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Public Administration and Constitutional Affairs Committee

PHSO review: Quality of NHS complaints investigations: Government response to the Committee's First Report of Session 2016–17

Second Special Report of Session 2016–17

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Public Administration and Constitutional Affairs

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Contacts

All correspondence should be addressed to the Clerk of the Public Administration and Constitutional Affairs Committee, House of Commons, London SW1A 0AA. The telephone number for general enquiries is 020 7219 3268, the Committee's email address is pacac@parliament.uk

Second Special Report

The Public Administration and Constitutional Affairs Committee published its First Report of Session 2016–17, PHSO review: Quality of NHS complaints investigations, as HC 94 on 2 June 2016. The Government response was received on 16 September 2016 and is appended to this report.

Appendix: Government Response

Further to the publication of the report of the Public Administration and Constitutional Affairs Committee *PHSO review: Quality of NHS complaints investigations* on 24 May 2016, I am pleased to provide a response to its recommendations and conclusions on behalf of Her Majesty's Government.

Firstly, the Government welcomes the report, and commends the Committee on its valuable contribution to the development of a model for an independent healthcare investigation function, now realised through the Healthcare Safety Investigation Branch, HSIB. The appointment of Mr Keith Conradi as the Chief Investigator of the new function on 4 June 2016 and the endorsement of the Committee for his appointment are important milestones on the way to establishment of HSIB by 1 April 2017.

We think it is important to consider HSIB in the context of the wider system for patient safety. A great deal is already in hand to foster a culture of learning, based upon a 'whole system approach'. The Government has adopted policies promoting a system that:

- Provides external scrutiny of safety and performance and a regulatory regime that addresses problems as they arise;
- Encourages local providers to review the safety of their own services, for example undertaking local reviews of avoidable deaths;
- Stresses the importance of openness and honesty with patients and staff (for example in response to the statutory duty of candour, and national and local guardians to support staff to speak up) and the need to recognise that the opinions of patients and staff are vital tests of the quality and safety of healthcare;
- Provides support and helps build capability both locally (through the Sign up to Safety campaign) and at scale (the National Patient Safety Collaborative programme).

There is more to do to encourage spread and adoption of ways of working that build providers' capability and capacity to be a safe and resilient organisation in the context of increasing financial and efficiency challenges. NHS Improvement will continue to play a central role along with its Arms-Length Body (ALB) partners.

HSIB will make an important contribution to this new culture of learning, but it is part of a bigger picture, and it will need to work within the limitations of its available resources. This will necessitate good partnership arrangements with NHS Improvement, CQC, NHS England, the professional regulators and a range of other system stakeholders.

The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016 ('The Directions') for HSIB were kept deliberately high level to provide the Chief Investigator with the freedom to shape the design and operations of the Branch in the run up to its becoming fully established by 1 April 2017. Pending Mr Conradi's arrival in post in September there has been an inevitable delay in establishing these details. The Department of Health is also still in the process of responding to the non-HSIB recommendations from the Expert Advisory Group's (EAG) report. Therefore this response provides a progress update and recognises that there is more to do.

This Government response addresses, in turn, the individual conclusions and recommendations of the Committee's report set out in bold below. The response is in normal type.

Responses have been grouped into the key themes addressed by the report:

Learning not Blaming

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 Government is committed to a learning culture across the NHS based upon the principles of candour, freedom for whistle-blowers to speak up, transparency and a safe space to discuss errors.

Learning not blaming[1] - The Government's response to the Freedom to Speak Up consultation, the Public Administration Select Committee report 'Investigating Clinical Incidents in the NHS', and the Morecambe Bay Investigation published in July 2015 set out a series of important steps upon which we are determined to build.

All investigations should explore the root causes of serious incidents and in particular examine processes and the systems within which people work, as evidence shows that systems and processes are much more likely than the failures of individuals to be the cause of incidents. This will be a guiding principle of investigations undertaken by HSIB, which should be adopted by all local investigations.

