In its final report the EAG recommended that “the objective of safety investigations must be to understand the causes of harm in order to improve systems and prevent future harm, not to apportion blame or liability” and that staff involved in HSIB’s investigations should be:

Secure in the knowledge that they will not be blamed for events that involve “honest mistakes” and have been openly shared [ … ] This has been described as providing a “safe space” in which staff can participate fully and without fear.

75 Final notes of 01 December EAG meeting.
However, the EAG also emphasised that “the Branch must provide families and patients with all relevant information relating to their care, reflecting the responsibilities of healthcare providers to uphold the duty of candour.”

This responsibility is discussed more fully later in this Report.

53. The Government has continued to support the ‘safe space’ principle. In oral evidence Mike Durkin told us that:

This is moving into a process of learning as a whole cultural shift. To do that, one of the key elements is to take away that compression is a reduction of fear. The fear that exists currently is an inadvertent one and it is an unintended one but it exists nonetheless.


When challenged by the Chair on the need for primary legislation “to provide that safe space” William Vineall told us that “safe space is complicated. We have not done it before. We need to see what the EAG says and then we need to have a look at that carefully” whilst Mike Durkin told us that there had been “considerable debate within the EAG … about how a safe space could be created … if there is no primary legislative vehicle.”

The Chair emphasised that “the Government … will not be implementing [PASC’s] recommendations, which you have all accepted, if there is not primary legislation to set up a safe space.”

The EAG’s final report was clear that:

As part of the Branch’s legislative base, there must be statutory protection of safety information provided to investigators solely for the purposes of safety investigation, to ensure that this information is not made available to other bodies. This would most obviously ensure that, for example, information given in an interview carried out as part of a safety investigation could not be used as evidence in subsequent criminal or regulatory proceedings against the interviewee except where specifically overridden, for example by court order. It should also provide exemption from Freedom of Information requests.

55. In principle the Secretary of State’s Directions reaffirmed the Government’s commitment to the ‘safe space’, laying down that the Investigation Branch should not disclose evidence provided to it “unless there is an overriding public interest or legal compulsion” causing it to do so. It also obligated HSIB to put in place protocols respecting the ‘safe space’ principle with professional regulatory bodies and other investigatory bodies (including PHSO) clarifying when and how these bodies might be able to use their statutory powers to require information given in the ‘safe space’ (for example, following a court order). However, the Government has failed to commit to bringing forward the

78 Q28
80 Q49
81 Q50
82 Q53
84 Department of Health, NHS Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016.
necessary primary legislation to fully protect the ‘safe space’ and ensure that evidence given in the course of a safety investigation cannot later be used as evidence in subsequent criminal or regulatory proceedings.

56. We regard the ‘safe space’ principle as being critical to the effective operation of HSIB. This protection is essential if patients and staff are to have the confidence to speak about the most serious risks to patient safety without fear of punitive reprisals. Its importance is underlined by the work of the Air Accidents Investigation Branch on which HSIB is modelled. In the Committee’s view, the only way to effectively establish this ‘safe space’ is for the Government to bring forward primary legislation that will guarantee its inviolability. The EAG’s final report also agreed that the ‘safe space’ must be given a “legislative base” in order to be effective. We will regard anything else as a failure to implement PASC’s original recommendation and evidence of a disregard for the consensus position of both healthcare experts and Parliament.

57. The Government must also spell out how protocols between HSIB and other regulatory and investigatory bodies will strike the right balance between respecting the ‘safe space’ principle and HSIB’s competing obligation to share information in certain, specified circumstances (such as following a court order). In particular, the ‘safe space’ must be protected from Freedom of Information requests, as are the similar bodies responsible for air, marine and rail accident investigations.
3 Improving clinical investigations at the local level

Accountability and national standards

58. Following the abolition of the National Patient Safety Agency in 2012 and the transfer of some patient safety functions to NHS England, the Patient Safety Domain of NHS England had responsibility for formulating and supporting NHS policy with regards to the local response to patient safety incidents and serious incidents. However, in its report PHSO recommended that there needed to be clearer lines of accountability for who was responsible for conducting quality NHS investigations at a national and local level.\(^{85}\) Mike Durkin responded that:

> For me there are two levels of accountability … The primary accountability route for clinical investigations is at a local level with the Trust board, with the Trust that is responsible for the employment and delivery of services for the patient that has been affected or their family has been affected. So that is a clear line of accountability.

