patient safety learning

Mind the implementation gap

The persistence of avoidable harm in the NHS

SAFETY FOR ALL

This report was published on the 7 April 2022 as part of the Safety for All campaign.

This Campaign is focused on driving awareness of the interrelationship between healthcare worker safety and patient safety, highlighting how poor healthcare worker safety standards and practice impact adversely on patient safety, championing the need for a systematic and integrated approach to improve safety practice in both healthcare worker safety and patient safety so that the sum is greater than the parts.

We are calling on the government and leaders in the health and social care sector to recognise that patient safety is to some degree dependent on the delivery of effective healthcare worker safety (and vice versa) and to implement nationwide standards, practice and structures on patient safety culture which take account and where possible align and combine both patient safety and healthcare worker safety.

The campaign is supported by Patient Safety Learning and the Safer Healthcare and Biosafety Network.

patient safety learning

SAFER HEALTHCARE & BIOSAFETY NETWORK

Contents

Executive Summary

> *"To err is human, to cover up is unforgiveable and to fail to learn is inexcusable"*
> Sir Liam Donaldson

This report by Patient Safety Learning highlights a patient safety implementation gap in the UK that results in the continuation of avoidable harm.

Patient Safety Learning is a charity and independent voice for patient safety. Our vision is to help create a world where patients are free from avoidable harm. We believe that urgent system-wide change is needed, with the healthcare system designed with safety at its core. We must mitigate the risk of harm, so that healthcare is safe for patients and for the staff who work in it.

The report forms part of the Safety for All Campaign, which calls for improvements in, and between, patient and healthcare worker safety to prevent safety incidents and deliver better outcomes for all.[1]

Avoidable harm in healthcare and the implementation gap

The World Health Organization states that unsafe care is one of the top ten leading causes of death and disability worldwide, with the NHS estimating that there are around 11,000 avoidable deaths annually due to safety concerns. However, despite a range of international and national initiatives aimed at reducing avoidable harm, it remains a persistent, wide-scale problem.

A key reason for this is the implementation gap, the difference between what we know improves patient safety and what is done in practice. In this report we highlight six specific policy areas where this gap acts as a barrier to patient safety improvement:

1. Public inquiries and reviews
2. Healthcare Safety Investigation Branch reports
3. Prevention of Future Deaths reports
4. When patients and families take legal action
5. Patient complaints
6. Incident reports

Having considered how the implementation gap manifests itself in these areas, we then highlight four common underlying themes:

- Absence of a systemic and joined-up approach to safety
- Poor systems for sharing learning and acting on that learning
- Lack of system oversight, monitoring, and evaluation
- Unclear patient safety leadership

Patient safety as a systems issue and recommendations

We argue that we need to take a systems-approach to improving patient safety.

We are calling the Government, parliamentarians, and NHS leaders to take action to address the underlying causes of avoidable harm in healthcare and inviting them to engage in a system-wide debate about how healthcare can reshape its approach to learning and safety improvement. We also detail specific recommendations relating to the areas of the

implementation gap highlighted in this report, which we hope can form part of a public discussion.

We will be writing to leadership organisations outlining these recommendations and welcome responses from them on our proposals.

1. **Patient safety inquiries and reviews need system-wide commitment and resources, with effective and transparent performance monitoring to ensure that the accepted recommendations translate into action and improvement.**

2. **HSIB reports and their recommendations need system-wide commitment and resources, with effective and transparent performance monitoring to ensure that their recommendations translate into action and improvement.**

3. **The Coroner's Prevention of Future Deaths system needs to be improved so that recommendations for patient safety improvements and organisational responses to the reports can be easily accessed. Processes need to be in place to provide assurance that learning from causal factors of avoidable deaths is captured consistently and the insight from these cases is disseminated and acted upon across all healthcare organisations.**

4. **NHS England and NHS Improvement and NHS Resolution need to work together to improve the process for identifying the causal factors of unsafe care identified through litigation, ensuring this can be disseminated widely and acted on to improve patient safety.**

