Report of the Expert Advisory Group

Healthcare Safety Investigation Branch

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Executive summary

We were brought together as an expert advisory group to give advice on establishing a national function, the Healthcare Safety Investigation Branch (HSIB). This Branch will be a key element in bringing about a much-needed improvement in the way in which we examine safety incidents, events in which something has gone wrong, causing actual or potential harm.

We have sought views from a wide range of people, including clinical staff and those harmed by safety incidents; and we have considered published material. All of this evidence points unequivocally to the unsatisfactory nature of the current system: it is seen as threatening by staff; untrustworthy by those affected; and fails to identify many opportunities to prevent future harm.

This has been a difficult and wide-ranging analysis, which has sought to address complex and challenging issues. Many health care systems around the world are struggling with these issues, and it is notable that the NHS is the first to address them systematically in this way. We are mindful that there are tensions and challenges.

We recognise that there are many people who have already been harmed, and also that what is being established comes too late for many. It is essential that, in future, patients and families are at the heart of all work on patient safety; and vitally important that they are treated with respect, honesty and dignity.

The purpose of this new safety investigation body is to act as an enabler, exemplar and catalyst for learning-oriented safety investigation. It is not to provide justice, or remedy, for patients and families. Nor are its purposes to determine liability, find fault or attribute blame. Those are important functions, but they belong elsewhere in the system, and they should not be undermined or diluted.

Safety is the responsibility of every NHS organisation. The primary purpose of investigation is to understand what has happened, so as to make improvements to the way in which care is delivered; to make healthcare safer for patients in the future;

and to reduce the likelihood that similar events will be repeated. HSIB will not take over the responsibility for safety, and it will not carry out itself the great majority of safety investigations. It is a new function that will add an important and much needed capability for learning and improvement.

Through our discussions and consideration of the evidence, we have been mindful that there are some patients, families and staff whose ongoing concerns remain unresolved; and that the way in which people are treated after adverse events can at times compound the distress and harm suffered. We recognise the distress and pain that result from serious safety failures, and acknowledge that this this can be amplified by poorly handled responses and investigations. In future, when the Branch identifies failings, it will describe and investigate them, and will provide patients and families with all relevant information.

Our work has been challenging, and sometimes difficult, particularly in reconciling the distinct perspectives of those involved and affected in different ways by safety incidents. We have been sustained throughout by the commitment shown by all participants identify the key points, and to resolve disparities in approach. If these recommendations help to bring about the improvement that is needed, their efforts will have been worthwhile.

We summarise our recommendations here for ease of reference.

INDEPENDENCE, ENGAGEMENT AND LEARNING

1. 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.
2. 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.
3. Patients, families and staff must be active participants in the process of investigation; and must be engaged with and supported compassionately and respectfully.

SYSTEM-WIDE INVESTIGATION AND IMPROVEMENT

4. HSIB must be empowered to investigate safety incidents and their causes anywhere across the entire healthcare system, including NHS organisations, national bodies, local government and commercial providers.
5. Investigations must be led by experts in safety investigation with deep knowledge of human factors, improvement science, healthcare policy and clinical practice appropriate to their role; the assistance and advice of subject matter experts should be co-opted as required. The Branch should provide leadership and expertise on safety investigation matters to the broader system.
6. HSIB must produce detailed reports that explain the causes of safety issues and incidents, and issue recommendations for improving patient safety across the system.
7. HSIB reports must be public documents, and recipients of recommendations must publish their response.

JUST CULTURE: TRUST, HONESTY AND FAIRNESS

8. The Branch must promote the creation of a just safety culture, a shared set of values in which healthcare professionals trust the process of safety investigation; and are assured that any actions, omissions or decisions that reflect the conduct of a reasonable person under the same circumstances will not be subject to inappropriate or punitive sanctions.
9. 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. To ensure the continued provision of safety information, and the confidence of healthcare professionals, all other information collected solely for the purposes of safety investigation will be protected, and will not be passed to any other body, or be admissible as part of another body's proceedings, other than when required on the instruction of a court of law.
10. Safety information must be provided to investigators honestly and openly on the understanding that it will not be used inappropriately. However, hiding or interfering with evidence is unacceptable, and should be made an offence. Similarly, when safety investigations uncover indications of wrongdoing, negligence, unlawful activity or other concerns that constitute an immediate danger to present or future patients, the Branch must inform the relevant responsible body and/or regulator, who may undertake their own inquiry and remedial action.

FURTHER ACTIONS REQUIRED ACROSS THE HEALTHCARE SYSTEM

11. We recommend a Just Culture Task Force be established, bringing together safety and improvement experts with representatives of the legal and complaints systems, healthcare professionals, and patients and families. This should determine the appropriate policies, practices and institutional arrangements that are required to move the healthcare system firmly towards a just culture of safety.
12. We recommend that a coordinated programme of capacity building and improvement of safety investigation should be undertaken across the healthcare system, building on the responsibilities of existing organisations and their respective roles as laid out in Appendix 1.
13. We recommend 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.

Background and introduction

It is well established that healthcare can cause avoidable harm as well as benefit, and all health systems are grappling with how best to reduce that harm. We know that the key lies in understanding both what goes wrong and what goes right, and that every occurrence of harm must be meticulously examined to understand why it happened and how the risk of recurrence can be reduced to protect future patients. This can only be achieved by systematic, rigorous and improvement-focused investigations. However, we know that many safety incidents go unreported and unexamined; and that, where investigations are carried out, they are often incomplete and fail to identify the underlying causes of harm, or lead to actions that improve safety.

