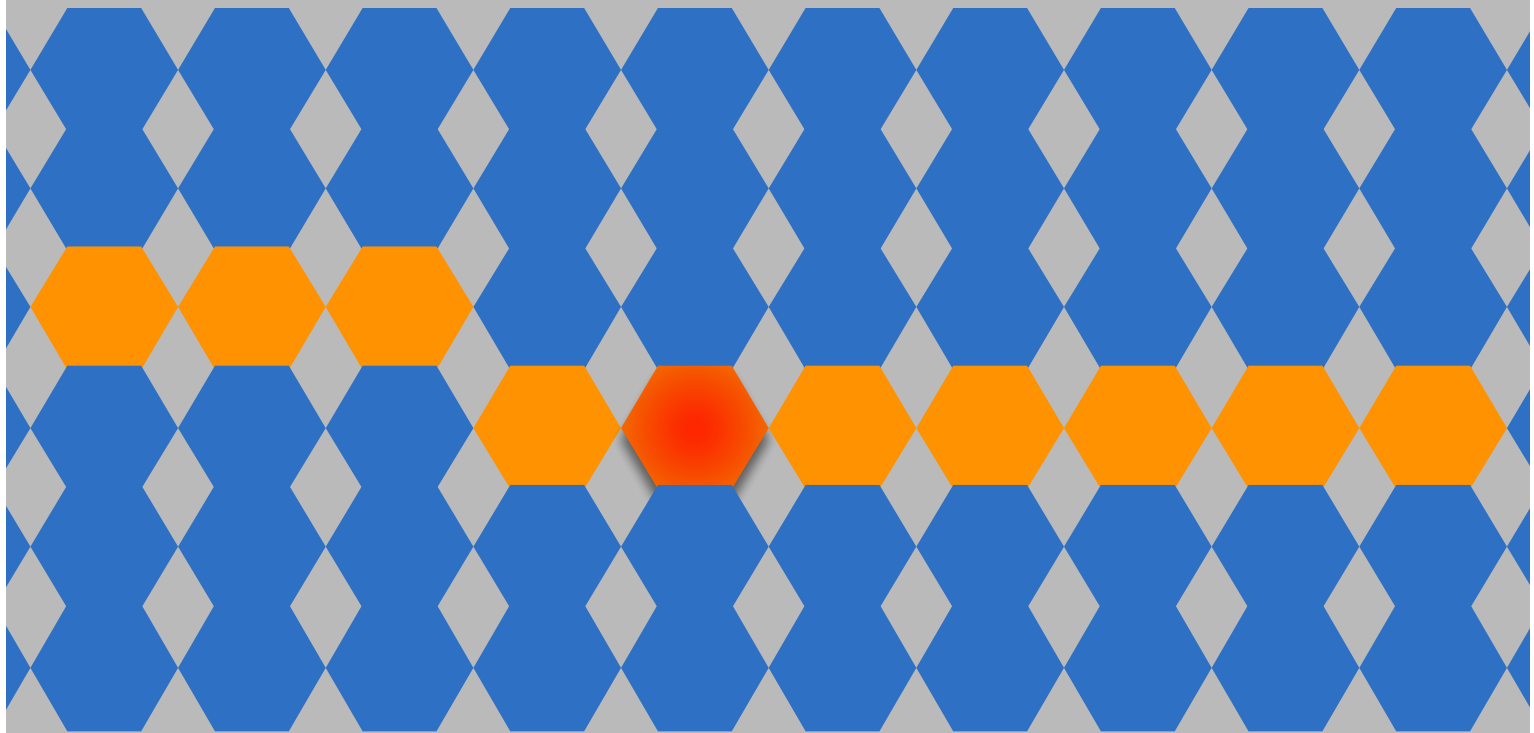


# Investigating for Improvement

Building a national safety investigator for healthcare

Carl Macrae and Charles Vincent  
University of Oxford



**Thought paper**

March 2017

This thought paper explores how healthcare systems can develop a system-wide approach to investigating and learning from the most serious patient safety issues, and examines the organisational infrastructure that is needed to support this. Many safety-critical industries depend on the work of an independent, national safety investigator to investigate the most serious risks that span the system and to develop safety recommendations that target any and all organisations that need to work together to address those risks—from front-line providers to regulators. This paper defines the fundamental principles, the practical challenges and the considerable opportunities that any healthcare system must grapple with in the development of a national safety investigator that supports system-wide learning.

## About the authors

Carl Macrae is Senior Research Fellow at the University of Oxford. His research explores how organisations achieve high levels of safety, reliability and resilience. Carl's 2014 book, *Close Calls*, examines the practical work involved in interpreting and learning from near-miss incidents in complex organisations. He was a Health Foundation Improvement Science Fellow from 2011-2014 and regularly advises organisations and policymakers on challenging safety, risk and improvement issues. Carl acted as Specialist Advisor to the Parliamentary Public Administration Select Committee inquiry into investigating clinical incidents, served as a member of the Healthcare Safety Investigation Branch (HSIB) Expert Advisory Group and is currently advising the HSIB Establishment Team.

Charles Vincent is Professor of Psychology at the University of Oxford, supported by the Health Foundation. Since 1985 Charles has conducted research on the causes of harm to patients, the consequences for patients and staff and methods of improving the safety of healthcare. He established the Clinical Risk Unit at University College London before moving to the Department of Surgery and Cancer at Imperial College, where he was the Director of the National Institute of Health Research Centre for Patient Safety and Service Quality from 2007-2013. Charles was a Commissioner on the UK Commission for Health Improvement from 1999 to 2003 and has advised many inquiries and committees including the Bristol Inquiry, the Parliamentary Health Select Committee, the Francis Inquiry and the Berwick Review.

## Acknowledgements

We would like to thank the many people who generously contributed their time and expertise to help shape various versions of this thought paper over the past two years, including the participants of a roundtable event hosted by the Health Foundation in June 2015, Nick Barber and Helen Crisp for originally initiating work on this thought paper and the Health Foundation for providing seed funding. We also thank Martin Bromiley and the Clinical Human Factors Group for their long-standing efforts to promote independent safety investigation and for enthusiastically supporting the publication of this paper.

# Contents

<b>Foreword</b>	4
<b>Executive summary</b>	5
<b>1. Introduction</b>	6
<b>2. Safety investigation: the purpose and the need</b>	7
<b>3. A national investigator: essential principles</b>	9
<b>4. Practices of a system-wide investigator</b>	13
When, and what, to investigate	13
Investigators, skills and capacity	14
Participation: engaging with patients, families and staff	16
Collecting and protecting safety information	17
Explaining risks and recommending improvements	19
<b>5. The future: a catalyst for system change</b>	22
<b>6. References</b>	23

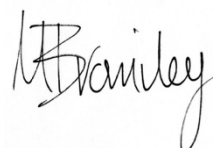
## Foreword

The vision of an independent, national and system-wide safety investigation body—and more importantly, the mindset of ‘learning not blaming’ that goes with it—has been at the heart of the Clinical Human Factors Group (CHFG) since we first formed. This vision is now becoming a reality in England with the establishment of the Healthcare Safety Investigation Branch, and so the CHFG is delighted to publish this timely thought paper that examines the challenges and opportunities for system-wide patient safety investigation, and considers what is needed to make this work in any healthcare system.