5. **The introduction of the new NHS Complaints Standards needs to be closely monitored, with clear guidance for organisations on how to implement this and clarity on who is responsible for this within the organisation. This should be accompanied by public transparent reporting by organisations on the rollout of the new standard, allowing for consistent monitoring and comparison.**

6. **NHS England and NHS Improvement and the MHRA must ensure that the development of the new PSIRF and changes to the Yellow Card scheme have a core focus on learning for action and improvement to tackle the implementation issues highlighted in this report.**

Introduction

Avoidable unsafe care kills and harms thousands of people each year in the UK and costs the NHS billions of pounds for additional treatment, support, and compensation costs relating to litigation by those harmed. As well as the moral imperative to ensure that healthcare follows its founding value of 'first do no harm', there is a strong economic and social incentive to make improvements; resources will be better spent delivering excellent quality care and preventing avoidable harm rather than addressing the consequences of unsafe care.

In this report we outline all-too frequent examples of where we fail to learn lessons from incidents of unsafe care and fail to take the action needed to prevent future harm. In some cases, insights from patient safety incidents and recommendations are simply left in reports gathering dust on the shelf. In others, changes may be implemented at a local level, but remains siloed within specific organisations, with a lack of means or commitment to share them or take system-wide action. Frustratingly, time and time again we find ourselves aware of issues that cause avoidable harm but not taking action to address their causes.

We consider that a key reason for the persistence of avoidable harm is an 'implementation gap' in patient safety in the UK, the difference between what we know improves patient safety and what is done in practice. This report focuses on six specific policy areas where this gap exists and acts as a barrier to patient safety improvement. We highlight four common underlying themes that lead to patient safety learning and recommendations falling through this gap and consider what is needed to tackle this and turn recommendations and insights into action and improvement.

Avoidable harm in healthcare

Before discussing how the implementation gap manifests itself in healthcare, we need to be clear about what we mean by avoidable harm and the scale of this problem.

Healthcare is an incredibly complex industry and there are a wide range of different ways in which avoidable harm can occur, some examples of which include:

- Diagnostic errors – delayed, incorrect or missed diagnoses.
- Medication errors – relating to the prescription, dosage, route of administration or omission of medication.
- Unsafe surgery – incidents such as retained foreign objects, wrong site surgery and anaesthesia errors.
- Healthcare associated infections – developing either as a direct result of healthcare interventions or from being in contact with a healthcare setting, such as methicillin-resistance Staphylococcus aureus (MRSA).
- Communication and information errors – between healthcare professionals and patients or between healthcare professionals themselves.

Each year, millions of patients suffer injuries or die as a result of avoidable harm, with the World Health Organization (WHO) stating that unsafe care is likely one of the top ten leading causes of death and disability worldwide.[2] In high-income countries, it is estimated that one in every 10 patients is harmed while receiving hospital care.[3] The harm can be caused by a range of adverse events, with nearly 50% of them being preventable.[4]

In the UK, the NHS estimates that that there are around 11,000 avoidable deaths annually due to safety concerns.[5] It is important to note that these figures were prior to the Covid-19 pandemic. We do not yet have estimates for the huge impact that the pandemic has had on patient safety, including the backlog in care and treatment.

Every avoidable death and disability is an unnecessary tragedy for patients, families and healthcare professionals. Beyond the cost in human lives, unsafe care also extracts other significant tolls, such as:

- The physical and psychological discomfort of patients who experience a long hospital stay or permanent disability because of errors.
- Loss of trust in the health care system by patients.
- Diminished satisfaction by both patients and health professionals.
- Loss of morale and frustration of health professionals at not being able to provide the best care possible.

Society also bears the wider cost of errors as well, in terms of lower levels of population health and indeed lost worker productivity.