Shortcomings in the current approach to investigating and learning from patient safety incidents have been highlighted by the reports of the Mid Staffordshire Inquiry, the Morecambe Bay Investigation, and the Public Administration Select Committee report “Investigating Clinical incidents in the NHS”. The latter made specific recommendations on the need to establish an independent, learning-focused patient safety investigation body that would investigate the most serious patient safety issues, and promote a just and learning culture across the healthcare system.

The Government, in their response to those recommendations, have made a commitment to establish an independent patient safety investigation function by April 2016. The report, “Learning not Blaming”[1], determined that the new investigation function will be based on five principles:

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

- Objectivity: its activities should focus on learning and improvement, and not finding fault, attributing blame or holding people to account.
- Transparency: acting as an exemplary model of openness and engagement with patients and their families throughout the investigation process.
- Independence in action, thought and judgement: able to operate without fear or favour, examine the causes of incidents and direct its findings to any organisation or individual.
- Expertise: be staffed by experts in patient safety, investigation, human factors and healthcare provision.
- Learning for improvement: produce findings that will help deliver practical solutions and address the causes of safety issues, and support local investigators and commissioners.

As the Expert Advisory Group, we have been asked to advise the Department of Health and Secretary of State for Health on the establishment of this function. In particular, we have been asked to provide advice on its purpose, role and operation. This report sets out our response. The full Terms of Reference are in Appendix 2.

A challenging context: widespread problems with incident investigation

Our examination of the evidence has reinforced that there is a range of shortcomings in the existing response to adverse events across the healthcare system. The creation of a new safety investigation function will not, on its own, address all of these problems. However, this range of problems represent the challenging context within which a new investigation body must begin its work.

Investigations are often delayed, protracted, and of variable or poor quality. They frequently fail to capture all relevant information, and may unhelpfully conflate efforts to learn and improve with attempts to determine liability and allocate blame.

Within individual healthcare organisations, safety investigation is often poorly resourced, with limited access to the required expertise and skills and insufficient allocation of time.

Across the healthcare system, there is little capacity to investigate effectively the common, system-wide causes of safety issues that can recur across different settings, or to address them consistently. There is a fragmentation of responsibility for rigorous investigation, both within individual organisations and across the healthcare system.

Patients, families and the public are too often let down by poor investigations, and the result is significant further distress on top of the harm caused by the events themselves. This additional distress that patients and families suffer can be made worse by the actions of healthcare organisations and staff when they are reluctant to engage openly and honestly with an investigation; or when they respond defensively; or, at worst, when they hide information.

Although it is not always their preferred course of action, patients and families can be left to pursue complaints or litigation as their only means of bringing problems to light and getting a truthful account of events. There remain a significant number of patients and families who have been failed by the system, and who continue to seek truth and resolution.

Health service staff are also let down by poor quality investigations, and the prevalent conflation with blame-seeking leads to suspicion of the process and fear of the consequences.

Patients, families and healthcare workers can all, in different ways, experience isolation, fear and emotional distress after serious events, and receive little support or guidance.

A long-term vision for effective investigation in healthcare

These problems will not all be solved by the creation of a single new investigation body. These are deep and long-standing problems and addressing them requires a wide range of concerted action across the healthcare system. However, we believe that very significant improvement is possible and the healthcare system as a whole should work towards a long-term vision for effective investigation. We believe that a system is required that will:

- ensure that safety investigation becomes routine, effective and trusted by patients, families, staff and the wider public, providing confidence that the

causes of adverse events will be identified and all necessary action will be taken to reduce the likelihood of recurrence;

- develop and implement a high-standard of rigorous, systematic safety investigation, along with building expertise and resources across the healthcare system that are needed to conduct locally-led safety investigations in all of the situations in which this is appropriate;
- carry out all investigations promptly and transparently, providing regular and clear communication to all involved and affected, and ensuring that patients and families are central participants in safety investigations;
- routinely conduct system-wide investigations to uncover common patterns of harm and the causes of failure across the healthcare system, and create a new system of public accountability for learning and improvement by publicly sharing safety recommendations and reporting on actions;
- ensure that there is a coordinated and proportionate response to the most serious failures and safety issues from all parts of the system, including regulators, professional bodies and the legal system; and
- ensure the needs of those patients, families and staff with outstanding and unresolved concerns are addressed, in order to secure openness, truth and promote reconciliation.

The establishment of the Healthcare Safety Investigation Branch

We believe that the creation of a new national body that can conduct safety investigations across the healthcare system will be a critical step towards developing a system that can perform as described above.

This body must have the authority and capability to conduct systematic safety investigations into the most serious risks and safety issues. It must develop 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 report its findings in detail, making recommendations for the improvement of safety. This will benefit patient safety across the entire healthcare systems, far beyond the individual cases or issues examined.

We have looked at the evidence, listened to the views of patients, families and staff, and debated extensively the principles to recommend. At an early stage, we formed the view that the interim name for the function ('Independent Patient Safety Investigation Service') was inadequate, and that the name 'Healthcare Safety Investigation Branch' more accurately described its role and intent. This has been accepted, and therefore we refer to the Healthcare Safety Investigation Branch (HSIB or 'the Branch') throughout.