In simple terms, it is not possible to learn and improve after an event if frontline professionals, leaders and policymakers do not understand the causes of tragedy in the first place. I have a personal desire to see that the system improves from every tragedy so that patients and staff in the future do not have to endure the pain, loss and heartbreak of disaster. But that simple desire is vastly complicated to deliver in healthcare because of the sheer numbers of systemic issues and the tragedies that play out daily, combined with the further harm of so many well-intentioned—but often broken—promises that ‘it will never happen again.’

Any system-wide investigative body will need to advance with careful steps in order to balance the development of systemic, engineered safety improvements with the very human, emotional need for understanding—let alone justice. For that reason, there is one word in this paper that stands out for me. It is very human: it is the need for *trust*. Trust can only be built on the foundations of thoughtful practice. As such, the content and timing of this paper is perfect, as England’s own Healthcare Safety Investigation Branch begins its work and confronts many of these challenges in reality.

As the paper makes clear, even a ‘simple’ error such as the administration of the wrong drug will often have many complex systemic causes, and it is increasingly recognised in healthcare that such systemic problems cannot simply be addressed by local initiatives. A national safety investigator needs to drive learning and improvement at scale while remaining compassionate and supportive to those harmed, and being trusted by all. This will require wisdom and care. What Carl Macrae and Charles Vincent set out in this paper is, I believe, wise guidance not just for England’s new investigation body, but any healthcare system attempting the same seismic change in how national safety issues are approached.



**Martin Bromiley OBE**  
**Chair, Clinical Human Factors Group**

## Executive summary

Investigating how and why things go wrong is a fundamental principle of safety improvement, and system-wide safety investigation is an essential feature of the safety management and learning systems in all safety-critical industries. In healthcare, major inquiries and reviews continue to reveal considerable difficulties in how healthcare organisations investigate and learn from safety incidents, both locally and nationally. Similar serious incidents continue to recur in different places and at different times, causing terrible harm in tragically similar ways. Ensuring that our healthcare systems can reliably investigate incidents and learn enduring lessons therefore remains a matter of urgent concern.

In this paper, we explore how the development of a national safety investigation body can play a critical role in improving patient safety across an entire healthcare system. The primary role of a national safety investigator is to thoroughly investigate the most serious risks that span the system, examine the role of any organisation that might contribute to those risks—from front-line providers to national regulators—and develop safety recommendations that target the underlying systemic issues. A key function of these activities is to build collaborative and trusting relationships with people throughout the healthcare system, in order support and develop a wide community of expert safety investigators.

Building a national safety investigator for healthcare presents both enormous opportunities and distinct challenges. *Investigating for Improvement* examines what is needed to make this work: the principles and the practices that underpin system-wide, learning-oriented safety investigation in healthcare. We identify five core principles that are required of a national safety investigator: that it is *independent* in its structure and practice, *learning-focused* in its work, *system-wide* in its purview, *expert* in its activities and *trusted* by patients, professionals and the public. We then analyse the range of key practices, and the practical challenges, that any national healthcare safety investigator must engage with. These range from decisions regarding what to investigate, to working with patients, families and staff; and from the skills and attributes of national investigators to the nature of system-wide safety recommendations.

Based in part on our work, the English National Health Service has become the first healthcare system in the world to establish a dedicated national safety investigation body: the Healthcare Safety Investigation Branch (HSIB). This thought paper has been in development for some time and has been circulated in various iterations before and during the establishment of HSIB. However, our focus in this paper is not on the specifics of the HSIB or the national context of England. The purpose of this paper is more fundamental: to define the underlying principles, the practical challenges and the considerable opportunities that any healthcare system must grapple with in the development of a system-wide safety investigator—and in building an infrastructure that supports investigating for improvement.

# 1. Introduction

The most fundamental principle of patient safety is that we should learn from the past in order to improve the future.<sup>1</sup> When things go wrong in healthcare, and when patients are harmed, the only honourable response to those affected is to honestly, compassionately and intelligently examine what happened and why—and then take action to ensure that similar events will not be repeated in future.

How our healthcare system can best learn from serious failures is an issue of urgent concern. In the UK, the past five years have seen a string of major inquiries and reviews into serious patient safety failings. The Francis inquiries into the disaster at Mid Staffordshire,<sup>2,3</sup> the Kirkup investigation into the tragedies at Morecambe Bay,<sup>4</sup> the Keogh review of hospital mortality outliers,<sup>5</sup> the Berwick review of patient safety in the NHS<sup>6</sup> and the Public Administration Select Committee inquiry into the investigation of clinical incidents<sup>7</sup> all insist on the critical importance of openly acknowledging, rigorously investigating and honestly learning from past events.

Our healthcare system clearly needs a more robust, reliable and effective way of understanding and learning the lessons of serious failures.<sup>8,9</sup> In a paper published in late 2014 we developed a proposal that explained what was needed and how it could be achieved in practice: creating a permanent, independent body that is charged with routinely conducting system-wide investigations into serious safety issues that span the healthcare system.<sup>10</sup> Our proposal triggered a UK Parliamentary select committee inquiry that explored these issues in detail and came to the same conclusion, recommending the creation of a new independent safety investigation body for healthcare.<sup>7</sup> The government accepted this recommendation<sup>11</sup> and in April 2016 the Healthcare Safety Investigation Branch was established.<sup>12,13</sup> The English healthcare system will therefore lead the world in pioneering the use of routine, system-wide, independent safety investigation. Over time, this approach has the potential to transform the way that our healthcare system learns from the most serious failures, and this model is likely to be widely applicable to healthcare systems around the world.<sup>14</sup>

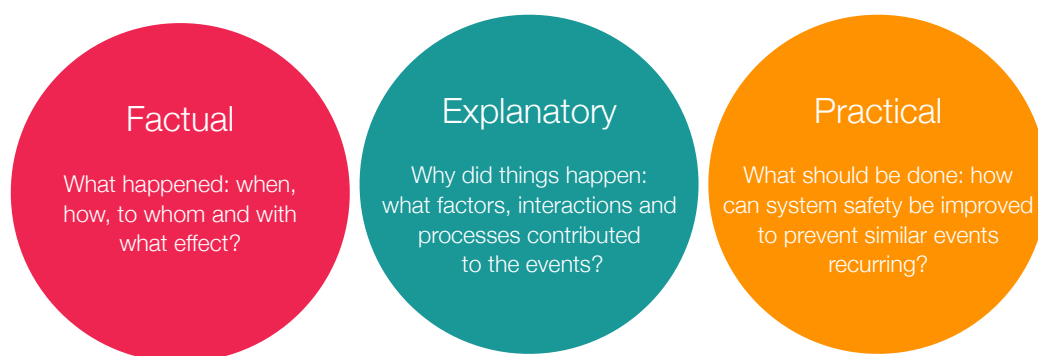
In this thought paper, we explore the principles and practicalities that are central to the successful development of a national patient safety investigator. We outline a vision for what could ultimately be achieved and explore what is needed to make that vision a reality. First, we revisit the core purpose of a national patient safety investigation body. Then we examine the underpinning practicalities and system-wide infrastructure that is needed to ensure it succeeds.