> In terms of accountability for setting the standards, for the setting the conditions across England, then I see that as currently sitting within NHS England and I exercise that role as the Director of Patient Safety for NHS England.\(^{86}\)

59. NHS England identified the need for HSIB “to set out its responsibilities in relation to safety investigations” in its written submission.\(^{87}\) The call for clarity was echoed by Action against Medical Accidents, who told us that “national standards for patient safety investigations need to be developed”.\(^{88}\) The Royal College of Physicians of Edinburgh also agreed that “clear principles and definitions will help”.\(^{89}\) The EAG’s final report agreed that HSIB “should provide national leadership on safety investigation matters across the healthcare system” and issue “a renewed set of patient safety investigation standards and guidance documents [ … ] that unequivocally specify the terms for good investigation practice.”\(^{90}\) The Secretary of State’s Directions confirmed that HSIB will have responsibility for “suggesting standards which may be adopted in the conduct of [local clinical investigations]”.\(^{91}\)

60. The Department of Health described for us the role of the revised Serious Incident Framework and the obligations of providers with regards to clinical investigations:

> The revised Serious Incident Framework published in March 2015 has sought to simplify the incident management process and ensure that serious incidents are identified correctly, investigated thoroughly and, most importantly, learned from to prevent the likelihood of similar incidents happening again.

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\(^{85}\) PHSO, Review into the quality of NHS complaints investigations where serious or avoidable harm has been alleged (2015).

\(^{86}\) CLI0004 (NHS England).

\(^{87}\) CLI0003 (Action against Medical Accidents).

\(^{88}\) CLI0001 (Royal College of Physicians of Edinburgh).


\(^{90}\) CLI0008 (Department of Health).
The NHS contract also stipulates that providers must consider and respond to the recommendations arising from any audit, Serious Incident report or Patient Safety Incident report.  

61. **HSIB should assume unambiguous responsibility for setting the national standards by which all clinical investigations are conducted. It should remain the responsibility of local NHS providers to deliver on these standards, according to the Serious Incident Framework. The Care Quality Commission should continue to fulfil its role as the regulator in assessing the quality of clinical investigations at a local level. These distinct functions must be clearly explained to patients to ensure that confusion does not persist.**

62. NHS England provided more detail in their written submission regarding the respective role of providers, commissioners, Clinical Commissioning Groups (CCGs) and the Care Quality Commission (CQC). The CQC is responsible for making “authoritative judgements on the quality of health and care services”, including “a role in encouraging improvement and may use the details of incident reports, investigations and action plans to monitor organisations’ compliance with essential standards of quality and safety, to assess risks to quality and to respond accordingly.”  

William Vineall told the Committee that the “Care Quality Commission isn’t responsible for the quality of investigations, but it does provide a mirror to what the quality is.” Other witnesses called for the CQC “to be proactive at assessing the quality of investigations conducted by organisations and make recommendations or take regulatory action where they do not meet the standards.”

63. The EAG’s final report called for HSIB to “establish and maintain effective relationships with other investigatory bodies, including professional regulators, organisational regulators, and the police” to ensure that NHS organisations respond to their recommendations, but noted that “the Branch should not itself regulate compliance with its safety recommendations or enforce implementation, although the Branch may recommend who should monitor implementation … [and] may issue safety recommendations to regulators regarding changes to regulatory standards or practice that it considers necessary.”

64. **HSIB, and in particular, the Chief Investigator, should develop a strong relationship with professional regulators to ensure that the Investigation Branch’s recommendations are acted upon by providers. In addition, HSIB should be empowered to suggest changes to national regulatory standards where this will result in systemic improvements to patient safety.**

**Accreditation and training**

65. PHSO’s report recommended that HSIB should not only develop the principles of a good investigation, as outlined above, but should lead on an accredited training programme for investigators with NHS Improvement. William Vineall was clear that...
HSIB needed to provide “better guidance and principles” for investigators. The Royal College of Physicians of Edinburgh emphasised that the new body must not only be able to “lead at a national level” but must also be able to “support downwards to a local level.” Action against Medical Accidents also told us that “there needs to be clarity from Department of Health, NHS England, and NHS Improvement (including [HSIB]) about who will take the lead on ensuring good quality of local investigations and the wider system changes need to ensure this.”

