

POLICY A changing view on patient safety: how the Healthcare Safety Investigation Branch has brought system-focused investigations to the fore

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ABSTRACT

In this perspective, the chair designate of the Healthcare Services Safety Investigation Body (HSSIB), the new arm's length body transitioning from the Healthcare Safety Investigation Branch (HSIB), reflects on how the Francis Inquiry was instrumental in changing the view of patient safety in the NHS, the role of HSIB over the last 5 years in identifying systemic causes of patient harm and what the future holds for HSSIB.

KEYWORDS: HSIB, HSSIB, healthcare safety, patient safety, healthcare safety investigations, safety management, patient harm

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Introduction

The Francis Inquiry brought unprecedented national attention to the fundamental importance of listening to patients, families, carers and staff when they raise concerns about patient safety, and of taking those concerns seriously. The Francis Report¹ was a pivotal event in my career that took me first to the regulation of healthcare and now the investigation of healthcare safety.

At the time it was the latest, and the highest-profile, of several national inquiries in the past decade that had identified persistent problems affecting patient safety across the NHS. The failings at Mid Staffordshire NHS Foundation Trust¹ resulted from closed cultures, the Trust management's emphasis on meeting financial targets set without consideration of patient safety impacts, repeated failure to listen to the concerns of patients and families, bullying and cover-up over harm, and the normalisation of poor care among worn-out, demoralised staff.

The formation of the Healthcare Safety Investigation Branch (HSIB) in 2017,² although not a direct consequence of the Francis Inquiry, aimed to address many of the governance and culture issues identified within it. Healthcare is not the only safety-critical sector where these problems have adversely impacted on safety. HSIB's core remit³ – independent expert-led

investigations into systemic patient safety harm – emerged from evidence⁴ of improved safety cultures and safety performance in other high-risk industries. Independent investigation bodies for aviation, rail, marine and nuclear industries in the UK and internationally had positively transformed safety through a systems-based approach. This involves investigations that focus on learning not blame, creating a climate where staff know that raising concerns about safety is welcomed, encouraged, and taken seriously.

Importantly, safety is recognised as inseparable from other corporate governance priorities – finance, productivity and operational effectiveness. Safety became embedded into the culture and the governance in these sectors. A safety management system (SMS) approach is widely used in other safety-critical industries, enabling proactive assessments of risks, specification of how risks should be managed and lines of responsibility. HSIB is exploring the potential need/role for SMSs in healthcare⁵ with the aim of better understanding the requirements, barriers to implementation and how everyday safety work could be supported.

HSIB has a unique role and a different perspective to offer. Although just one part of the NHS patient safety landscape, it is beginning to positively influence a stronger systemic safety culture in the NHS, through investigations that illuminate where healthcare policy, procedures, working environments and operational systems are more vulnerable to error, as well as mitigating actions to address them. We recognise that there is a crowded patient safety landscape, with many national organisations having individuals and teams focused solely on this area. It is important that different agencies continue to work effectively together and at HSIB we are aiming to identify some of those opportunities to join up the system and work towards a coordinated SMS approach.

Identifying the systemic causes of recurrent patient safety harm

Evidence from national inquiries, as well as NHS incident reporting, suggests that the same patient safety problems kept repeating,⁶ which suggests systemic not individual factors. There was an ethos in the past in which it was assumed that safety events happened because individuals were not trying hard enough. HSIB has been instrumental in changing our understanding of risk and why things

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go wrong. Error is seen as a symptom of system safety problem and not the cause.

HSIB have recognised that similar issues were arising in investigations that were undertaken in very different clinical fields. An analysis reported in our thematic national learning report⁷ used a robust, scientific approach and identified the following three recurring patient safety themes:

- > access to care and transitions of care (when patients move between care providers or care settings)
- > communication and decision making
- > checking at the point of care.

These three themes represent the most significant threats to patient safety that HSIB has found, based on its investigations, so far. HSIB's investigations have aimed to identify the interfaces between trusts and stakeholders when targeting recommendations for improvement. This identification process has revealed that many patient safety problems cannot be tackled without developing an overarching system-wide view and involving multiple stakeholders.

Box 1. Case studies

Action to reduce harm to patients in emergency care settings

In March 2022, we launched an investigation looking at the harm that is caused to patients when there is delays in transferring them to the right place of care.⁸ During investigations we may publish what is known as an interim bulletin but in this case, we have published three interim bulletins which we have never done before (two bulletins also contain safety recommendations to DHSC and NHSE). This was to ensure that we were communicating what we had found so far from a patient safety perspective, given the urgent nature of the challenges currently being seen in emergency care. The investigation is ongoing but the calls to action in the bulletins have received support from those working in on the frontlines of urgent and emergency care and leaders in national healthcare organisations (such as the Association of Ambulance Chief Executives). The high-profile coverage of the interim reports means our commentary on what are seeing in our investigation has reached a wider public level and have resulted in referrals, with people sharing their own experiences with HSIB. The three areas the bulletins covered are patient flow through hospitals,⁹ patient safety accountability¹⁰ and staff wellbeing.¹¹

MHRA issue drug safety update in response to HSIB report

The Medicines and Healthcare products Regulatory Agency (MHRA) produced a drug safety update¹² in January 2023 in response to our report on weight-based medication errors in children.¹³ The investigation was undertaken following a case in which a child received a 10-times overdose of an anticoagulant medicine due to errors in the prescription, dispensing and administration processes. Our report noted that although electronic prescribing and medicines administration systems (ePMAS) are considered an effective way to reduce medication errors, they may cause new technology-related errors. The MHRA has been undertaking work with manufacturers of ePMAS devices to improve reporting of potential errors with ePMAS to MHRA, to reduce these risks.