Avoidable harm also comes with a huge financial footprint. The Organisation for Economic Co-operation and Development (OECD) estimates that the direct cost of treating patients who have been harmed during their care in high-income countries approaches 13% of health spending.[6] A report last year by the G20 Health and Development Partnership forecast that patient safety issues would cost the global economy a staggering $383.7 billion by 2022.[7]

These costs come from both the corrective action required in response to avoidable harm caused to patients and the costs of litigation and compensation. A recent inquiry by the Health and Social Care Select Committee highlighted that the bill for settling claims in the NHS in 2020/21 came to £2.26 billion, with a further £7.9 billion spent on compensation claims settled in previous years.[8] [9]

While avoidable harm continues to persist at such high levels, thousands of people each year will be harmed or die and scarce funds that could be spent to proactively improve the quality of care will instead be used to deal with the cost of error and harm.

Patient safety and the NHS

Awareness of the impact of avoidable harm in healthcare and the need to make significant improvements to patient safety is a well-established concept.

There was a growing recognition of this during the 1980s and 1990s. In 1999, the Institute of Medicine released a report, *To Err is Human*, which set out that hospital deaths from avoidable harm in the United States could be as high as 98,000 per year.[10] At around the same time in the UK, the Chief Medical Officer published *An organisation with a memory*, analysing the scale and nature of avoidable harm in the NHS and the importance of understanding patient safety incidents and learning from errors.[11]

Patient safety as a concept entered the mainstream of healthcare, and in the last twenty years there has been an increased consciousness of the need to better understand the causes of unsafe care and the action needed to reduce harm, with a range of new roles, programmes and initiatives created to this end.

Table 1: Patient safety

NHS definition:

"Patient safety is the avoidance of unintended or unexpected harm to people during the provision of health care. We support providers to minimise patient safety incidents and drive improvements in safety and quality. Patients should be treated in a safe environment and protected from avoidable harm."[12]

WHO definition:

"Patient safety is a framework of organized activities that creates cultures, processes, procedures, behaviours, technologies and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make error less likely and reduce its impact when it does occur."[13]

At an international level, last year the WHO published its *Global Patient Safety Action Plan*, aimed at providing a framework for countries to develop their national patient safety plans over the next ten years.[14] It sets out a vision of "a world in which no one is harmed in health care and every patient receives safe and respectful care, every time, everywhere". Patient safety has also been recently recognised as a key issue for the G20, included in 2020 as one of the five priorities of G20 Health Ministers.[15]

In the UK, the national *NHS Patient Safety Strategy* was published in July 2019, describing how the NHS aims to improve patient safety over the next five to ten years.[16]

Table 2: The NHS Patient Safety Strategy

To continuously improve patient safety, the NHS Patient Safety Strategy states that it needs to build on two foundations: a patient safety culture and a patient safety system. It details three strategic aims to develop both foundations:

1. Insight – improving understanding of safety by drawing intelligence from multiple sources of patient safety information.
2. Involvement - equipping patients, staff and partners with the skills and opportunities to improve patient safety throughout the whole system.
3. Improvement - designing and supporting programmes that deliver effective and sustainable change in the most important areas.

This Strategy has resulted in a series of new initiatives aimed at improving our approach to patient safety, including:

- Development of a new patient safety incident reporting system.[17]
- A new framework for proposals for involving patients in patient safety.[18]
- Development of a new framework for reporting patient safety incidents.[19]

Another recent announcement aimed at improving patient safety in the NHS has been the decision to create the new role of Patient Safety Commissioner. This is a response to one of the main safety recommendations in the *First Do No Harm* report, published in July 2020 by the Independent Medicines and Medical Devices Safety (IMMDS) Review.[20]

Table 3: The Independent Medicines and Medical Devices Safety Review

This review, led by Baroness Julia Cumberlege, examined how the healthcare system in England responded to reports about harmful side effects of medicines and medical devices, focusing on three specific interventions: Hormone pregnancy tests, Sodium valproate and Pelvic mesh implants.