Much of the detail of the operation of the Healthcare Safety Investigation Branch should rightly be a matter for the Chief Investigator, and for the Branch itself; and we have been mindful of the need not to be too prescriptive about how the principles described here should be translated into practice. We are also aware that some of the recommendations we make may not be immediately deliverable, such as the primary legislation that is required. This does not, however, lessen the importance of these principles, or the weight that we place upon them, and we strongly and unambiguously recommend that the necessary steps are urgently taken — including the primary legislation that is needed to underpin the powers of the Branch — and that practical issues do not dilute or divert attention from what is needed.

Although our recommendations are focused on the role and operation of this new body, we are also mindful that, to be fully effective, the establishment of an independent healthcare investigator must be accompanied by other essential improvements across the system. These include, in particular, raising the standard of local investigations, and addressing the needs of patients and families who feel that they have been failed by the current investigation process.

Summary of recommendations

Our recommendations for the establishment of the Healthcare Safety Investigation Branch are grouped into three themes. These concern:

- Independence, engagement and learning
- System-wide investigation and improvement
- Just culture: trust, honesty and fairness.

All of our recommendations are interrelated. It is our view that each of these recommendations must be acted on fully in order to ensure that the Branch is properly able to investigate the causes of harm across the healthcare system; to direct safety recommendations to any and all those required to act to address; and to secure and maintain the trust and confidence of patients, of families, and of healthcare workers.

In addition, we supplement our key recommendations for the establishment of the Branch with recommendations on action for the wider healthcare system.

Recommendations for the establishment of the Branch

INDEPENDENCE, ENGAGEMENT AND LEARNING

Recommendation 1: Independence

1. **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.**

The Healthcare Safety Investigation Branch must be independent in action, thought and judgement; able to operate without fear or favour; and be wholly autonomous in its decision making. It must neither seek nor take instruction from any person or organisation. This independence must be established through primary legislation.

The independence of the HSIB is in our clear view the most fundamental principle underlying its functioning. There are three reasons.

Firstly, the Branch must have a permanent and stable institutional base, able to operate across the whole healthcare system, and consider any relevant factors. Where appropriate, this will include investigating and making recommendations relevant to the Care Quality Commission, NHS Improvement, the Department of Health, NHS England, and other national bodies.

Secondly, the Branch must be able to operate in a way that is not considered threatening or risky by any of those participating in an investigation. An independent HSIB must have no role in regulation, commissioning or other operational activities, ensuring that it has no purpose other than to understand the causes of harm, and to make recommendations to improve safety.

Thirdly, HSIB's findings and recommendations must be impartial, and must be perceived as such. Investigation must be disinterested, dispassionate, and objective in the sense that it is conducted for no other purpose than learning; and free from any perception of vested or political interest. It is essential that HSIB commands the confidence and trust of the public, of patients, of relatives, and, equally, of staff.

To demonstrate these essential features of independence clearly and unambiguously, and to provide the long-term institutional stability that is required to develop a strong investigative infrastructure across the healthcare system, the Healthcare Safety Investigation Branch must have its independence and other powers established through primary legislation.

We recommend that primary legislation is brought forward at the earliest possible opportunity. However, we understand that a development phase will be required to establish the function from April 2016 pending legislation. We have not made recommendations for this development phase, as we do not wish to suggest that an interim model would be an acceptable alternative. However, we stand ready to assist with advice on interim arrangements during the development phase should this be sought.

A Chief Investigator of Patient Safety should be appointed to lead the Branch, to direct its operation, and to protect and promote its independence across the healthcare system. It will be important to appoint the right Chief Investigator to lead the Branch. The Chief Investigator will not only require the necessary skills, experience and competencies, he or she will need to have credibility with patients, families and staff.

The Branch needs its own governance arrangements and this should include a forum of lay and professional people who will act as the “guardians” of the principles we propose here. This forum will ensure that the Branch operates in line with these principles at all times. We suggest that this forum is styled as a Commission; and that membership should include patients, families and staff with experience of investigation and those with expertise in patient safety and investigations.

The Chief Investigator should be made answerable to the Secretary of State for Health to provide an additional foundation for her or his independence, and should report annually. Scrutiny should also be exercised by Parliamentary select committees (the Health Select Committee and Public Administration and Constitutional Affairs Committee). In addition, we recommend that some of the Commission meetings are held in public to allow for greater public scrutiny.

Recommendation 2: Learning-focused investigations

2. 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.

The Healthcare Safety Investigation Branch should be set up to conduct and promote safety investigations. We have followed the definition of Carl Macrae and Charles Vincent[2] who said that a safety investigation "is a preventative, future-oriented activity that aims to drive learning and improvement". The purpose of safety investigation is not to attribute liability or apportion blame. We expect the majority of investigations conducted by the Branch will be into circumscribed adverse events or safety issues. On some occasions, these may encompass complex and sensitive issues where, for instance, trust has broken down between different parties; and situations have arisen that pose significant continuing threats to patient safety. We believe that the Branch will need the capability to investigate these, but we stress that the principle of investigations must remain the same, and the overall aim will remain to learn from the events that occurred in order to prevent them happening again.

In considering what and when to investigate, the Healthcare Safety Investigation Branch must focus on incidents and issues that provide the greatest potential for learning. The ultimate aim must be to deliver the greatest improvement in patient safety across the healthcare system. We expect that this will be achieved most effectively, making best use of finite resources, by focusing on conducting investigations into the most serious risks and patient safety issues that span the healthcare system, and conducting these investigations to an exemplary standard. The Branch should create and publish a set of principles to help determine which incidents it will investigate, but it will be for the Branch alone to decide what to investigate.