66. Calls for HSIB to play an active role in developing local investigative functions were supported by the EAG, who recommended that HSIB “should be sufficiently resourced to act as a national centre of leadership and expertise on safety investigation” and that:

Over time the activities of the Branch should contribute to the development of a cadre of expert and professionally qualified investigators working across the healthcare system.

67. The Secretary of State’s Directions set out HSIB’s responsibility for “encouraging the development of skills used to investigate local safety incidents in the health service and to learn from them.” However, neither the Department of Health nor NHS England have provided the Committee with much detail about how HSIB will fulfil its responsibilities in this area. The proposals which have been made have largely focused on how NHS Improvement as a whole will help Trusts to respond to recommendations made by HSIB or by the CQC. William Vineall told us that:

With NHS Improvement coming together and bringing together Monitor and the TDA, NHS Improvement will be providing support when necessary for the trust to respond as quickly as possible.

68. It is undeniably important that NHS Improvement assist Trusts in implementing recommendations made by HSIB or by the CQC, but this alone cannot deliver the necessary improvements to patient safety across the NHS in England. Given its own limited capacity, HSIB as the national clinical investigations function and exemplar of good practice, must work closely with NHS organisations to build a highly-trained and professionalised cadre of local investigators, who are respected by other healthcare professionals and trusted by the public. These local investigators should be capable of examining those serious patient safety incidents not investigated by HSIB and helping NHS Trusts to learn the right lessons from their reports. If HSIB fails to provide national leadership in improving the quality of clinical investigations then it will not only be failing one of its primary objectives, but it will also be failing the public.

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4  “The world’s largest learning organisation”

The statutory Duty of Candour

69. In a speech given to the Global Patient Safety Summit in London in March 2016, the Secretary of State promised to turn the NHS into “the world’s largest learning organisation”. This intervention echoed many of the themes first developed by the Government in its July 2015 response to PASC, *Learning not Blaming*, highlighting the role that innovations such as HSIB should play in NHS England “learning for improvement” in the future. Over the past 18 months the Department of Health has brought forward a programme of change that it has argued will result in the necessary transformation to the NHS’s culture.

70. Since November 2014, all registered healthcare providers have been subject to a statutory Duty of Candour. According to the NHS Litigation Authority, “The Duty of Candour is a legal duty on hospital, community and mental health Trusts to inform and apologise to patients if there have been mistakes in their care that have led to significant harm. The Duty of Candour aims to help patients receive accurate, truthful information from health providers.” The Department of Health’s written evidence claimed that:

The statutory duty of candour, which now applies to all providers registered with the Care Quality Commission, should help to some extent in ensuring investigations into serious incidents are conducted openly with the patient or service user and they provide reasonable support, truthful information and an apology when things go wrong.

71. However, the PHSO report noted that NHS staff that it spoke to during the course of its review cited “the lack of an open and honest culture despite the introduction of the Duty of Candour in November 2014” as one barrier to “getting to the heart of why something has happened.” Action against Medical Accidents also told us that “training and support [should be] provided to relevant staff on the Duty of Candour”.

72. During our oral evidence session we invited the Minister’s comment on the view that “there is not a culture of candour in the NHS. It is very difficult for senior officials to tell Ministers and advisors, special advisors, the truth at all times and that affects the entire system.” He responded that:

If you see the way the Secretary of State approaches this about candour on never events, his openness about avoidable mortality, not uncontroversial I

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104 Secretary of State for Health, “From a blame culture to a learning culture”, transcript of speech given to Global Patient Safety Summit at Lancaster House, 3 March 2016.

105 The statutory Duty of Candour was introduced following the publication in March 2014 of *Building a culture of candour*, a report made on behalf of the Royal College of Surgeons by Sir David Dalton and Professor Normal Williams.

106 NHS Litigation Authority, *Duty of Candour guidance*.

107 CLI0008 (Department of Health).

108 PHSO, *Review into the quality of NHS complaints investigations where serious or avoidable harm has been alleged* (2015).