## 2. Safety investigation: the purpose and need

There is a deep asymmetry at the heart of safety investigation: safety investigations are primarily concerned with understanding the past, but the past is examined solely for the purpose of improving the future. At core, safety investigation is a preventative, future-oriented activity that aims to drive learning and improvement. Serious patient safety incidents can have devastating effects on patients and their families and staff may also be deeply affected. All those affected must be treated with compassion, honesty and respect and given a full explanation of how the tragedy occurred. However, the commitment of safety investigation is not only to those harmed, but to those who might be harmed by similar events in future. Learning is one of the highest expressed priorities for harmed patients and families themselves.<sup>15</sup> Learning and the prevention of future accidents is the pre-eminent purpose of a national patient safety investigator.

Safety investigations are organized around three core questions (Figure 1). The first question is *factual*: what exactly happened? The second question is *explanatory*: why did these events happen and what do they reveal about the vulnerabilities of the healthcare system? The third question is *practical*: how can such events be prevented from happening again in future? The first and the second questions are always answered in service of the third. The core focus of safety investigation should always be to understand the past in order to improve the future. The fundamental purpose of a national patient safety investigator is therefore *investigating for improvement*: examining and explaining the causes of the most serious risks to patient safety that span the healthcare system, and developing recommendations to reduce those risks and prevent harm to future patients.

Figure 1: Three questions for safety investigation



Such system-wide safety investigation activities have been routine for many years in other industries that manage the risks of harming citizens. Safety investigation represents a distinct approach to learning and improvement that has a long history.<sup>16</sup> The UK Air Accident Investigation Board (AAIB) recently celebrated its 100<sup>th</sup> birthday

and the US National Transportation Safety Board (NTSB) has a history spanning over 90 years. These and similar agencies have had a huge impact and are an essential component of the safety architecture in many industries. Healthcare is a notable exception. The practices and infrastructure of safety investigation are under-developed in most healthcare systems, both at national and local levels.<sup>17,18</sup>

Healthcare faces particular challenges in developing a successful national safety investigator. Two of the most difficult issues concern the scale of harm and the culture of blame. First, enormous numbers of serious safety events harm thousands of people each year. Clearly no single safety investigation body could investigate every single one of these events on its own—and nor should it. The primary responsibility for safety investigation and improvement should always lie with the organisations in which these events occur. However, the enormous scale of harm in healthcare is not a reason to be hopeless about the potential for a national safety investigator. Arguing that there are simply too many harmful incidents in healthcare to systematically investigate and learn from the most serious is both perverse and defeatist. For anyone who takes safety seriously, the opposite should clearly be the case: the enormous scale of preventable harm in healthcare urgently demands that actions are taken to learn system-wide lessons from as many events with as broad an impact on safety as possible. The practical challenge, discussed later, is how to determine which events might be most valuable to focus on.

Second, healthcare faces a challenge of immediate and unthinking blame. The work of impartially investigating events to learn and improve is often confused or confounded by the legal, regulatory and complaints systems that seek to attribute blame, establish liability, institute regulatory or professional sanctions and seek remedy after harmful events. These activities of judgment and justice serve important and essential functions. But the adversarial, legalistic and defensive climate they can create is often at odds with the need for dispassionate, open and systematic investigations that underpin long-term learning and improvement.<sup>19</sup> In other safety-critical industries, there is a clear and careful separation between processes that seek to learn and processes that seek to blame.<sup>20</sup>

Establishing a national patient safety investigator represents one of the most important steps that can be taken to begin formalizing the distinction between learning and blaming in healthcare. Most critically, a national safety investigator can introduce a new and important form of accountability into the healthcare system: it creates an active responsibility to make things better in the future, allowing people and organisations to be held to account for responding to publicly issued safety recommendations and for acting to improve safety. This is very different to retrospective and passive approaches to accountability that seek to blame people for things they have done and hold them accountable for things that have gone wrong in the past.<sup>21</sup>

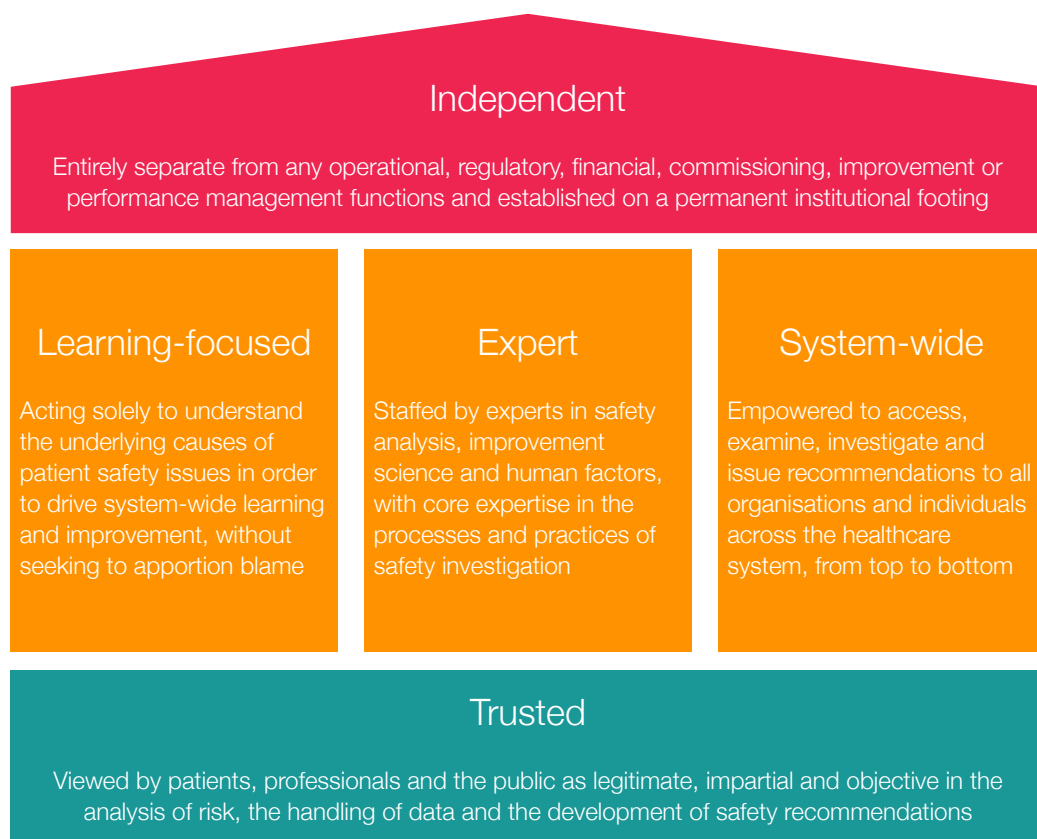
### 3. A national investigator: essential principles

The primary objective of a national patient safety investigator is to maximise system-wide learning. It should also act as a leading exemplar of investigatory practice and act as a catalyst for wider cultural and system change. There are five core principles that must underpin any national patient safety investigator (Figure 2). A national safety investigation body must be:

- *independent* of all other parts of the healthcare system it investigates;
- *learning-focused* and uninvolved in attributing blame or determining liability;
- *expert* in the science, methods and practices of safety investigation;
- *system-wide* in its powers, purview and recommendations; and
- *trusted* by staff, patients, families and system stewards.