The selection of incidents by the Branch will need to be considered in some detail, much of which should best remain for the Chief Investigator to decide. However, we would expect that the Branch would have the capacity to monitor and proactively determine potential areas for investigation; as well as responding to triggers such as clusters of events, or empirically determined thematic priorities, or notifications from

[2] Macrae, C. and V incent, C. (In press). Investigating for improvement. London: The Health Foundation.

other system-monitoring bodies. For example, having determined that a key safety issue is a priority, the Branch may initiate an investigation into the next serious event of that type that occurs.

To determine those safety issues and incidents with most potential for learning, criteria for selection could include:

- the level and extent of harm caused to patients and families;
- events that occur frequently and are common across the healthcare system;
- new or novel forms of harm or failure that are poorly understood; and
- events signalling systemic issues with significant impact in many settings.

This would guide the Branch in giving priority to investigations that would generate learning with the maximum beneficial impact. The Branch should conduct investigations into specific safety issues and incidents that are currently active and relevant to the healthcare system, and should launch investigations in a timely manner, allowing the rapid and contemporaneous gathering of all relevant information.

There are some instances, however, of unresolved cases where the principles of safety investigation that we have set out cannot reasonably be applied because of the time that has elapsed. Nevertheless, those harmed may have been left deeply dissatisfied that they have been unable to discover the truth of what happened, or have it acknowledged. We recommend that the Department of Health look urgently at these long-standing and unresolved cases, and consider how it will respond to the patients, families and others who feel that the system has failed them repeatedly. It is important that those affected are offered a form of resolution which listens to their concerns and addresses them. This issue is addressed later in Recommendation 13.

Recommendation 3: Participation and treating people with respect

3. Patients, families and staff must be able to be active participants in the process of investigation, and must be engaged with and supported compassionately and respectfully.

The Branch should encourage full and inclusive participation in a safety investigation, including by patients and their families, healthcare staff, commissioners, regulators, and educators. All knowledge should be valued equally; and all voices, including those of patients, of their families, and of staff, should be heard equally, in order to foster a genuine motivation to learn and to improve safety. The Branch should embrace learning as an active and a continuous process, beginning at the start of any investigation to the finish. The outcome, the investigation report and its recommendations, should be a product of this process of engagement with all those concerned, and should reflect their desire for improvement.

Those involved or harmed in safety incidents - whether patients, relatives or staff - must have the opportunity to be fully involved in investigations into what has happened. At the outset, the account of those involved or affected by the events should be sought, and their views as to what happened heard.

Patients and families must be offered the opportunity to be involved throughout the investigation, not just be at the outset, and must be given the chance to hear the findings and conclusions before they are published. Crucially, patients and families must have the opportunity to set out what questions they need answering, and to record the chronology of events experienced by patients and families. Otherwise, investigations can end up addressing only the questions that professionals believe to be relevant, and ignoring the concerns and insights of those harmed. The extent to which patients and relatives wish to be involved at each stage will vary, and some may wish no involvement. Investigators must remain flexible to their needs.

All those involved in a safety incident are likely to suffer personal distress as a result. The Branch should have a specialist liaison function to serve the different needs of patients, families and staff, such as providing them with information about the investigation process, and information on sources of emotional support and practical advice.

SYSTEM-WIDE INVESTIGATION AND IMPROVEMENT

Recommendation 4: Systematic and system-wide investigations

4. HSIB must be empowered to investigate safety incidents and their causes anywhere across the entire healthcare system, including NHS

organisations, national bodies, local government and commercial providers.

Safety issues and related incidents are often the result of complex local, organizational and system-wide processes, with similar events recurring repeatedly in different places across the healthcare system. The purpose of safety investigation is to understand the patterns of causality that produce harm, and to make recommendations that can address those causes across the healthcare system in order to improve the safety of all patients.

We expect that a significant proportion of Branch-led safety investigations will address specific and serious adverse events. It is important to recognise that the causal and contributory factors that lead to these events can be system-wide. Some events may result from the often complex inter-relationships of different organisations involved in health care. As such, HSIB investigations must be empowered to look across the entire healthcare system, to identify both common system-wide problems as well as causal mechanisms that span different organisations. These organisations will include, but are not necessarily limited to, health service regulators, professional bodies, NHS commissioners, the Department of Health, local authorities, equipment manufacturers, and education providers.

We do not think the Healthcare Safety Investigation Branch should routinely receive and consider requests for investigation from individual patients or staff. Allowing direct referrals would lead rapidly to an overwhelming volume of requests that would prevent HSIB from operating effectively. We are also concerned that direct 'referrals' from Ministers or others in authority may be perceived as jeopardising HSIB's independence and raise questions as to why another case was not referred. Our recommendation is that the office of the Secretary of State respects the independence of the Branch and the mechanisms by which the Branch prioritises investigations. We do recognise, however, that HSIB must remain vigilant to concerns raised through political, regulatory, media and other routes; and should work cooperatively with others in identifying areas to investigate.

Recommendation 5: Expert leaders in safety investigation

5. Investigations must be led by experts in safety investigation with deep knowledge of human factors, improvement science, healthcare policy and clinical practice appropriate to their role; the assistance and advice of subject matter experts should be co-opted as required. The Branch

should provide leadership and expertise on safety investigation matters to the broader system.

Investigations must have access to the requisite skills, knowledge and experience to make findings on causes and remedies that are regarded as trustworthy and authoritative by patients and relatives, health service staff and the wider public.