109 CLI0003 (Action against Medical Accidents)

110 Q33
would posit at the moment, all of this suggests that the leadership from the top at an official and at a political level is there. But has that yet permeated through the entire organisation? No.\textsuperscript{111}

73. There was also general agreement amongst witnesses about the need to better involve families and carers at the right time during an investigation process. Mike Durkin stated that “patients are not involved early enough in the conversation that needs to happen.”\textsuperscript{112} The Patients Association concurred that the current system “results in fragmented outcomes for patients and their carers.”\textsuperscript{113} This view was echoed by the EAG’s final report.\textsuperscript{114}

74. \textit{The Committee welcomes the Minister for Care Quality’s admission that more work must be done to fully implement the statutory Duty of Candour. We urge the Department of Health to press ahead with training staff across all NHS organisations in applying this principle.} There must be a greater focus across the system on dealing with patients and their families and carers with compassion and respect when their case is the subject of a clinical investigation. HSIB must embody this in its own investigations, but responsibility for delivering this change across the whole healthcare system sits with NHS Improvement and NHS England more widely.

A “whole system approach”

75. The Department of Health also brought to the Committee’s attention other changes aimed at improving the quality of NHS investigations, including:

- The appointment of Dame Eileen Sills as the first National Guardian of the NHS, responsible for leading, advising and supporting individuals named within NHS Trusts as ‘local guardians’ in carrying out investigations on how concerns are being handled, share good practice, report on national or common themes, and identify any cultural barriers to the NHS embracing openness; to date 36 local guardians have been appointed in 23 Trusts;
- Ensuring that whistleblowers are viewed and considered as an asset and receive proper support, as well as strengthening guidance from the GMC and NMC that professional tribunals should give credit to doctors, nurses and midwives who admit failings early;
- Work by NHS Improvement and NHS England to develop a standard integrated policy and procedure for reporting incidents and raising concerns;
- Health Education England continuing to develop training materials for NHS organisations to ensure that staff understand how to raise concerns and how to deal with them;
- Publishing estimates by every NHS Trust of the annual number of avoidable deaths, as well as a league table grading the openness and honesty of reporting cultures in hospitals; once these new data sets have been validated the CQC will include them in a new annual report on the state of hospital quality.\textsuperscript{115}

\textsuperscript{111} Q33
\textsuperscript{112} Q4
\textsuperscript{113} CLI0010 (Patients Association).
\textsuperscript{115} CLI0008 (Department of Health).
76. The Minister for Care Quality told us that “for the NHS, becoming a learning system is a cultural change probably unprecedented in its period of existence.” In their written submission the Patients Association called for several of the changes already announced by the Department of Health and NHS England. However, they raised a very real concern that:

There is currently a complete lack of coordination of lessons to be learnt from all of the regulators, system regulators and the regulators of individuals providing healthcare.

77. The EAG’s final report also made recommendations for how to achieve “an effective, system-wide approach” to safety investigation and addressing substantial risks to patient safety. These suggestions included the creation of a “Just Culture Task Force” to bring together safety and improvement experts with representatives from the legal and complaints systems, other healthcare professionals and patients’ representatives. The EAG recommended that this Task Force “should determine the appropriate policies, practices and institutional arrangements that are required to move the healthcare system firmly towards a just culture of safety.”

78. The EAG further recommended that “the Secretary of State establish a process to address unresolved cases, aimed at providing truth, justice and reconciliation to address the concerns of patients, families and staff affected”, warning that unless outstanding and historic cases are reopened and re-examined “this baggage of history will continue to taint future safety investigations.”

79. The Government should be commended for adopting the “whole system approach” first recommended by PASC in March 2015. The steps that have been taken to date are positive, although the Committee will continue to monitor their implementation and efficacy. However, we still have reservations regarding the Government’s ability to draw the results of these changes together and deliver a co-ordinated programme of improvements to patient safety on the ground. The Department of Health and NHS England must now focus their efforts on developing this feedback mechanism, to ensure that lessons learnt about the most serious patient risks are always acted upon.

80. The Committee endorses the creation of a Just Culture Task Force as a positive step towards delivering “improvement, accountability and justice” across the healthcare system as a whole.

81. We also support the EAG’s proposal for the re-opening of historic “unresolved grievances”, but only where there is a clear argument that doing so would assist in improving patient safety in the future, or where serious outstanding legitimate grievances persist. This process might take the form of a single public inquiry, to consider which legacy cases to review, to hear the selected cases, and make recommendations arising from them. This should be seen in the context of other wide-reaching inquiries in recent years, such as the public inquiry into historic child sexual abuse, the Hillsborough Independent Panel’s inquiry into the Hillsborough disaster, and the Saville inquiry.