These interventions had resulted in a truly shocking degree of avoidable harm to patients over a period of decades and the Review described the healthcare system's response to this as "disjointed, siloed, unresponsive and defensive". It set out nine patient safety recommendations of which the Government accepted four, accepted two in part, one in principle and rejected two.[21] One of the recommendations accepted by the Government was:

"The appointment of a Patient Safety Commissioner who would be an independent public leader with a statutory responsibility. The Commissioner would champion the value of listening to patients and promoting users' perspectives in seeking improvements to patient safety around the use of medicines and medical devices."

As part of the Medicines and Medical Devices Act 2021, the UK Government committed to establishing a Patient Safety Commissioner for England. The core role of the Commissioner will be "to promote the safety of patients in the context of the use of medicines and medical devices and to promote the importance of the views of patients and other members of the public in relation to the safety of medicines and medical devices".[22] The Scottish Government also set out proposals to create a Patient Safety Commissioner as part of its Programme for Government 2020-21. Both these new posts were subject to consultation in 2021 and the Department of Health and Social Care is currently in the process of appointing the inaugural office holder in England.[23]

It is clearly recognised, at both an NHS and Government level, that improving patient safety is a key challenge that faces the healthcare system. The implementation of the NHS Patient Safety Strategy and the creation of new Patient Safety Commissioners has continued to progress in that last two years, despite the enormous pressures and challenges faced by both the Department and the NHS as a result of the Covid-19 pandemic.

However, can we be confident that these initiatives will succeed where we have so far failed, in tackling the persistent and wide-scale problem of avoidable harm? We believe that this will not be achieved while the implementation gap in patient safety remains unaddressed. As we will outline next, this present a significant barrier to the vision of continuously improving patient safety and delivering the NHS's commitment and plans for high quality care.

The implementation gap

The implementation gap, referred to in the *Global Patient Safety Action Plan* as the "knowing-doing gap", is the difference between what we know improves patient safety and what is done in practice.[24] This gap can emerge for a number of different reasons:

- Difficulties implementing changes across healthcare – it can be a complex task to change the ways of working and behaviour of many individuals and organisations.

- Patient safety guidance working in theory, but not in practice – actions that may appear to address patient safety issues failing to account for a wide variety of organisational context, culture, and capacities.
- Insights and learning remaining in silos – patient safety improvements remaining locked in specific organisations, with a lack of means or commitment to widely share and disseminate new knowledge.

This challenge is not unique to healthcare. In other safety-critical industries, such as aviation, construction, and nuclear power, eliminating causes of harm and prioritising safety is also of paramount importance. Though these industries differ significantly from healthcare, they face the same challenges in terms of translating the investigation and analysis of safety incidents into practical improvements. However, these industries are often far more effective at adopting a systems approach to this issue, which we will discuss later.

The implementation gap in the NHS was identified as far back as year 2000 in the Department of Health report *An organisation with a memory*:

> *"The NHS record in implementing the recommendations that emerge from these various systems is patchy. Too often lessons are identified but true 'active' learning does not take place because the necessary changes are not properly embedded in practice. Though there is some good evidence of meaningful medium and long-term change as a result of Confidential Inquiry recommendations, for example, these are rarely driven through into practice and the onus for implementation and prioritisation is very much on local services. Takeup can tend to 'plateau' once changes have been implemented by those who are most naturally receptive to them, and there is some evidence that progress nationally can slip back if efforts are not sustained."*[25]

Over twenty years on, it is highly disconcerting that the findings of this report remain deeply relevant, with the implementation gap continuing to undermine our ability to translate insights and lessons from avoidable harm into safety improvements. Too often patients continue to experience harm from problems that have already been identified or addressed elsewhere.

This gap between learning and improvement exists at multiple levels. In this report we will focus on the policy issues and where the gap is broadly exhibited in relation to insights, learning and recommendations. There is much that needs to be done to ensure that the knowledge of best clinical practice is disseminated widely and implemented consistently. However, this report will focus on the systems and organisational implementation gap, the issues relating to specific clinical guidance are out of scope.