Investigations must be led by experts in safety investigation. They must be able to draw on skills, experience and methodological expertise in investigation, patient safety, improvement science, human factors, healthcare provision and clinical services, as well as experts by experience.

The Chief Investigator should promote a team approach that embodies trust, compassion, clarity, consistency, flexibility and open-mindedness, as well as deep expertise. The Branch should seek to be seen as independent, legitimate, authoritative and impartial, acting as a champion of patient safety, striving for continuous improvement.

The Branch and the Chief Investigator must establish and maintain effective relationships with other investigatory bodies, including professional regulators, organisational regulators, and the police, as well as with other parts of the healthcare system.

The Branch should provide national leadership on safety investigation matters across the healthcare system, acting as a catalyst to promote high-quality safety investigation, and as a resource of skills and expertise. Investigations conducted by the Branch should be in line with national and international best practice, and the Branch should adopt well-established safety science methods to analyse and explain data, and to develop explanations of the underlying processes involved in safety issues. It should be a leader in the analysis of risk and safety.

The Branch should aim to encourage best practice across healthcare organisations in investigative standards and techniques, by making its own techniques and standards freely available. A renewed set of patient safety investigation standards and guidance documents should be produced that unequivocally specify the terms for good investigation practice; and that incorporate the very latest thinking in investigation and safety science.

These standards and methods should be reflected in the exemplary practice of the Branch in its own investigations. The Branch should be sufficiently resourced to act as a national centre of leadership and expertise on safety investigation.

The Branch should seek the assistance and advice of specialists and subject matter experts in relation to technical matters, co-opting a broad range of experts as and when required. In the conduct of its investigations, the Branch should work participatively with healthcare staff and local investigators, both in order to gain the necessary input to its investigations, and also to enable and promote good investigatory practice and share skills and knowledge. 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.

Recommendation 6: Safety investigation reports and recommendations

6. HSIB must produce detailed reports that explain the causes of safety issues and incidents, and issue recommendations for improving patient safety across the system.

The primary goal of the Healthcare Safety Investigation Branch is to generate learning to support improvements in the safety of healthcare. The Branch must publish investigation reports into safety patient safety issues or incidents that determine what has happened, how it happened and why it happened, in order to explain the causes of harm and to make recommendations to prevent recurrence.

Safety investigations should focus on understanding the causal and contributory factors that underlie safety incidents and issues and will need to identify and explain deficiencies in the structural, operational, regulatory and policy features of the healthcare system. The Branch must apply established and rigorous models of safety investigation and its reports should act as an exemplar of good investigative practice, given the large quantity of safety investigations that are carried out — and will continue to be carried out — locally across the healthcare system.

The Branch should develop and issue safety recommendations that address the causes of the issue or incident investigated. The Branch should target recommendations at the organisation or individual most appropriate to address the problem, and recommendations should address key problems and be proportionate, deliverable and as far as possible developed with recipients to ensure they are fit for

purpose. However, the Branch should not itself be responsible for developing, implementing or monitoring specific solutions or improvement actions. The investigation report must be shared first with affected patients, relatives and staff before publication.

The Branch should be committed to innovate and continually improve its own processes and procedures for investigations, and this includes embracing new ways of sharing the lessons arising from investigations, such as the use of social media and using patient stories.

Recommendation 7: Response to HSIB reports and recommendations

7. HSIB reports must be public documents, and recipients of recommendations must publish their response.

The Branch must make public its reports and recommendations, to promote an open approach to learning and improvement, and for public accountability.

Recipients of HSIB recommendations must be required to publish a formal response setting out whether they accept the safety recommendation or dispute it, and what actions they will take and by when. We recommend that legislation be brought forward to this end.

The Branch should not itself regulate compliance with its safety recommendations or enforce implementation, although the Branch may recommend who should monitor implementation and require compliance.

While the Branch will therefore not act as a regulator, it may issue safety recommendations about how the activities of regulatory agencies might be improved, and it may issue safety recommendations to regulators regarding changes to regulatory standards or practice that it considers necessary.

The Branch should have an interest in the impact and efficacy of its recommendations. It should collate responses to its recommendations into a formal statement of their impact on a regular basis. The Branch should carry out a review of its effectiveness every other year, including the extent to which recommendations have been actioned and have led to improvement.

JUST CULTURE: TRUST, HONESTY AND FAIRNESS

Recommendation 8: Promoting a just culture

8. The Branch must promote the creation of a just safety culture, a shared set of values in which healthcare professionals trust in the process of safety investigation and are assured that any actions, omissions or decisions which reflect the conduct of a reasonable person under the same circumstances will not be subject to inappropriate or punitive sanctions.

The purpose of safety investigation is to identify and explain the circumstances that lead to harm, in order to develop recommendations to improve safety in the future. This is only possible with the active, honest and open engagement of healthcare professionals. This is essential to ensure that the underlying causes of harm have been fully uncovered, to bring about changes in processes and practices to improve safety, and to provide patients and families with full and truthful accounts of past events.

Securing the trust and confidence of healthcare professionals depends on establishing a ‘just culture’. A just culture is one in which healthcare professionals are able to report safety incidents, and participate in safety investigations secure in the knowledge that they will not be inappropriately blamed or penalized for any actions, omissions or decisions that reflect the conduct of a reasonable person under the same circumstances.