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116 Q22
117 CLI0010 (Patients Association).
119 ibid.
into the events of Bloody Sunday. The purpose of this single public inquiry would be to provide closure to those affected by patient safety incidents, which cannot otherwise be obtained.

**Proposals for complaints handling**

82. Much of the evidence received by the Committee discussed the role that HSIB could play in improving the clinical complaints system. There appeared to be a general misunderstanding that HSIB would sit at the apex of this system. For example, the Patients Association asked:

What number of complaints is it expected that this service will have to handle?
What number of staff do you think will be needed to triage and then investigate them? What will be the triage criteria?\(^{120}\)

83. However, as was noted above, it is now clear from the Department of Health’s written evidence and the Secretary of State’s Directions that HSIB will not play any formal role in the NHS complaints handling process. This is in keeping with the remit of the Air Accidents Investigation Branch. With this in mind we have assessed what other action the Department of Health and NHS England intend to improve complaints handling.

84. In January 2015 the Health Committee published its report, *Complaints and Raising Concerns*, which found that the system for handling NHS complaints was too variable. It stated that:

Too many complaints are mishandled with people encountering poor communication or at worst, a defensive and complicated system which results in a complete breakdown in trust and a failure to improve patient safety.\(^{121}\)

Furthermore, the Health Committee stressed that “the relationship between the provider and the commissioner is [ … ] key to determining the day-to-day quality of services provided under NHS contracts”, noting that “it is the commissioner which is best placed to work constructively with the provider on delivering improvements.”\(^{122}\) The Committee added that it expected “the CQC to examine the culture of complaints handling by providers.”\(^{123}\)

85. The Chair of the Health Committee, Dr Sarah Wollaston MP, wrote to PACAC during the course of our inquiry, highlighting the setting up by the Department of Health of a Complaints Programme Board to oversee the delivery of “a series of individual projects to deliver improvements to the way health and social care complaints are handled”, and suggesting that PACAC “may wish to ask the Government what steps it is now taking to drive improvement in complaint handling in the NHS.”\(^{124}\)

86. The PHSO report also found that there were missed opportunities for learning in the handling of complaints:

\(^{120}\) CLI0010 (Patients Association).
\(^{122}\) Ibid.
\(^{123}\) Ibid.
\(^{124}\) Letter from Dr Sarah Wollaston MP to Bernard Jenkin MP, Chair, PACAC, 11 February 2016.
• 25% of the complaints managers that it surveyed were unsure whether sufficient processes existed to prevent a recurrence of incidents. A further 10% believed that sufficient processes were not in place.

• Divisions within hospitals often work in isolation to each other; learning from investigations also appears to be trapped in high level meetings.\textsuperscript{125}

87. PHSO recommended that HSIB and NHS England should consider how the role of complaints managers can be better recognised, valued and supported; and that Trusts should demonstrate to their Boards they have clear objectives, both for their organisations and their staff, to be open and honest, learn from investigations, and resolve complaints; Boards should be using \textit{My expectations for raising concerns and complaints} to assess to what extent local complaints services are meeting the needs of people who use the service.\textsuperscript{126}

88. However, several witnesses were critical of the role played by the PHSO itself in the complaints process. In particular, the Patients Association argued that:

\begin{quote}
The PHSO, itself, is failing families, leaving them distressed … There are fundamental flaws inherent in the system, the lack of understanding of the clinical issues that patients are raising, the lack of training of those undertaking investigations and the very long time delays that appear to be built into the system.\textsuperscript{127}
\end{quote}

Other witnesses were critical of the recommendations made by the PHSO, particularly with regards to the advice given to NHS Trusts. Action against Medical Accidents told us that:

\begin{quote}
This is so general as to be almost useless. We agree “My Expectations” should be used as a tool to assess complaints services, however we would have expected more specific and stronger recommendations, together with a commitment from the PHSO itself to be vigilant on checking the quality of investigations when complaints are brought to its attention, and to come down hard on NHS bodies whose investigations have been inadequate or been lacking in openness and honesty.\textsuperscript{128}
\end{quote}

89. Despite these criticisms of the specifics of the PHSO report, there was an acceptance from the Government that, although there had been “significant improvements in some parts of the system”, there is still much to be done. The Minister for Care Quality told us that:

\begin{quote}
Those who are at the cutting edge of work in this area in the NHS understand what other great organisations understand, which is that you must love complaints. You must embrace them and encourage them when they arise because that is how you learn. There are some organisations that are really
\end{quote}

\begin{footnotes}
\footnotetext[125]{PHSO, \textit{Review into the quality of NHS complaints investigations where serious or avoidable harm has been alleged} (2015).}
\footnotetext[126]{ibid.}
\footnotetext[127]{CLI0010 (Patients Association).}
\footnotetext[128]{CLI0003 (Action against Medical Accidents).}
\end{footnotes}
living that at the moment, but there are some, right at the other end of the scale, that hate them, that have significant problems with them. What we have to do, like in so much of the NHS, is to level up the worst to the best.  