1 Learning not blaming: The government response to Freedom to Speak Up consultation, the Public Administration Select Committee report 'Investigating Clinical Incidents in the NHS', and the Morecambe Bay Investigation; Department of Health; July 2015

The Government wants to see the development of a 'just culture' rather than a 'no blame' culture. A just culture is one in which individuals are not unfairly blamed and punished for making mistakes but which does hold people to account for wilful acts of neglect, mistreatment and gross negligence

We will be consulting shortly on how the principle of 'safe space' can extend to HSIB and local investigations.

Role of HSIB

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)

The Directions which establish HSIB, set out principles under which the Branch will operate, including its investigatory function. These have been kept deliberately high level to provide the Chief Investigator with the scope to implement them and develop the necessary working protocols with other bodies. There will be greater clarity, for example, on how HSIB will discharge its responsibilities to create a 'safe space' and support local investigations when the Branch becomes fully operational by 1 April 2017.

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)

One of the functions that HSIB should exercise in accordance with Paragraph 5 (1) (e) of the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016 is "encouraging the development of skills used to investigate local safety incidents in the health service and to learn from them, including suggesting standards which may be adopted in the conduct of such investigations."

We would expect HSIB to work closely with the Care Quality Commission (CQC), NHS Improvement, NHS England and commissioning organisations to agree how best to support local organisations and encourage improvement. However, HSIB will be unable to oversee improvements at a local level. That responsibility sits with local providers with the CQC checking the results.

NHS Improvement is also likely to reflect on capacity and capability in this area, based upon the information it receives through its own investigations and more generic intelligence from system partners. In particular, CQC has undertaken a review of the quality of investigation reports across 24 NHS acute hospital trusts to improve understanding how such organisations investigate, learn and communicate when things go wrong. The results of this review were published in June 2016 as Briefing "Learning from serious incidents

in NHS acute hospitals"[2]. The Briefing is structured around five opportunities for improvement aimed at providers. It calls upon the relevant agencies to work together and agree what more they can do to support hospitals to develop the capacity and capability that is required, to encourage them to embed good investigative practice into their wider approach to learning and improvement, and to make sure that patients and their families are informed and involved, in line with the Duty of Candour.

The Secretary of State for Health has also agreed to a special, thematic review by CQC under Section 48(1) of the Health and Social Care Act 2008 of the investigation of deaths across NHS mental health, acute and community settings. This will give rise to a national report at the end of the year outlining CQC's findings and making a number of recommendations for improvement. These recommendations will outline changes required from trusts and commissioners, but also from CQC and other national bodies.

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)

The Government expects the Chief Investigator, Keith Conradi, to draw upon his considerable experience to secure the right professional resources and expertise, and shape HSIB into an organisation that will support a step change in the quality of investigations undertaken across the NHS.

Independence of HSIB

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)

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)

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

2 Briefing: Learning from serious incidents in NHS acute hospitals; CQC; June 2016

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)

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)

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)

The Government remains committed to the independence of HSIB, and DH Ministers are open to future options for implementing this in practice.

The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016 provide for a direct line of accountability from the Chief Investigator to the Secretary of State for Health in relation to the performance of functions by HSIB. The Chief Investigator of HSIB is required to produce an annual report direct to the Secretary of State; and their appointment and dismissal will only take effect if agreed by the Secretary of State. NHS Improvement must ensure that HSIB exercises the investigatory functions set out in Paragraph 5(1) of the Directions, take reasonable steps to protect the independence of HSIB and provide the organisational support (for example finance and human resources) to allow HSIB to discharge its function. There is also the additional scrutiny exercised by Parliamentary Committees as well as the public to ensure the Branch is acting impartially.

The Government maintains the view that HSIB should be hosted by NHS Improvement. We believe HSIB can remain independent by putting in place practical measures through legal Directions to enable it to operate separately from its host body without fear or favour. We would need primary legislation to further bolster the independence of HSIB which we do not have. However, we are absolutely determined that HSIB will operate independently. We have agreed to review the current arrangements within two years.