The vast majority of safety incidents are associated with inadvertent or unintentional errors on the part of caring and committed staff. These errors are typically provoked by poorly designed systems, equipment, or work contexts. A just culture depends on establishing a clear distinction between the ‘honest mistakes’ of well-intentioned

healthcare workers where punitive responses are neither warranted nor helpful; and the rare acts that involve reckless neglect or mistreatment.[3]

Although it will not be the responsibility of the Branch to deliver this change, which is the responsibility of all NHS bodies, it must promote a just culture across the healthcare system, and contribute to it by ensuring that staff involved in investigations led by the Branch are secure in the knowledge that they will not be blamed for events that involve 'honest mistakes' and have been openly shared. This must include mechanisms to protect staff from unwarranted blame by others on the basis of the information provided during an investigation. This has been described as providing a 'safe space' in which staff can participate fully and without fear.

The creation of a just culture is vital in gaining the trust of healthcare professionals. The trust of those affected by safety incidents is equally vital, and it is important that a just culture also recognises those rarer incidents of individual culpability.

Recommendation 9: Provision and use of safety information

9. 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. To ensure the continued provision of safety information and the confidence of healthcare professionals, all other evidence collected solely for the purposes of safety investigation will be protected and will not be passed to any other body or be admissible as part of another body's proceedings, other than when required on the instruction of a court of law.

During its investigations, the Branch will gather a wide variety of information relating to the safety issue or events under investigation. All information that is relevant to the findings of a safety investigation must be included in the public report of that investigation. To increase the generalisability of findings, this would not include the identity of individuals; and the wishes of patients and relatives to exclude identifiable information must also be respected.

During its investigations, a subset of information gathered by the Branch may not be relevant to the report findings but may directly relate to the care and treatment of a patient affected by a serious safety incident. This information must be shared with the

[3] National Advisory Group on the Safety of Patients in England. (2013). A promise to learn—a commitment to act. London: Department of Health.

patient and with the patient or patient's family, who are free to use this information as they wish. This is not only essential in line with their full participation in the investigation, and with compassionate practice, it is also required by the duties of candour that apply to NHS care. In the majority of cases this information will already have been provided to patients and families by the organisations involved in an event, either immediately following the incident or during the course of their local investigations. However, if this is not the case, then the Branch will make this information available to the patients and/or relatives affected. Importantly, if organizations have failed to provide relevant information to patients and families after serious events, then this in itself may indicate weaknesses in local safety management and investigation processes. These issues may be investigated by the Branch to understand the causes and issue recommendations on, for example, improving communication with patients and families about safety issues, and building a culture of openness and candour.

In order to underpin a just culture that ensures the continued provision of safety information and the confidence of healthcare professionals, all other evidence collected solely for the purposes of safety investigation must be used solely for the purposes of safety improvement. It should not be made available to other bodies or admissible as part of another body's proceedings.

We believe 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.

We stress that all information relevant to the care and treatment of a patient would be shared with the patient and their family, who are of course free to use it as they wish, and all information required to explain, fully and rigorously, the causes of a safety issue would be published in the public investigation report. We stress also that, should concern arise during a safety investigation over potential intentional wrongdoing, gross negligence, or other concerns that constitute an immediate danger to present or future patients, this would be notified to the relevant bodies for them to conduct their own investigation. These protections must not interfere with the proper administration of justice, and would not prevent any legal or professional

regulatory proceedings in response to intentional wrongdoing or gross negligence. Appropriate co-ordination of any parallel investigations should be considered in the enabling legislation, and the Branch should draw up Memorandums of Understanding with other key bodies to facilitate co-ordination.

It is also the case that information gathered during an investigation may include material that is of no relevance to the episode of care, or to the safety event that occurred; for example, a recording taken in an operating theatre may include a conversation that revealed personal details of another patient, or a member of staff. Such material must not be shared or made available to other parties. Where there is any doubt over relevance the Chief Investigator must be the final arbiter.

Information and reports published by the Branch will reflect the principle that all investigations are for the purpose of improving systems and practices, and not for holding individuals to account for past events. Therefore, the Branch must not identify the individuals involved in a safety issue or event under investigation. This is in order to avoid any perception that individuals are being found at fault, and instead to focus attention on the processes and mechanisms that cause a safety issue and that may be widely present across different parts of the healthcare system. While individuals will not be named or identified in reports beyond their job titles or roles, the purpose is not to provide any broader guarantee of anonymity to individuals, who may well be identified in other proceedings related to a serious safety event such as an inquest.

Recommendation 10: Rights, responsibilities and wrongdoing

10. Safety information must be provided to investigators honestly and openly in the understanding that it will not be used inappropriately. However, hiding or interfering with evidence is unacceptable and should be made an offence. Similarly, when safety investigations uncover indications of wrongdoing, negligence, unlawful activity or other concerns that constitute an immediate danger to present or future patients, the Branch must inform the relevant responsible body and/or regulator, who may undertake their own inquiry and remedial action.

For investigations to be high quality and for their findings to be robust, it is essential that investigators have access to all relevant information and are able to interview all relevant persons. Only in this way can the outcome be regarded with confidence by the public, patients and staff.

We believe that primary legislation should be brought forward to give powers to compel organisations and individuals to participate in safety investigations, and to share information with investigators in a timely fashion. This is in line with the position in other industries, where these powers are available, but where the need to invoke legislation rarely arises in practice. The knowledge of its existence would help to deter the troublesome and time-consuming arguments about participation that often arise in the current system, and would create a strong and clear set of responsibilities to participate openly and honestly in safety investigations.

The same legislation should make it an offence to conceal or tamper with evidence. We recommend that both of these requirements are taken forward at the earliest opportunity as part of the primary legislation required to establish the Branch.