90. The Department of Health also provided details of a number of other steps aimed at improving how NHS organisations handle complaints:

- Since August 2015 quarterly hospitals complaints data has been published, with the most recent data coming out on 13 April 2016;
- HealthWatch England is working with Citizens Advice to ensure that there is accurate information about how to complain available online;
- New education training tools and advice about how to manage complaints has been produced by Health Education England and the Royal College of Nursing;
- New commitments have been made in the NHS Standard Contract 2015/16 on the importance of promoting information about how to complain locally and where to get advocacy support;
- The development of a framework for governance reviews produced by Monitor which encourages trust boards to listen to patients, and through complaints and other feedback, to identify and address deficiencies;
- A CQC inspection process that considers complaints as part of every inspection in primary, secondary and social care, taking a sample of complaints to look at how they have been handled.  

91. There was a further suggestion from the Minister for Care Quality during our oral evidence session that he felt he had “unfinished business” with complaints handling, that there was a “lacuna in the architecture at the moment”, and that he would like “to come back to [the Committee] with some really good policy in a few months’ time”.  

92. The Committee acknowledges the concern expressed by some witnesses regarding the specific findings and recommendations for complaints handling in the PHSO report. PASC addressed the question of Ombudsman reform during the last Parliament. PACAC now expects the Government soon to respond further to the PASC recommendations with the necessary legislation to create the Public Service Ombudsman.  

93. The Committee welcomes the programme of work to improve NHS complaints handling commissioned by the Department of Health and NHS England. However, we believe that there is still a long way to go to deliver a credible and uniform NHS complaints process that the public can trust and rely on. We expect the Minister for Care Quality to honour his commitment to finish the job and will not hesitate to call him before the Committee again to explain future policy developments.
Conclusions and recommendations

Introduction

1. During the course of our inquiry, the Department of Health and NHS England both gave positive and constructive responses to the PHSO’s report. We commend their honesty in acknowledging that NHS England currently lacks a high quality clinical investigations capability and that it does not deal with complaints effectively. The establishment of HSIB is a critical step towards improving how NHS organisations handle clinical investigations, although its remit does not include complaints handling. However, the Department of Health and NHS England must go further to achieve the transformation “from a blame culture to a learning culture” as quickly as possible. The rest of this Report will assess the proposals that have been made to date and consider what more must be done to deliver the “whole system approach” first called for by PASC in March 2015. In particular we are in agreement with many of the HSIB EAG’s recommendations and believe that there is a consensus across the sector in favour of an independent, transparent and “no blame” Investigation Branch, which Government cannot ignore and must implement in full as a matter of urgency. Despite statements to the contrary, the Secretary of State’s Directions currently fall short of providing this framework. (Paragraph 25)

The Healthcare Safety Investigation Branch

2. The Committee welcomes the creation of the Healthcare Safety Investigation Branch as a national clinical investigations function. It is right that this body should focus on those risks which pose the greatest threat to patient safety. However, following the publication of the Secretary of State’s Directions, there are still serious questions to be answered regarding how principles will be translated into the design and operations of the new Investigation Branch. (Paragraph 36)

3. The Department of Health must also be very conscious of the limits of what HSIB can achieve with a limited budget and a remit to investigate only 30 cases per year. In this respect it is crucial that HSIB is not only an exemplar of high quality clinical investigations but is also focused on setting national standards and ensuring improvements at a local level - where the vast majority of clinical investigations will continue to take place - is not neglected. (Paragraph 37)

4. We are pleased that the EAG agrees with the Committee on HSIB’s role and remit. Government must now take strong action to show that it is serious about turning the new Investigation Branch into a body of real authority and professional capability. (Paragraph 38)