Each of these principles is essential and none can be viewed in isolation. Each depends on and contributes to the whole. These principles are discussed in turn below. Then follows a more detailed analysis of the practicalities of building a national patient safety investigator.

Figure 2: Principles of national safety investigation



## *Independent*

Independence is both critical and fundamental: it is the source of much of an investigator's authority, legitimacy, trustworthiness and influence. A national patient safety investigator must be entirely independent of the healthcare system it investigates. There are three reasons for this. First, the causes of safety issues can span the entire healthcare system, from front-line professionals to commissioners, educators and regulators. A national safety investigator must be able to impartially investigate all areas of the healthcare system free from any conflicts of interest. Second, a national investigator needs to ensure that staff and organisations are confident that investigations are conducted solely for the purposes of learning and are not fearful of participating openly with the investigation. Therefore, the investigator must be able to investigate and act independently of any regulatory, financial or performance management functions. Third, a national investigator must not become directly involved in the design or implementation of safety improvements. This is to ensure it does not end up investigating failures that it may itself have contributed to in the past. The responsibility for improvement, and for future safety, ultimately rests with those who work in, manage, finance and regulate the healthcare system. The task of a safety investigator is to explain how safety is lost, recommend how safety should be improved and reflect on progress towards those improvements.

Ensuring independence is complex and depends on structural, practical and perceptual factors. The institutional *structure* of a safety investigator must establish a clear separation from other parts of the system, ensuring that funding, strategy, operations and leadership are not subject to interference. The *practices* of a safety investigator must continually demonstrate that its actions, thought, decisions and leadership are impartial and self-determined. Perhaps most importantly, a safety investigator must be *perceived* to be independent. This can be influenced by, for example, having its own corporate identity and separate offices, but is primarily determined by its actions and whether these demonstrate honesty and impartiality. Whilst independence is essential it should not mean distant or out of touch. A safety investigator must stand apart from the system it investigates but its staff must retain deep and current knowledge of healthcare practice. A safety investigator should therefore strive to occupy a place of *embedded independence*: maintaining a deep appreciation of the practical realities of the healthcare system whilst also standing apart from that system.

## *Expert*

A national safety investigator must represent the pinnacle of investigative expertise, setting the standard for the whole healthcare system to aspire to. It should apply well-established and rigorous safety investigation methods<sup>22</sup> and be a leader in the analysis of risk and safety. It should also be at the forefront of developing new safety analysis and investigation techniques, and have the capacity to provide guidance and leadership on safety investigation to the wider healthcare system. The staff of a national patient safety investigator should have deep knowledge and experience in safety investigation: the core staff should be experts in safety investigation first, and in healthcare second. If

highly technical and specific knowledge on particular aspects of clinical practice or healthcare technology is needed, for instance, then an investigator should be able to draw on appropriate external specialist knowledge. As discussed later, investigation teams will, in practice, almost always consist of a core staff of safety specialists and a complement of clinical staff with the expertise relevant to any particular investigation.

### *System-wide*

A safety investigation body must be able to take a system-wide view and conduct safety investigations that span the healthcare system. Even seemingly simple events, such as the delivery of an incorrect dose of drug, can have causes that span many different organisations across the healthcare system—such as the setting of standards, commissioning decisions, regulatory approaches or training and education. James Reason, whose work has helped to define the field of patient safety, emphasized that “one of the most challenging issues in healthcare is that the same situations keep creating similar kinds of error across the system”—and addressing these systemic issues is one of the greatest opportunities for a national safety investigator.<sup>23</sup> It is essential that a national safety investigator is in a position to investigate the sources of risk wherever they arise right across the system, from a hospital ward or general practice clinic to commissioners, regulators, educators and equipment manufacturers. As well as being able to investigate all parts of the healthcare system, a safety investigation body must be able to issue safety recommendations to any organisation or individual that has a role in the healthcare system. In this way, a national safety investigator can act as a systems-integrator, analysing problems from an integrated and systemic perspective.<sup>24</sup>

### *Learning-focused*

The core purpose of a patient safety investigation body must be to conduct safety investigations for the purpose of maximizing learning and improvement across the healthcare system and reducing the risk of harm to future patients. There are two elements to this. First, the focus of all investigative activities should be on developing a detailed understanding of the underlying causes of safety issues and making recommendations to address those deficiencies. Second, the activities of a safety investigator must explicitly avoid attributing blame or liability for past events. This does not prevent an investigation from determining the details of what happened or why. This also does not preclude individuals or organisations being held to account when things go wrong, but this is most certainly not the role of an independent safety investigator. Any assessment of blame, fault or liability is the responsibility of other parties, such as the relevant professional or regulatory bodies. The sole purpose of safety investigation must be to identify and explain the causes of safety deficiencies and make recommendations for safety improvement.

## *Trusted*

A patient safety investigation body must be trusted in order to achieve any of its objectives. Patients, families and the public must trust that safety investigations are impartial, free of any conflict of interest and have the best interests of patients and service users at heart. Staff, healthcare professionals and system leaders must equally trust that safety investigations are being conducted fairly and in the interest of improving care. All parties must feel that the investigator is entirely impartial and is acting in the best interests of the public good. Building and maintaining trust is a slow and challenging process. As David Gaba, Associate Dean at Stanford Medical School and an international leader in patient safety, puts it, “no single case establishes trust in an investigator. It takes time to build through its history, slowly demonstrating what it has done and what it has achieved.”<sup>25</sup> There are no shortcuts, and trust can be lost rapidly.

## 4. Practices of a system-wide investigator

The work of safety investigation involves examining the past in order to improve the future. For a national safety investigator, this work entails first identifying which events to investigate. This is followed by an iterative investigative process of gathering evidence and piecing together what happened and why, by explaining the underlying causal factors and system weaknesses. Finally, it requires the development of a set of targeted recommendations to improve safety. In the sections that follow we examine the five key areas of practice and infrastructure that must be addressed to build a successful national patient safety investigator. First, when—and what—should a safety investigation agency investigate? Second, what people, knowledge and skills are required to conduct investigations? Third, how should a national safety investigator engage with participants in a safety investigation, including patients, families and staff? Fourth, how should safety information be gathered, handled and analysed? And fifth, how should findings and recommendations be developed?