In this report we have chosen to focus on six specific areas where this gap exists on a policy level and acts as a barrier to patient safety improvement.

1. Public inquiries and reviews

Over the past twenty years there have been a considerable number of independent inquiries and reviews into serious patient safety failings in the UK.

In some cases, these have taken the form of statutory inquiries. These are governed by rules set out in the Inquiries Act 2005 with legal powers to require witnesses to give evidence and produce documents. There are also specific provisions regarding establishing their Terms of Reference and the procedures that they follow. A recent example of this is the Infected Blood Inquiry, examining the circumstances in which men, women and children treated by NHS were given infected blood and infected blood products, since 1970.

There have also been many non-statutory public inquiries. These are established by a Government minister, but not under an Act of Parliament. They possess a great degree of flexibility on procedure and rules, not being bound by the Inquiries Act, but are unable to compel witnesses to give or produce evidence relevant to their work. A recent example of this is the Independent Medicines and Medical Devices Review, detailed earlier in Table 3.

Table 4 below includes some of the key patient safety inquires and reviews in England over the last decade. This is far from an exhaustive list, there have been many more before and during this time across the whole of the UK and covering a wide range of different services, which also have significant patient safety implications.

Table 4: Key patient safety inquiries in England (statutory and non-statutory) and reviews between 2010-2022

- 2012 – Winterbourne View Hospital: Department of Health review.[26]
- 2013 – The Mid Staffordshire NHS Foundation Trust Public Inquiry.[27]
- 2013 – Berwick review into patient safety.[28]
- 2015 – The Morecambe Bay Investigation.[29]
- 2018 – Independent review into Liverpool Community Health NHS Trust.[30]
- 2018 – The Infected Blood Inquiry.[31]
- 2018 – The Gosport Independent Panel.[32]
- 2020 – The Independent Inquiry into the issues raised by Paterson.[33]
- 2020 – The Independent Medicines and Medical Devices Safety Review.[34]
- 2022 – The Independent Review of Maternity Services at the Shrewsbury and Telford Hospital NHS Trust.[35]
- Ongoing – The Muckamore Abbey Hospital Inquiry.[36]
- Ongoing – Essex Mental Health Independent Inquiry.[37]
- Ongoing – Independent Investigation into East Kent Maternity Services.[38]

Since the introduction of devolution there have #been specific inquiries commissioned by the Welsh Government and the Scottish Government, such as the investigation of maternity services at the Cwm Taf University Health Board, and the Scottish Hospitals Inquiry.[39] [40] There are also significant wider points of patient safety insights and learning that can emerge from the reports by regulatory bodies, such as the Care Quality Commission (CQC), and invited reviews by Royal Colleges'.

Public inquiries and reviews can act as a vital source of insight and learning that can be applied to improve patient safety. They can be used consider in detail the most serious incidents of avoidable harm in healthcare, helping to establish a full series of events, identify points of learning, hold organisations to account and set recommendations to prevent a recurrence of similar failings in future.

However, they also form a major part of the implementation gap in patient safety policy in the UK. A key contributing part of this concerns the inconsistency in the approach to these inquiries. They can often vary significantly in format, process and outcomes depending on the terms of reference and the preferences of the Chair. These inconsistencies also apply to how their final reports are responded to by the Government. In its 2018 report, *Investigation into government-funded inquiries*, the National Audit Office noted:

> *"There is no specific guidance as to how government departments should respond to an inquiry, and the minister has discretion about how to respond. The government's initial response to the inquiries included in our sample ranged from written or oral ministerial statements to Parliament to published reports. All inquiries were acknowledged in a statement to Parliament but, for those inquiries that made recommendations, varying levels of information were included in the government's response."*[41]