The role of the Branch, and of any safety investigation, is not to assign blame, find fault or establish culpability. People who make unintended errors and freely report them to investigators must be confident that they will not be subject to any internal or external sanction and that the information they provide will be used solely for the benefit of learning, as would be expected in line with a just culture.

In some instances, the Branch may find indications that individuals may have acted dishonestly, recklessly or negligently. In a few cases, investigations may determine that incidents or relevant information have been concealed or interfered with in other ways. Where such indications are found, the Branch will set this out factually, within the context of how and why they happened. The Branch will not pursue professional regulatory or legal processes against individuals, but where it identifies concerns that may endanger future patients, it will notify the relevant authorities, who will be responsible for addressing concerns through their own, separate, processes.

Further actions required across the health system

In addition to our recommendations regarding the structure, operation and remit of the Healthcare Safety Investigation Branch, we believe there are three related areas of further work that are required to move towards an effective, system-wide approach to safety investigation.

DEVELOPING A JUST CULTURE

Through our review of the evidence and deliberations, we have explored many of the complex and challenging facets of developing a just culture of safety. We recognize that there are many tensions and unresolved issues regarding what constitutes a just culture; how that can and should be implemented across a healthcare system; and what the appropriate interactions are between systems of improvement, accountability and justice. We believe that these issues need to be urgently and properly addressed. The Branch should be a leading voice in promoting and modelling just culture, but it cannot be expected to resolve these single handedly across the entire healthcare system. They require concerted and coordinated action from across the system, based on careful and coordinated analysis from a wide group of experts and stakeholders.

11. **We recommend a Just Culture Task Force be established, bringing together safety and improvement experts with representatives of the legal and complaints systems, healthcare professionals, and patient and families representatives. This should determine the appropriate policies, practices and institutional arrangements that are required to move the healthcare system firmly towards a just culture of safety.**

IMPROVING THE WIDER INFRASTRUCTURE OF INVESTIGATION

For the Branch to be successful, and for the quality of safety investigation to be improved across the whole healthcare system, significant improvements need to be made to the capacity, expertise, skills and resources available for safety investigation. Co-ordinated work across the system is needed to develop the required training, standards and assurance systems.

12. **We recommend that a coordinated programme of capacity building and improvement of safety investigation should be undertaken across the healthcare system, building on the responsibilities of existing organisations and their respective roles as laid out in Appendix 1.**

OUTSTANDING AND UNRESOLVED CASES IN NEED OF RESOLUTION

We have taken evidence regarding many distressing individual cases of patients, families and staff being treated poorly after adverse events, many of whom are still seeking to establish the truth of events and seek appropriate remedy. It will not be possible for the Branch to undertake review of these unresolved cases, because of its remit, and the nature of unresolved grievances. Those harmed include patients, bereaved families and whistleblowers. While we do not see this as a role for the Branch, it is our strong view that these cases need to be addressed as part of creating an open and just culture. Otherwise, this baggage of history will continue to taint future safety investigations.

13. **We recommend 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.**

Conclusion

We consider that the key element underlying transparency, engagement and support is trust, and that for Branch's success it must be trusted alike by patients, families, staff, the public, politicians, policy makers, and leaders. Engendering this trust will require the Branch to create its own track record of honesty, fairness, integrity and competence.

For patients and relatives, trust will depend principally on knowing and believing that nothing relevant to their care or treatment is being withheld from them; for them and for the public, it will also depend on knowing that nothing is being covered-up.

For staff, trust will depend principally on knowing that they will be treated fairly and not blamed for genuine mistakes. They must feel safe from unwarranted blame when taking part in an investigation. We are struck by work that has shown that the most effective learning takes place in conditions of psychological safety, characterised by a shared belief that participants will not be embarrassed, rejected, or punished for speaking up. The Branch should seek to establish that safety investigations will be carried out under these conditions.

Trust will also depend crucially on the whole healthcare system demonstrating a clear commitment to learning when things have gone wrong; and ensuring that effective action is taken to reduce future risk.

This is the beginning of a long journey towards creating a healthcare system that is able to routinely, rigorously and honestly examine its failures, understand the common causes of harm and address these right across the system. This will involve building up investigative capacity and capability across the whole healthcare system, and will take time.

We are aware that there are tensions between some of the principles we have set out, not least between the need to share information openly and the need to protect individuals from unwarranted criticism. We believe that, in practice, it will be for the Chief Investigator and the Branch to use their expert judgement, integrity and

compassion to achieve the correct balance in this and other aspects of HSIB's operation. Equally, we trust that the NHS will respond.

Appendix 1: Relevant roles of existing organisations

For the Healthcare Safety Investigation Branch to be successful, the rest of the system will need to do its job effectively. We have summarised these roles below:

NHS provider organisations, and any provider of NHS commissioned healthcare, are responsible for conducting the vast majority of patient safety incident investigations now and will continue to do so. These must be of high quality in order to learn from incidents and providers should use, without significant modification, the standards and techniques that will be used by the HSIB. Providers must implement effective action plans and monitor their implementation. Where relevant they must cooperate fully with HSIB investigations.

NHS commissioners are responsible for holding their providers to account for the quality of the investigations those providers carry out, according to the standards and techniques that will be used by the HSIB. Commissioners must monitor the effective implementation of action plans implementation. In a small number of cases, they will commission independent investigations into serious incidents. The NHS Serious Incident Framework sets out the circumstances where this may be necessary. These investigations are likely to be carried out by existing independent investigators, but they should use the same standards and techniques that will be used by the HSIB.