### When, and what, to investigate

When, and what, should a national patient safety investigation agency investigate? This question is challenging due to the large number of serious safety incidents that regularly cause harm to patients. All serious safety incidents must be investigated by the organisation in which they occurred. The question for a national safety investigator with finite resources is how to prioritise those resources to deliver the greatest benefit to patient safety. As such, decisions regarding when, and what, to investigate should be based on an assessment of the “safety value”<sup>16</sup> that will likely result from an investigation: the potential for system-wide learning and improvement. A range of criteria will help focus investigative attention on areas that are likely to yield the most learning and benefit for patient safety. These should aim to identify serious underlying systemic risks to patient safety, and may include:

- Safety issues and patterns of incidents that are the cause of considerable harm to patients and share common features across the healthcare system.
- Individual incidents that result in particularly severe and widespread harm, and that represent a potentially exemplary case of a common and system-wide issue that is amenable to system-wide intervention.
- Patterns of events that are suggestive of an emerging systemic safety issue with the potential to impact across different areas of the healthcare system and that can be investigated to mitigate future harm.
- Serious safety events where there appears to be a substantial and systematic breakdown in local investigation and learning mechanisms, or a significant and serious collapse in relationships between the key parties involved in an investigation.
- Safety issues and events where there appears to be the potential to generate significant new knowledge, generate considerable insight and galvanise system-wide action around a serious risk to patient safety.

### *Safety issues not incidents*

A national safety investigator should ultimately focus its investigative efforts on understanding and addressing systemic risks—underlying and cross-cutting *systemic safety issues* that span the healthcare system. This requires an assessment and evaluation process that defines the highest priority safety issues currently facing the healthcare system, and then investigates those safety issues by using individual incidents and specific events as exemplary cases to generate system-wide lessons. For example, rather than simply identifying and investigating a single serious incident where an incorrect drug dose caused catastrophic harm to a patient, a national investigation agency might determine that prescribing errors of high-risk medications represent a high-priority systemic risk to patient safety, and as a result undertake an investigation into this systemic safety issue by investigating a set of related serious incidents in different healthcare settings.

### *Identifying systemic risks*

How might a national safety investigator identify high-priority safety issues in the first place? A range of analytical approaches can be taken using an array of safety information and other data. For instance, safety investigators in other industries identify systemic risks by reviewing incident and safety data to uncover related patterns of failure, connections between major safety concerns and recent events, disjunctions between expectations and reality, and novel or entirely new risks.<sup>27</sup> A safety investigation agency staffed by expert investigators and safety analysts would be well placed to develop clear criteria and a robust scanning and assessment process in-house. Clear criteria and processes should be established, but a national safety investigator should always retain flexibility in its decisions to investigate. This allows investigations to be responsive to changing threats to patient safety, open to undertaking proactive investigations into emerging risks, and flexible to changes in understandings of risk as knowledge evolves. It also ensures that a national safety investigator retains its independence of thought and action.

### **Investigators, skills and capacity**

Who should lead major safety investigations and what knowledge and skills are needed to do this effectively? Safety investigation is challenging and specialist work. In other safety-critical industries, safety investigation represents a well-established and respected professional community with a long history.<sup>16</sup> The safety investigation profession remains in its infancy in healthcare.<sup>17</sup> As a result, the quality of safety investigations is highly variable,<sup>28,29</sup> and can be extremely poor. James Titcombe, whose son Joshua died in 2008 aged just 8 days and who has since become a leading campaigner and national figure in patient safety, personally experienced the poor quality of investigations into serious failures in healthcare. “In my work in the nuclear industry, I had seen more comprehensive investigation reports about rusty bolts on machinery than the process we had been through regarding the preventable death of our child.”<sup>30</sup> An important part of building a national patient safety investigator will therefore involve building a cadre of professional safety investigators skilled at

conducting system-wide investigations, while at the same time helping develop the skills and capacity for all safety investigation activities across the healthcare system.

### *Technical and analysis expertise*

A national safety investigation agency will need to be staffed by highly skilled, well trained and experienced safety investigators. These investigators require a range of specialist knowledge and skills: technical, analytical and social. It is important that safety investigators have *technical* knowledge and a broad understanding of healthcare systems. They may or may not have a clinical background but many safety investigators should have professional experience in healthcare, and remain up to date and ‘current’ in their area of professional practice. However, clinical and technical expertise is not the primary knowledge needed by investigators. Investigators must primarily be experts in safety investigation: they should have extensive *analytical* expertise in collecting and interpreting data on organisational failure; explaining and analysing system safety; and developing practical recommendations for improvement and risk reduction. Coupled with this, patient safety investigators, like those in other industries, should embody a professional predisposition to curiosity, systems thinking and explanatory analysis.

### *Social skills and values*

To make effective use of their technical and analytical expertise, investigators need advanced *social* skills and must be adept at working in the messy realities of healthcare. This can involve engaging with a range of professionals and technical experts to determine the best points of intervention for improvement. It can involve engaging in robust and challenging conversations with healthcare leaders, regulators, commissioners and policymakers to determine where safety needs to be improved. And underpinning all of this, it involves communicating compassionately and honestly with patients, families and the public who depend on the healthcare system and suffer tragic consequences when it fails. Safety investigators must embody the principles and values of safety investigation: they must earn the respect and trust of patients, families and staff by honestly communicating deficiencies in the healthcare system and championing the actions needed to improve safety. This will be particularly challenging in the early days of a new safety investigation body. Unlike other safety-critical industries, there is little tradition or widespread understanding of the role and purpose of system-wide, learning-focused safety investigation in healthcare. The leaders of a new patient safety investigator agency will need to educate, explain and demonstrate the power and value of this new organisation.

### *Apprenticeship and training*

In addition to running its own major investigations, a national safety investigator should build broader investigative capacity, and establish a professional cadre of safety investigators, through two other processes. First, a wide variety of healthcare professionals could be offered secondments, fellowships and shadowing opportunities within the safety investigation agency. This will bring specialist expertise into the

investigator itself, and importantly will gradually build investigative knowledge and experience across the healthcare system as secondees or fellows move back to roles across the system. Second, in-depth and extensive safety investigator training should be developed. This training must go far beyond the short courses and workshops currently relied on to educate those running patient safety investigations. Advanced qualifications in patient safety investigation are needed, based on those in other sectors, along with clear training and certification standards. A national safety investigator would be well placed to both offer bespoke training, as well as expert guidance on the standards, curriculum and practical knowledge required of safety investigators.