5. PASC made clear that HSIB must be independent, and the Secretary of State for Health appeared to have accepted this recommendation. Therefore the Government’s decision to locate HSIB within NHS Improvement, instead of making it directly accountable to the Secretary of State, is both disappointing and unacceptable. This appears to be solely to comply with the Government’s general stricture against forming new public bodies, or because Departmental spending is subject to cuts, whilst NHS spending is not. (Paragraph 45)
6. HSIB should be part of the Department of Health, rather than part of the NHS, the organisation which it is being created to investigate. It is the Secretary of State who is ultimately accountable to Parliament for the safety of the NHS in England, not NHS Improvement. Furthermore it is the Secretary of State who is responsible for setting up a public inquiry, should this prove necessary. Therefore, like its parallel bodies who conduct aviation, marine and rail accident investigations, HSIB should report directly to the Secretary of State. (Paragraph 46)

7. However, we agree that Parliament can and should provide additional safeguards and direct oversight so that the Secretary of State is not exposed to any suspicion of untoward ministerial influence. We therefore reiterate the recommendation that 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. (Paragraph 47)

8. The Government must commit in its response to this Report to bringing forward the necessary primary legislation to secure HSIB’s independence as soon as possible. If the Government does not do so then the Committee will call the Secretary of State for Health to give evidence to account for this failure. (Paragraph 48)

9. The first Chief Investigator of HSIB will have considerable responsibilities for establishing the new body, including the developing and publishing of Investigation Principles and creating and sustaining the much discussed ‘safe space’. It is essential that the successful candidate is of the highest calibre and commands public confidence. As the Chief Investigator will play a key role in protecting and safeguarding the public’s rights and interests, it is also vital for the reputation and credibility of HSIB that the post holder is, and is seen to be, independent of Ministers and Government. We are unconvinced by the external commitments that have been made to the Chief Investigator’s independence, and do not believe that the new appointee being made directly accountable to the Secretary of State can be said “to provide an additional foundation for his or her independence.” Therefore we believe that a pre-appointment hearing would strengthen public confidence in the new body. (Paragraph 49)

10. We regard the ‘safe space’ principle as being critical to the effective operation of HSIB. This protection is essential if patients and staff are to have the confidence to speak about the most serious risks to patient safety without fear of punitive reprisals. Its importance is underlined by the work of the Air Accidents Investigation Branch on which HSIB is modelled. In the Committee’s view, the only way to effectively establish this ‘safe space’ is for the Government to bring forward primary legislation that will guarantee its inviolability. The EAG’s final report also agreed that the ‘safe space’ must be given a “legislative base” in order to be effective. We will regard
anything else as a failure to implement PASC’s original recommendation and evidence of a disregard for the consensus position of both healthcare experts and Parliament. (Paragraph 56)

11. The Government must also spell out how protocols between HSIB and other regulatory and investigatory bodies will strike the right balance between respecting the ‘safe space’ principle and HSIB’s competing obligation to share information in certain, specified circumstances (such as following a court order). In particular, the ‘safe space’ must be protected from Freedom of Information requests, as are the similar bodies responsible for air, marine and rail accident investigations. (Paragraph 57)

**Improving clinical investigations at the local level**

12. HSIB should assume unambiguous responsibility for setting the national standards by which all clinical investigations are conducted. It should remain the responsibility of local NHS providers to deliver on these standards, according to the Serious Incident Framework. The Care Quality Commission should continue to fulfil its role as the regulator in assessing the quality of clinical investigations at a local level. These distinct functions must be clearly explained to patients to ensure that confusion does not persist. (Paragraph 61)

13. HSIB, and in particular, the Chief Investigator, should develop a strong relationship with professional regulators to ensure that the Investigation Branch’s recommendations are acted upon by providers. In addition, HSIB should be empowered to suggest changes to national regulatory standards where this will result in systemic improvements to patient safety. (Paragraph 64)

14. It is undeniably important that NHS Improvement assist Trusts in implementing recommendations made by HSIB or by the CQC, but this alone cannot deliver the necessary improvements to patient safety across the NHS in England. Given its own limited capacity, HSIB as the national clinical investigations function and exemplar of good practice, must work closely with NHS organisations to build a highly-trained and professionalised cadre of local investigators, who are respected by other healthcare professionals and trusted by the public. These local investigators should be capable of examining those serious patient safety incidents not investigated by HSIB and helping NHS Trusts to learn the right lessons from their reports. If HSIB fails to provide national leadership in improving the quality of clinical investigations then it will not only be failing one of its primary objectives, but it will also be failing the public. (Paragraph 68)