The Government accepted the Committee's recommendation that a pre- appointment hearing should be held for the new Chief Investigator, and Mr Keith Conradi appeared before the committee in June 2016. At that hearing Mr Conradi agreed with the principle that the Chief Investigator is independent of Government, as far as possible, and we expect

him to draw upon his considerable experience to shape HSIB into an organisation that reflects the principle of independence. The Secretary of State has confirmed that all future Chief Investigator appointments should also be subject to a pre-appointment hearing.

Safe Space

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)

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)

The Government agrees that the concept of safe space is critical to the effective operation of patient safety investigations, including those conducted by HSIB. The Secretary of State for Health announced in March that the Government will bring forward measures for investigators from the Healthcare Safety Investigation Branch to offer the kind of 'safe space' that applies to those speaking to the Air Accident Investigation Branch. The Secretary of State was clear that the concept of "safe space" be established as a fundamental principle of all Healthcare Safety Investigation Branch safety investigations, and this has been reflected in the Directions. The details of how a 'safe space' operates in HSIB will be determined by the Chief Investigator within these parameters.

We expect the Chief Investigator, when in post, to produce protocols and memoranda of understandings with other regulators and investigatory bodies which clarify how information should be shared across organisations. We envisage that information obtained during healthcare investigations in accordance with safe space principles would not be disclosable under the Freedom of Information Act 2000 and the Data Protection Act 1998. However, this would have to be balanced with the principle of transparency and right to make Freedom of Information requests to ensure that patients and families have access to the information they need.

The Government is considering how the principle of 'safe space' can extend to HSIB and local investigations. Our future work on Just Culture will also help to address this.

Improving patient safety at the local level

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)

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)

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 Government notes these recommendations. We would expect the influence of HSIB to extend beyond purely clinical investigations and encompass all local investigations of healthcare harms, including those within primary, community and mental health services. However, it is important that HSIB not be drawn into local investigations that do not form part of its own, formal work programme.

It is important to bear in mind the distinction between professional and system regulation. We would expect HSIB to establish strong working relationships with both sets of regulators and agree the necessary protocols for the exchange of information where appropriate. The relationship between HSIB and professional regulators will be an important one, but we would consider CQC, NHS Improvement and commissioners to have a particular role in assuring adherence to HSIB recommendations by providers.

We expect CQC to review how it inspects for the quality of serious incident investigations in the light of its review of investigation reports and its forthcoming thematic review of the investigations of deaths in healthcare. We would also expect HSIB to be able to recommend changes to national regulatory standards in the same way that it might address its recommendations (arising from its own investigations) to any part of the system, including the Department of Health.

Similarly, we would expect HSIB to advise on the skills and training requirements of local investigators in accordance with Paragraph 5 (1) (e) of the National Health Service

Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016, working closely with training providers and the relevant professional organisations. This will take into account the learning from recent and ongoing CQC reviews of the quality of investigations and changes to national guidance. How this function will be exercised will be further determined by the Chief Investigator once he has taken up his post.

However, HSIB will be unable to oversee improvements at a local level. That responsibility sits with local providers and commissioners, with the CQC checking the results.

Creating the conditions for openness, learning and reconciliation

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)

The Government agrees that there needs to 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 an investigation, and that this should extend beyond HSIB investigations to all local investigations. Existing guidance in the *Serious Incident Framework*[3] is already clear that affected patients, families and carers should be involved and supported throughout the investigation, and that involvement begins with a genuine apology.

CQC has issued guidance on the statutory Duty of Candour which was last updated in April 2015. The NHS Litigation Authority has also issued guidance in this area. This sits alongside its existing *Saying Sorry* leaflet, published in 2013, which makes clear that saying sorry is not an admission of legal liability, but is the right thing to do.

It is the responsibility of NHS providers to implement training for their staff to meet their statutory responsibilities.

The Commission on Education and Training for Patient Safety[4] has recommended that Health Education England (HEE) "helps create a culture of openness and transparency by reviewing existing training packages to ensure they support the duty of candour regulations. They should commission relevant educational tools where needed and work with professional regulators to reflect the inclusion of a duty of candour in professional codes, extending beyond the legal duty for organisations and building on existing work in this area." HEE will be responding to the recommendations of the Commission on Education and Training for Patient Safety in the autumn.