Box 1 gives two examples of how our investigations have had demonstrable impact through involving multiple stakeholders.^{8–13}

Standardised and consistent investigations led by expert, professional patient safety investigators

Common themes that have been brought to HSIB's attention are that local investigations are often not of high quality, don't involve patients and families, lack a robust methodology, are focused on individual actions and produce ineffective actions for improvement.

Involvement of patients and families is central to our investigations and has been since we were set up in 2017. It has been important to ensure that their experience is included, and their voices heard all the way through the investigation process. We recognised that effectively involving those affected in investigations^{14,15} is fundamental to bringing about safety improvements for all. There have been many reports in the healthcare system where there has been little to no involvement for patients despite evidence that meaningful engagement is crucial part of the learned response. Over the last 5 years, we have built a renowned model of patient and family engagement¹⁶ and are now sharing that learning in various ways.

In 2021, HSIB launched an investigation education programme¹⁷ which is helping to cultivate consistency in local healthcare investigations. It is available to any NHS healthcare provider in England. Overall, our aim with our education programme is to provide a solid academic and theoretical introduction to human factors and systems approaches to healthcare safety investigations, as well as providing practical applications to help inform and assist staff with their own investigations.

Our courses directly also align with and support staff to implement the new NHS Patient Safety Incident Response Framework (PRSIF).¹⁸ PSIRF strongly highlights the importance of involving patients, families, and staff in incidents investigations in an effective and compassionate way. The courses vary from a self-directed training programme with a weekly live discussion to a 1-day live small group session. They have filled up quickly, with enrolments surpassing our expectations and emphasising that there really is an appetite for change from those colleagues working in all areas of healthcare across the system.

We have continued to adapt our offering based on feedback from our learners – we now stand at over 5,000 enrolments – and many have told us through our feedback mechanisms that now they feel much more confident in reviewing their investigations to make sure they are taking that individual approach and not attributing blame.

Focus on learning investigations helps staff to feel more confident to speak about safety

The Francis Inquiry and many subsequent inquiries have laid bare how staff often feel too afraid to speak up about patient safety risks and poor culture and this leads to low psychological safety, cultures of defensiveness, blame, denial and the risk of cover-ups and scandals.^{1,19–22} HSIB investigations have shown healthcare staff greatly value the opportunity to speak with investigation teams who combine safety science and human factors knowledge alongside multidisciplinary clinical expertise. Speaking openly about what happened is easier when staff know that the purpose

of the conversation is to identify the systemic risks that made delivering healthcare safely more difficult, rather than to pinpoint individuals for blame.

We've also learned through anonymised feedback to our investigation programme that staff themselves very much want to learn how to understand patient safety from a systemic perspective themselves, to better proactively identify risk and appropriate mitigating actions. HSIB's investigation programme has alumni networks provide trained individuals with direct ongoing support from HSIB staff and peer support from other trained patient safety investigators. As new courses are developed, a network of 'critical friends' is used for pilots before general release.

Becoming HSSIB

A new organisation, The Health Services Safety Investigations Body (HSSIB), will be established²³ as an independent agency later in 2023. It became a non-departmental body in the Health and Care Act 2022 that was given Royal Assent in April 2022. The Act sets out some of the statutory duties of HSSIB, including increased powers that we do not currently have at HSIB. This will include the provision of 'safe space' protections for evidence gathered during HSSIB investigations, formally described as 'prohibition on disclosure.' We will also have enhanced powers that require people and organisations to cooperate with patient safety investigations. Another key difference is that we will be able to investigate all healthcare services in England, including those in private care which will very much extend our reach, remit and influence. This independence is vital to give full confidence that our investigations are impartial and solely to learn – we have already been operating in this way but the Act sets out a statutory duty for us to not assess blame or liability and to protect the identity of individuals.

We are developing an organisational strategy to support our transition to HSSIB, which builds on everything that I have mentioned above and more. We have learnt a lot over the last 5 years and the strategy will reflect this and provides an opportunity for us to work with our national partners across the system as well as build strong relationships with those people providing care and those receiving care, the voices of patients and families involved or harmed by safety events are central to ensuring safer healthcare for all.

It is important for us to also ensure internally that we are living by our values²⁴ and keep ensuring we have an open, safe and transparent culture in our own organisation – where colleagues feel supported and able to share, a place where they can help shape the new organisation, where they can innovate and are working towards our aim of having a demonstrable impact on the safety of care for patients.

HSSIB's establishment will provide an unparalleled opportunity for us. Our challenge will be how the new body will use its new approach to investigations effectively to have the greatest impact on patient safety and to be a champion of much needed changes in both safety culture and how safety is managed by health services. ■

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