For reports concerning patient safety issues, this means that responses can vary in terms of timeframes, details, and the approach taken to implementing recommendations. Processes can lack transparency and will often not provide any framework for subsequently monitoring and evaluating the effectiveness of the recommendations that have been implemented. Again, this absence of follow up has was noted by the National Audit Office:

> *"Once inquiries have concluded, there is no central repository or responsibility across government for tracking whether recommendations have been implemented and ensuring that inquiries have an impact"*[42]

This is not a new problem, with *An organisation with a Memory* noting in 2000 that "there has been little formal evaluation of these processes of inquiry to see what impact they have".[43] Guidance provided in the Inquiries Act is quite broad, there is no rigid template and standards for how inquiries are undertaken, with much scope for interpretation by the Chair, nor any obvious quality assurance oversight. Given this, it is not possible to be assured that all inquiries fully identify the causal factors of avoidable harm and make recommendations that, if implemented, will address these. Simply put, we lack the tools to assess how effective inquiries recommendations are in addressing the patient safety problems they identify.

We also see specific themes around issues such as blame cultures and failure to listen to and respond to patient concerns occur time and again, which would seem to indicate that often recommendations fail to address the underlying causes of these issues.

Without a publicly available central repository and transparent reporting, we cannot easily assess how many of the same recommendations are being made and whether there is a systematic approach in place to implement recommendations. There is currently no way a patient, member of the pubic, parliamentarian, policymaker, or journalist to assess what recommendations have been implemented, whether in full, in part of not at all, across the whole of the NHS or individual organisations. This is a shocking conclusion that is an affront to all those patients and families who have been assured that 'lessons have been learned' and 'action will be taken to prevent future avoidable harm to others'.

Considering one of the reoccurring themes in across patient safety inquiries and reviews, blame culture, in 2013 this was identified as one of the key issues in the Mid Staffordshire Inquiry and the subsequent Berwick Review. The Mid Staffordshire Inquiry highlighted that this was not a new issue, citing its appearance in previous reports:

> *"The evidence to this Inquiry has shown that we have still not managed to move successfully away from the culture of blame which Professor Sir Liam Donaldson, in Organisation with a Memory, and Professor Sir Ian Kennedy, in the report of the Bristol Inquiry, were so keen to banish."*[44]

Seven years later, the Independent Medicines and Medical Devices Safety Review highlighted the continued persistence of this issue:

> *"We heard about the failure of the system to acknowledge when things go wrong for fear of blame and litigation. There is an institutional and professional resistance to changing practice even in the face of mounting safety concerns."*[45]

Two years later, this was mentioned again in the Independent Review of Maternity Services at the Shrewsbury and Telford Hospital NHS Trust, which highlighted fear of speaking out within the maternity services team, noting "a lack of psychological safety in the workplace, and limited the ability of the service to make positive changes".[46]

The importance of moving away from blame culture, towards a positive safety culture, is now identified as a key aim in the NHS Patient Safety Strategy. However, despite this coming up repeatedly as an underlying cause of avoidable harm over two decades of inquiries and reviews, we still only have in the NHS an outline of proposed activity around this. We are yet to see specific and robust measures proposed to address this, such as organisations publishing and reporting on goals to change culture and intervening where poor performance is identified. The results of the NHS Staff Survey over the last three years make clear that too many staff still do not feel safe about speaking up about errors, patient safety incidents and near misses.[47] [48] [49]

Published in 2019, the NHS Interim People Plan reinforces the importance of culture and leadership' changes in the NHS in England but offers few suggestions on *how* organisations should address this challenge. It states that its future full five-year plan will:

> *"…set out how we will embed the culture changes and develop the leadership capability needed to make the NHS the best place to work over the next five years."*[50]

We await with interest the publication of plans for embedding culture change across the NHS, an essential foundation to patient safety. To date however, this still remains a clear example of an issue raised by multiple inquiries and reviews time and time again but that we struggle to address with practical action.