### **Participation: engaging with patients, families and staff**

How should a national safety investigator conduct its investigations, and how should it engage and interact with patients, families, staff and other healthcare organisations? Effective safety investigation depends on respectful and positive relationships between safety investigators, those people they are investigating and those people who are depending on them for honest explanations and improvement recommendations. A national safety investigator will be dealing with the most challenging and wide-ranging issues in patient safety. It is essential that its interactions with patients and families are compassionate, respectful and honest, and its dealings with staff and healthcare organisations build mutual respect and trust.

#### *Patients and families*

A national safety investigator must engage with patients and families openly and compassionately. It is, after all, the safety of patients that is the driving purpose of this work. There are clear moral and legal duties that require organisations to disclose the truth to patients and families after serious failures of care. Nothing a safety investigation agency does should interfere with these duties. Moreover, patients and families should have a central role in the investigation of safety issues. Their perspective and insight is uniquely valuable and enormously important.<sup>31,32</sup> It is often only patients and families that see the entire trajectory of care that unfolds over time, across multiple care providers and within different parts of the health system.<sup>33</sup> This hard won knowledge should be central to investigations, and the concerns and questions of patients and families should be a touchstone for investigative work. Patients and families should be provided with an emotionally and psychologically safe environment to discuss issues, ask questions and express their concerns openly and free from fear.<sup>34</sup>

#### *Engaging with staff*

It is equally imperative that staff and all other parties to a safety investigation are able to engage whole-heartedly and to honestly work with a safety investigation in a constructive environment. It is impossible to properly understand the nature of patient safety issues without open and honest interaction with healthcare professionals. To ensure the full participation of staff, the processes of safety investigation must be entirely separated from any processes of punitive sanction or performance

management. Healthcare professionals must trust that any process of safety investigation will not seek to allocate blame or liability to their actions, but will focus solely on understanding and explaining the causes of safety issues and the ways patient safety can be improved. Much of this trust hinges on the ways that information collected during a safety investigation is used. This issue is addressed in more detail shortly.

### *Participative investigation*

Safety investigation is a participative process:<sup>35</sup> it depends on the active participation of a range of experts, specialists and other key parties from across the healthcare system to help build a complete picture of the events and risks in question. Widespread participation of all those involved in or impacted by a safety issue is important because it allows a relatively lean investigation body to access the data, insight and knowledge of a wide range of experts to understand the causes of safety issues and their possible solutions. In addition, widespread participation in investigations in itself helps to foster a broader culture of inquiry, reflection and learning. The process of safety investigation is not simply a technical one: people who participate in safety investigations can gain a deeper understanding of how safety issues should be investigated, what questions are important and how they should be answered. The work of a national safety investigator can improve knowledge of particular safety issues across the system, and it can also improve knowledge of the process of safety investigation itself.

### **Collecting and protecting safety information**

The causes of major patient safety issues are rarely limited to a single ward or organisation, but can span the healthcare system—from providers to manufacturers to regulators and beyond. Powers to access safety information must be supported by powers to protect that information from inappropriate use. A national patient safety investigator needs the necessary powers to access and analyse safety information from all relevant sources, including information on clinical practice, financial decisions, regulatory activities and technological designs. Without powers to access all relevant safety information, the underlying systemic causes of safety issues will remain hidden. However, to maintain the trust of staff and their willingness to participate fully and openly, a safety investigator must be able to protect the safety information it collects from inappropriate uses.

If staff fear that anything they say may be used to unfairly blame or inappropriately punish them, then it can be hard—if not impossible—to access the detailed, rich information that is needed to diagnose and address the causes of safety issues. Scott Morrish, whose three-year-old son Sam died in 2010 due to patient safety failings, explains this elegantly: “Fear leads to defensiveness—a bunker mentality that prevents conversation, let alone understanding, learning and improvement. It distorts everyone’s behaviour, no matter how kind people are, or how good their intentions”.<sup>36</sup> To maintain trust and ensure staff are not fearful of participating in a safety investigation, information that is gathered solely for the purposes of safety improvement should only be used for the purposes of safety improvement. This principle lies at the heart of a just culture.

### *Powers to access data, and responsibilities to provide it*

A national safety investigator must have the necessary powers to access all the information it needs, including access to any relevant physical sites or materials, and digital or documentary data held by any individuals or organisations. In particular, safety investigators must be able to meet with and interview any relevant party, and request and expect full and honest cooperation. In other industries such as aviation, national air safety investigators have the power to require people to provide any information useful to an investigation, including signed statements, and it is an offence to obstruct or impede a safety investigation.<sup>37</sup> In practice, these legal powers almost never need to be used in aviation and it would be unthinkable for any individual or organisation to resist efforts by the air accident investigator. But these powers signal the seriousness and importance of openly participating in safety investigations. A national patient safety investigation body needs similar powers. It should be an offence to provide false or misleading evidence to a national patient safety investigation, or in other ways obstruct or resist investigators conducting their duties. It is simply unacceptable to lie, cover-up or otherwise hide information that is needed to understand and improve the safety of healthcare and protect the lives of future patients. This sort of behaviour only serves to amplify the pain and suffering of those who have been harmed.<sup>38</sup>

### *The protection of safety information*

While a legal duty should be placed on staff and healthcare organisations to provide safety investigators access to all relevant safety information, these responsibilities need to be balanced by legal protection of the safety information provided. A national patient safety investigator must above all encourage a culture of openness and learning: staff should trust in the investigative process enough to willingly, actively and openly engage with it. In other industries, a primary source of this trust arises from the confidence that professionals have that information collected solely for the purposes of safety improvement will only be used for the purpose of safety improvement, and will not be automatically made available to the courts or other bodies for punitive purposes or to allocate blame. This means that staff have no reason to fear openly and fully participating in safety investigations—and eliminating fear is important. As Don Berwick, an international leader in healthcare quality and safety, made clear in his review of patient safety in the NHS: “fear is toxic to both safety and improvement”.<sup>6</sup> The protection of safety information from inappropriate use is a founding principle of all successful safety investigators in all other industries. This should be the case in healthcare too, and in England the Secretary of State has indicated that such protections will be put in place to create a ‘safe space’ for staff to participate in safety investigations.<sup>39</sup>

### *Principles of protection*

Putting this into practice in healthcare is challenging. Two principles are important.<sup>16</sup> First, the sole purpose of protecting safety information is to ensure the continued availability of that information: to make sure that staff and organisations remain willing

to openly disclose detailed and extensive data to safety investigators that might not otherwise be available in adversarial or legalistic processes. Second, protecting the safety information collected by safety investigators from automatic disclosure to courts or regulators must neither prevent the proper administration of justice, nor prevent patients and families from receiving clear and honest explanations of how harm occurred. If, during an investigation, potential indications of recklessness or criminality are uncovered, then the relevant bodies in the healthcare system should be notified and may undertake separate inquiries. But a safety investigation agency should have no role in assigning liability or determining blame, or collecting information on behalf of those who do. To do so would undercut the very founding principles of safety investigation and the purpose of an independent safety investigator: of independence, trust and learning. If healthcare staff and organisations view safety investigators as simply an extension of the legal system or other adversarial and punitive modes of investigation, it should be unsurprising if they respond in kind: defensively and legalistically.