The Department of Health has commissioned research into understanding how the NHS has responded to the policy proposals to make the service more open and transparent, specifically as a result of the Government's response to the recommendations of the Mid

3 Serious Incident framework: Supporting learning to prevent recurrence; NHS England Safety Domain; March 2015

4 Improving Safety Through Education and Training; Report by the Commission on Education and Training for Patient Safety; Health Education England; March 2016

Staffordshire NHS Foundation Trust Public Inquiry, and whether this has affected the quality of care. Final decisions on the successful tender will be made shortly, with the intention that the contract for the research will be awarded in September 2016.

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)

The Government notes this recommendation. The Defence Safety Authority provides an example of how an independent investigation function can work effectively alongside a regulator. We had already committed to concentrate and consolidate national expertise and capability on safety within a single organisation that can provide strategic leadership across the whole healthcare system. Accordingly, the Government has brought under the single leadership of NHS Improvement the responsibility for leading the patient safety functions that formerly sat with NHS England. This move builds on the post-Francis reforms that have been designed to ensure that there is greater clarity about the standards for safe care, and about the roles and responsibilities of organisations in the system for safety. Dr Mike Durkin, NHS National Director for Patient Safety is the system leader for patient safety and will work closely with HSIB to develop a more strategic approach to the co-ordination of feedback for learning and development. It is also important that the public is clear on the purpose of the bodies making up the regulatory system and how they relate to one another. In particular patients, their families and carers need to be clear to whom they should go if they wish to complain and be confident that the learning will be shared.

NHS Improvement already has channels for the dissemination of learning following an analysis of patient safety incidents, including by issuing a patient safety alert using the National Patient Safety Alerts System. This provides a route to alert NHS organisations to new and under-recognised risks, provide advice and guidance for reducing those risks, and requiring action where appropriate. Patient safety alerts and other existing mechanisms are therefore also likely to provide an effective vehicle for the spread of learning from HSIB investigations. CQC is in receipt of all such alerts, which inform future inspections.

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)

The Government agrees that the principles addressed by the proposal to set up a Just Culture Task Force (as already established for the aviation sector) are also important to support the whole healthcare system to move towards a just culture of safety. However, it is important to recognise that whilst HSIB can model and promote a 'just culture', it cannot be expected to resolve these issues across the entire healthcare system. Implementation of a just culture is reliant on the entire NHS; at provider, commissioner and system level and

across all aspects from human resource policies, to ensure a consistent and proportionate response when things go wrong through to learning and putting those lessons in place – the just culture taskforce would need to reflect this

Some work is already happening across the NHS to promote a just culture and to help individuals and organisations to understand what a just culture is, for example through the Sign Up to Safety Campaign.

We are giving further consideration to the proposal and will continue to discuss this with our stakeholders. We will respond to the EAG proposal in due course.

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)

The work of the EAG shone an important light upon the need to address unresolved cases, aimed at providing truth, justice and reconciliation to address the concerns of patients, families and staff affected. The Government wants to explore what further work would be involved to understand better the needs and expectations of all stakeholders in this area and scope possible solutions.

There are a number of different models for providing resolution or reconciliation and we want to work with patients, families and staff to develop a model which best suits their needs. We are clear this should not duplicate existing mechanisms to resolve complaints or whistleblowing concerns.

Whilst the Government has an open mind on this issue, we anticipate that a large public inquiry to consider such historic cases is unlikely to meet the aims of the EAG and might prove unsustainable, without providing the intended resolution in the face of many diverse and complex cases.

We will be working to develop options and will respond to the EAG proposal in due course.

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)

The Government is making good progress and will publish draft legislation to create a public service ombudsman in due course.

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)

The Government remains committed to this work. When appearing before your Committee, the former Care Quality Minister accepted that the Department of Health is mid-way through trying to take forward the specific issues on complaints. We will wish to take stock of this programme before committing to any further action.

Final comments

Finally, on behalf of the Government, I would like to thank the Committee again for its continued interest in this important area.