“*The world's largest learning organisation*”

15. The Committee welcomes the Minister for Care Quality’s admission that more work must be done to fully implement the statutory Duty of Candour. We urge the Department of Health to press ahead with training staff across all NHS organisations in applying this principle. There must be a greater focus across the system on dealing with patients and their families and carers with compassion and respect when their case is the subject of a clinical investigation. HSIB must embody
this in its own investigations, but responsibility for delivering this change across the whole healthcare system sits with NHS Improvement and NHS England more widely. (Paragraph 74)

16. The Government should be commended for adopting the “whole system approach” first recommended by PASC in March 2015. The steps that have been taken to date are positive, although the Committee will continue to monitor their implementation and efficacy. However, we still have reservations regarding the Government’s ability to draw the results of these changes together and deliver a co-ordinated programme of improvements to patient safety on the ground. The Department of Health and NHS England must now focus their efforts on developing this feedback mechanism, to ensure that lessons learnt about the most serious patient risks are always acted upon. (Paragraph 79)

17. The Committee endorses the creation of a Just Culture Task Force as a positive step towards delivering “improvement, accountability and justice” across the healthcare system as a whole. (Paragraph 80)

18. We also support the EAG’s proposal for the re-opening of historic “unresolved grievances”, but only where there is a clear argument that doing so would assist in improving patient safety in the future, or where serious outstanding legitimate grievances persist. This process might take the form of a single public inquiry, to consider which legacy cases to review, to hear the selected cases, and make recommendations arising from them. This should be seen in the context of other wide-reaching inquiries in recent years, such as the public inquiry into historic child sexual abuse, the Hillsborough Independent Panel’s inquiry into the Hillsborough disaster, and the Saville inquiry into the events of Bloody Sunday. The purpose of this single public inquiry would be to provide closure to those affected by patient safety incidents, which cannot otherwise be obtained. (Paragraph 81)

19. The Committee acknowledges the concern expressed by some witnesses regarding the specific findings and recommendations for complaints handling in the PHSO report. PASC addressed the question of Ombudsman reform during the last Parliament. PACAC now expects the Government soon to respond further to the PASC recommendations with the necessary legislation to create the Public Service Ombudsman. (Paragraph 92)

20. The Committee welcomes the programme of work to improve NHS complaints handling commissioned by the Department of Health and NHS England. However, we believe that there is still a long way to go to deliver a credible and uniform NHS complaints process that the public can trust and rely on. We expect the Minister for Care Quality to honour his commitment to finish the job and will not hesitate to call him before the Committee again to explain future policy developments. (Paragraph 93)
Formal Minutes

Tuesday 24 May 2016

Members present:

Bernard Jenkin, in the Chair
Ronnie Cowan  Mr David Jones
Mr Paul Flynn  Gerald Jones
Kelvin Hopkins  Tom Tugendhat

Draft Report (PHSO review: Quality of NHS complaints investigations), proposed by the Chair, brought up and read.

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

Paragraphs 1 to 93 read and agreed to.

Summary agreed to.

Resolved, That the Report be the First Report of the Committee to the House.

Ordered, That the Chair make the Report to the House.

Ordered, That embargoed copies of the Report be made available, in accordance with the provisions of Standing Order No. 134.

[Adjourned till Tuesday 7 June at 9.15am.]
Witnesses

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

Tuesday 23 February 2016

**Ben Gummer MP**, Parliamentary Under Secretary of State for Care Quality, **William Vineall**, Director of Quality, Department of Health, and **Mike Durkin**, National Director of Patient Safety, NHS England

Q1–53
Published written evidence

The following written evidence was received and can be viewed on the inquiry publications page of the Committee’s website. CLI numbers are generated by the evidence processing system and so may not be complete.

1. Action against Medical Accidents (CLI0003)
2. Department of Health (CLI0008)
3. Dr Minh Alexander (CLI0002)
4. Murray Anderson-Wallace (CLI0006)
5. NHS England (CLI0004)
6. Patients Association (CLI0010)
7. Royal College of Physicians of Edinburgh (CLI0001)
List of Reports from the Committee during the current Parliament

All publications from the Committee are available on the [publications page](#) of the Committee’s website.

The reference number of the Government’s response to each Report is printed in brackets after the HC printing number.

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