One of the most tireless advocates of independent safety investigation in healthcare is Martin Bromiley, an airline pilot who founded the Clinical Human Factors Group after his wife Elaine died in 2005 during a routine operation. Martin emphasises that the way that investigations are actually conducted and the ways that safety information is used in practice will be key to the success of any new patient safety investigator. “The reality will be driven by a safety investigator who can demonstrate to patients, staff and Parliament the highest standards of both investigation and of compassion for all those involved. This will be needed to build trust that any decisions around the use of safety information are managed with the best interests of all at heart”.<sup>40</sup>

## Explaining risks and recommending improvements

A national safety investigator must routinely explain the causes of risks to patient safety, publicly report on its findings and issue recommendations for improvement. The primary vehicle for doing all this is the final safety investigation report. These reports must be publicly available and widely accessible, presenting the facts, describing the events, explaining the causes and making safety recommendations to specific parties. The ultimate purpose of safety investigation is to make risks visible within the healthcare system and to drive practical change and improvement—not simply to issue a report. However, by regularly and openly publishing detailed reports into safety issues and the causes of harm a patient safety investigator will, over time, build up a rich open repository of practical knowledge, useable theories and specific explanations of the systemic causes of risk and the practical sources of safety in different healthcare settings.

### *Analysing and explaining risk*

The investigation and analysis of safety issues is ultimately a theory-building process: it requires the systematic interpretation and synthesis of data to produce a clear, accurate and detailed explanatory account of safety issues and harmful events—an explanation of both what happened and why. Providing public explanations of the system-wide sources

of risk to patient safety is one of the most powerful functions of a national safety investigator. Explanations, or theories, are essential to understanding and guiding future action to improve the safety and quality of healthcare.<sup>41</sup> There are many sophisticated methods that can be used to analyse and explain systemic risks and sociotechnical failures.<sup>22,42,43,44,45,46</sup> A national patient safety investigator should act as a highly visible leader in adapting, developing and applying advanced safety analysis methods, and demonstrating their value in healthcare. Moreover, a national investigator should also develop and embrace innovative methods for circulating new knowledge and spreading safety lessons. For example, informative and emotionally powerful films about serious adverse events can engage front line staff and senior leaders and help to explain risks in compelling ways.<sup>47,48</sup> A national patient safety investigator should seek to combine moving personal stories with insightful analysis to engage and influence a wide audience.

### *Recommendations for safety improvement*

The ultimate purpose of safety investigation is to understand the past in order to improve the future. Safety recommendations provide the main instrument through which a national safety investigator can initiate and guide safety improvement across the healthcare system. A safety investigator needs the power to make safety recommendations to any relevant organisation or individual, including provider organisations, commissioners, professional bodies, regulators, educators, equipment manufacturers or government policymakers. Part of the power of a national safety investigator is in its ability to examine the sources of risk that span the entire healthcare system: but it also needs the power to issue recommendations across the entire healthcare system too.

Safety recommendations need to be targeted at specific actors and be clear about what needs improving, and by whom. However, a safety investigator should not seek to define or design the specific solutions to safety problems, nor should it be involved in enforcing action or monitoring performance. Both of these tasks would damage the independence of a safety investigator, turning it into a regulator enforcing compliance or an improvement body developing solutions—and placing it in the untenable position of potentially investigating its own failures of enforcement or improvement in future. Instead, the safety investigator should recommend what improvement is needed, who would be best placed to deliver this and who may be required to regulate, monitor and enforce those improvements. It should also regularly and publicly review the responses to and impact of its recommendations across the healthcare system.

### *Accountability for improvement*

The safety recommendations issued by a national safety investigator must be made public, and the recipients of those recommendations must be required to respond publicly, explaining the actions they will take—or the reasons for their inaction. This public forum is extremely important: it produces public accountability for making improvements. This form of accountability creates an active responsibility to make things better in the future—which is very different to holding people accountable for

things they have done wrong in the past.<sup>21</sup> Publicly issuing safety recommendations and requiring a public response creates a new form of accountability within a national architecture of patient safety: it creates public accountability for improving patient safety across the entire healthcare system.

Moreover, by publicly issuing safety recommendations to a wide variety of organisations and individuals, a national safety investigator creates distributed responsibilities for reflecting on the safety of practices, inquiring into the design of systems and working on and implementing improvements. In this way the work of a national safety investigator should, over time, increase the capacity for learning and capability for improvement across the healthcare system. Ultimately, the processes of participative and system-wide safety investigation can be a practical improvement process itself. In the best of all possible worlds, by the time a final investigation report is released a safety investigator might simply be reporting on the actions and improvements that have already taken place across the system—and there may be no need to issue any further recommendations at all.

## 5. Conclusion: A catalyst for system change

The success of a new national patient safety investigation body requires more than the careful design of a single organisation. Much of the power that a safety investigator has is derived from the influence its actions have on the broader infrastructure of improvement across a healthcare system: the capacity for professionals, providers, commissioners, designers, regulators and manufacturers to work together to examine and improve the delivery of healthcare. Much of this infrastructure of improvement remains underdeveloped, fragmented or entirely absent in healthcare. The quality of many locally-led safety investigations remains variable, and many harmed patients and families remain trapped in processes of complaints and legal action simply to find out the truth and assure themselves that lessons will be learnt, and that others will not suffer as they have. A safety investigation agency on its own will not immediately solve all of these issues. But there are many reasons to be optimistic.

A truly independent, expert, learning-focused, system-wide and trusted safety investigator can be a catalyst for system change. It will be able to identify and explain the most serious risks to patient safety that span the healthcare system, and develop specific recommendations for addressing these risks. It will be able to demonstrate the importance and value of systematic, rigorous and improvement-oriented safety investigation, and provide expert leadership in developing and applying new approaches to safety improvement in healthcare. It will be able to engage widely and openly with patients, staff, the healthcare system and the public on issues of safety, shining a light on what needs to be improved and acting as a tireless champion for the safety of patients. It will be able to model an approach to investigation and shape a new approach to instituting a just culture in healthcare, in which staff feel able to report safety incidents and participate fully in safety investigations—without fearing that they will be inappropriately blamed or punished for actions which any reasonable person might have taken in similar circumstances.

Perhaps most importantly of all, a system-wide safety investigator will be able to continually examine safety across the whole system to reveal weaknesses in the infrastructure that underpins learning and improvement, creating a healthcare system that is able to routinely diagnose and treat itself. But all of this will only be possible if a national safety investigator commands the confidence and trust of patients, families, professionals, policymakers and the public. Safety investigation is an engine of learning, but the fuel that drives that engine is trust.