NHS England, in addition to its role as a national commissioner, must oversee the operation of the local commissioning system with respect to investigations, holding local commissioners to account for their role.

The Care Quality Commission (CQC) is responsible for considering the quality of investigations and the implementation of subsequent action plans as part of its inspection regime. All independent investigations must be notified to the CQC.

Professional regulators are responsible for holding professionals to account for any breach of professional standards, including those identified through investigations.

NHS Improvement is responsible for supporting the NHS to develop its learning culture, and to implement safety improvements that are identified..

The **NHS complaints system** must ensure all complaints to NHS bodies are handled effectively, efficiently and with sensitivity, ensuring complaints that reveal patient safety incidents are referred to local patient safety management systems.

All those working in the NHS, and all organisations providing care commissioned by the NHS, are responsible for implementing any relevant recommendations from the HSIB.

HSIB are responsible for investigating the incidents that it decides to investigate and for making recommendations for action to any person or body it considers relevant.

Appendix 2: Terms of Reference

Independent Patient Safety Investigation Service Expert Advisory Group, Terms of reference

Background

The Public Administration Select Committee report (PASC) in March 2015 characterised investigations into serious incidents in the NHS as "complicated, take far too long and are preoccupied with blame or avoiding financial liability" and falls far short of what patients, their families and NHS staff are entitled to expect. The Committee recommended that that there should be a new independent patient safety investigation body to conduct patient safety investigations in the NHS.

In its response, the Government agreed that there should be an independent capability at national level to offer support and guidance to NHS organisations on investigations, and to carry out certain investigations itself[4].

Timescales have been set by Ministers to have a new Independent Patient Safety Investigation Service (IPSIS) established by April 2016.

Purpose and operation of the group

An Expert Advisory Group (EAG) will be established to advise the Department of Health and Secretary State for Health on the purpose, role and operation of a new independent investigation function for healthcare. The Group will be relied upon to make use of its expertise in patient experience, safety, healthcare and investigation, to draw on the views and the available evidence from a broad range of stakeholders (including service users and staff) and to reach independent conclusions on how

[4] Learning Not Blaming: The government response to the Freedom to Speak Up consultation, the Public Administration Select Committee report 'Investigating Clinical Incidents in the NHS', and the Morecambe Bay Investigation July 2015

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/445640/Learning_not_blaming_acc.pdf

IPSIS should function. Evidence will be gathered through existing evidence as well as a 'call for evidence' and views for each meeting.

Its key objective is to deliver independent recommendations as to how IPSIS should operate, taking into account:

- The IPSIS vision – creating a system which instils confidence and drives improvement in safety;
- The key principles of operation – objectivity, transparency, independence, expertise and learning for improvement;
- The views of a broad, inclusive and diverse range of stakeholders as well as available evidence;
- The system which it will work within;
- Available resources.

Its proposed method of operation is to meet every two weeks, with work being progressed between meetings. Each meeting will be based around a theme for which the Secretariat will provide evidence in advance as well as invite speakers to give their views.

The Expert Advisory Group will regularly meet and hear evidence throughout July, August and September 2015. At around this point the way in which the Group functions – and how it hears and brings in evidence - will be reviewed.

The Secretariat will work to ensure that there are different opportunities for a range of interests and individuals to contribute to the work of the Expert Advisory Group such as:

- A web presence for key information about the Expert Advisory Group and minutes of its meetings;
- A digital system which could host the 'call for evidence' for each meeting and collect the information it generates;
- Open forum, small group and round table events to gather specific views or perspectives; and

- Social media to reach other individuals and groups.

Membership

- Julian Brookes, Deputy Chief Operating Officer, PHE, and member of the Morecambe Bay Investigation team
- Alison Cameron, Chair, Patient Safety Champion Network, Imperial College Health Partners
- Fiona Carey, Co-chair of the East of England Citizen Senate
- Deborah Coles, Co-Director INQUEST
- Keith Conradi, Chief Inspector of the Air Accidents Investigations Branch (with David Miller, Deputy Chief Inspector of Air Accidents deputising)
- Dr Mike Durkin, NHS National Director for Patient Safety (and Chair)
- Dr Sunil Gupta, GP and Clinical Lead for Quality and on the Governing Body of Castle Point and Rochford CCG
- Dr Bill Kirkup CBE, Chairman of the Morecambe Bay Investigation
- Kate Lampard, CBE, former barrister and NHS strategic health authority chairman who provided oversight on the NHS's Savile investigations.(Until December 2015)
- Dr Carl Macrae, Senior Research Fellow, University of Oxford
- Prof Martin Marshall CBE, Professor of Healthcare Improvement at UCL
- Prof Jonathan Montgomery, Professor of Healthcare Law at UCL and member of the Morecambe Bay Investigation team
- Scott Morrish
- Will Powell, NHS advisor for Mistreatment.com
- Dame Eileen Sills, Chief Nurse and Director of Patient Experience, Guy's and St Thomas's NHS Foundation Trust. (Until February 2016)
- James Titcombe OBE, CQC National Advisor on Patient Safety, Culture & Quality

- Dr Nick Toff, Director for Clinical Quality, Cambridge University Hospitals NHS Foundation Trust

The EAG also had a number of advisers – Ken Sutton and Ann Ridley (Home Office), Martin Bromiley and Peter Walsh (AvMA).