## References

1. Department of Health. An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS Chaired by the Chief Medical Officer. London: Department of Health, 2000.
2. Francis, R. Independent Inquiry into Care Provided by Mid Staffordshire NHS Foundation Trust January 2005–March 2009. London: The Stationery Office, 2010.
3. Francis, R. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry. London: The Stationery Office, 2013.
4. Kirkup, B. The Report of the Morecambe Bay Investigation. The Report of the Morecambe Bay Investigation, London, 2015.
5. Keogh, B. Review into the Quality of Care and Treatment Provided by 14 Hospital Trusts in England: Overview Report. London: NHS, 2013.
6. National Advisory Group on the Safety of Patients in England. A Promise to Learn – A Commitment to Act. London: Department of Health, 2013.
7. House of Commons Public Administration Select Committee. Investigating Clinical Incidents in the NHS. London: The Stationery Office, 2015.
8. Macrae, C. Inquiries alone will not tackle failures of care. *Health Service Journal*, April 10th 2013, available online at: <https://www.hsj.co.uk/home/innovation-and-efficiency/inquiries-alone-will-not-tackle-failures-of-care/5056561.article?blocktitle=Resource-Centre&contentID=8630>
9. Macrae, C. Early warnings, weak signals and learning from healthcare disasters. *BMJ Quality and Safety*, 2014; 23: 440–445.
10. Macrae, C and Vincent, C. Learning from failure: the need for independent safety investigation in healthcare. *Journal of the Royal Society of Medicine*, 2014; 107(11): 439–443.
11. Department of Health. Learning Not Blaming. London: Department of Health, 2015.
12. Department of Health. The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016. London: Department of Health, 2016.
13. HSIB EAG. Report of the Expert Advisory Group: Healthcare Safety Investigation Branch. London: Department of Health, 2016.
14. Macrae, C and Vincent, C. A New National Safety Investigator for Healthcare: The Road Ahead. *Journal of the Royal Society of Medicine*, 2017; 110(3): 90–92.

15. Vincent, C., Young, M. and Phillips, A. Why do people sue doctors? A study of patients and relatives taking legal action. *Lancet*, 1994; 343(8913): 1609-13.
16. International Civil Aviation Authority. Annex 13 to the Convention on International Civil Aviation, Aircraft Accident and Incident Investigation. Montreal: ICAO, 2007.
17. Macrae, C. The Problem with Incident Reporting. *BMJ Quality and Safety*, 2016; 25(2): 71-75.
18. Peerally, MF, Carr, S, Waring, J, Dixon-Woods, M. The problem with root cause analysis. *BMJ Quality and Safety*, Published Online First: 23 June 2016. doi:10.1136/bmjqs-2016-005511
19. Public Administration and Constitutional Affairs Committee. Will the NHS never learn? Follow-up to PHSO report 'Learning from Mistakes' on the NHS in England. London: TSO, 2017.
20. Michaelides-Mateou, S and Mateou, A. Flying in the Face of Criminalization: The Safety Implications of Prosecuting Aviation Professionals for Accidents. Aldershot: Ashgate, 2010.
21. Braithwaite, J. The Essence of Responsive Regulation. *UBC law Review*, 2011; 44(3): 475-520.
22. Australian Transport Safety Bureau. Analysis, Causality and Proof in Safety Investigations. Canberra: Australian Transport Safety Bureau, 2007.
23. James Reason, personal communication, May 2015.
24. Dixon-Woods, M and Pronovost, PJ. Patient Safety and the Problem of Many Hands, *BMJ Quality Safety*, 2016; 25: 485-488.
25. David Gaba, personal communication, June 2015.
26. Macrae, C. Close Calls: Managing Risk and Resilience in Airline Flight Safety. London: Palgrave, 2014.
27. Macrae, C. Making Risks Visible: Identifying and Interpreting Threats to Airline Flight Safety. *Journal of Occupational and Organisational Psychology*, 2009; 82: 273-93.
28. Parliamentary and Health Service Ombudsman. Learning from mistakes: An investigation report by the Parliamentary and Health Service Ombudsman into how the NHS failed to properly investigate the death of a three-year old child. London: PHSO, 2016.
29. Care Quality Commission. Learning from serious incidents in NHS acute hospitals: A review of the quality of investigation reports. London: CQC, 2016.
30. James Titcombe, personal communication, Feb 2015.

31. National Patient Safety Foundation's Lucian Leape Institute. *Safety is Personal: Partnering with Patients and Families for the Safest Care*. Boston, MA: NPSF, 2014.
32. Donaldson, LJ. The Wisdom of Patients and Families: Ignore it at our Peril *BMJ Quality and Safety*, 2015; 24: 603-604.
33. Vincent, C and Amalberti, R. *Safer Healthcare: Strategies for the Real World*. London: Springer, 2016.
34. Zimmerman, TM and Amori, G. Including Patients in Root Cause and System Failure Analysis: Legal and Psychological Implications. *Journal of Healthcare Risk Management*, 2015; 27(2): 27-34.
35. Macrae, C. Learning from Patient Safety Incidents: Creating Participative Risk Regulation in Healthcare. *Health, Risk and Society*, 2008; 10: 53-67.
36. Morrish, S. If Fear Hadn't Ruled the NHS my Son Might Have Lived. *The Times*, 12 March 2016.
37. The Civil Aviation (Investigation of Air Accidents and Incidents) Regulations 1996, available online at: <http://www.legislation.gov.uk/ukxi/1996/2798/contents/made>
38. Titcombe, J. *Joshua's Story: Uncovering the Morecambe Bay NHS Scandal*. London: Anderson Wallace, 2015.
39. Department of Health. *Providing a 'Safe Space' in Healthcare Safety Investigations: Consultation*. London: Department of Health, 2016.
40. Martin Bromiley, personal communication, April 2016.
41. Davidoff, F, Dixon-Woods, M, Leviton, L, Michie, S. Demystifying Theory and its Use in Improvement *BMJ Quality and Safety*, 2015; 24: 228-238.
42. Reason, J. *Managing the Risks of Organizational Accidents*. Aldershot: Ashgate, 1997.
43. Turner, B and Pidgeon, N. *Man-Made Disasters*. 2nd edn. Oxford: Butterworth-Heinemann, 1997.
44. Vincent, C, Taylor-Adams, S, Chapman, EJ, Hewett, D, Prior, S, Strange, P and Tizzard, A. How to investigate and analyse clinical incidents: Clinical Risk Unit and Association of Litigation and Risk Management protocol. *British Medical Journal* 2000; 320(7237): 777-781.
45. National Patient Safety Foundation. *RCA2: Improving Root Cause Analyses and Actions to Prevent Harm*. Boston, MA: NPSF, 2016.
46. Duchescherer, C and Davies, JM. *Systematic Systems Analysis: A Practical Approach to Patient Safety Reviews*. Health Quality Council of Alberta: Alberta, 2012.

47. Just a Routine Operation. Available online at: [https://vimeo.com/ 970665](https://vimeo.com/970665)
48. The Human Factor: Learning from Gina's Story. Available online at:  
<https://www.youtube.com/watch?v14IJfoLvLLoFo>