While we lack the means to assess and monitor the impact of recommendations from patient safety inquiries in a holistic and joined up manner, it seems unlikely that these underlying patient safety issues will be addressed. Without this, patient safety concerns will continue to fall through the implementation gap, with avoidable harm inevitably reoccurring for years to come.

Recommendation 1: Patient safety inquiries and reviews need system-wide commitment and resources, with effective and transparent performance monitoring to ensure that the accepted recommendations translate into action and improvement.

2. Healthcare Safety Investigation Branch reports

The Healthcare Safety Investigation Branch (HSIB) came into operation in April 2017 as a division of NHS Improvement, with the aim of improving patient safety through independent investigations into NHS-funded care in England. This was modelled on the approach taken in other safety-critical industries, such as aviation, with learning-focused investigation bodies which are separated from processes that allocate blame, determine liability, or deliver justice.[51]

HSIB undertakes approximately 1,000 independent maternity investigations a year, which are referred to it directly by the NHS trust where the incident took place. These are not

directly published individually but are summarised by an annual publication highlighting outcomes and impacts, key themes, and priorities areas for future work.

Table 5: Healthcare Safety Investigation Branch

HSIB was formed in 2017 to help improve patient safety through independent investigations into NHS-funded care across England. HSIB is funded by the Department of Health and Social Care.

Its investigations primarily fall into one of two categories:[52]

1. National investigations – any group, organisation or person can refer a patient safety concern to HSIB who then assess this against their investigation criteria before deciding whether to conduct a formal investigation.
2. Maternity investigations – these concern incidents in NHS maternity services that meet criteria set out within the Royal College of Obstetricians and Gynaecologists' 'Each Baby Counts' report or the MBRRACE-UK 'Saving Lives, Improving Mothers' Care' report. They are referred to them directly by the Trust where the incident took place.

The Health and Social Care Bill 2021-22 current proceeding through Parliament would give HSIB statutory independence as the new Health Service Safety Investigations Body (HSSIB). The new HSSIB will conduct investigations using 'safe space' powers, which prohibits, on a legal basis, the undisclosed disclosure of protected information held by HSSIB. Alongside this change, responsibility for maternity investigations will be transferred to a new Special Health Authority.[53]

For its national investigations, proposals for these can be submitted to HSIB by any group, organisation, or person. HSIB then reviews these concerns against their investigation criteria before deciding whether to conduct a national investigation, the outcomes of which are published in reports on their website. These investigation reports have several key aspects in common:

- Use a specific 'reference event' to highlight the patient safety incident that is being investigated and its impact.
- An analysis of the key findings from reference event and consideration of the wider context around this.
- Safety recommendations and safety observations. Recommendations are directed at specific organisations who are asked to respond in 90 days of publication of the report. Safety Observations may or may not be directed at a specific organisation and require no formal response.

HSIB reports highlight important gaps in safety in the NHS in England and make well-informed and well-thought-out recommendations for improvement. However, in practice this is another area where there is a significant implementation gap.

A practical limit is that HSIB does not have the responsibility or authority to ensure that its patient safety recommendations are implemented. While organisations are asked to respond in 90 days to a national investigation recommendation, there is no compulsion for them to accept or implement the recommendation. There are also no criteria for responding, meaning if organisations do accept the recommendation, they are under no obligation to provide clear plans or timeframes for implementing them.

If is not the responsibility of HSIB to make sure its recommendations are implemented, or to evaluate their impact and assessing their effectiveness, this begs the question, whose is it? Jeremy Hunt MP, Chair of the Health and Social Care Select Committee last year asked how many of the 1,500 maternity safety recommendations from HSIB had been implemented in full. The response from the Minister for Patient Safety and Primary Care, Maria Caulfield MP, responded as follows:

> *"Responsibility for monitoring the implementation of the Healthcare Safety Investigation Branch's (HSIB) national patient safety recommendations rest with the recipient organisations. The National Patient Safety Committee, coordinated by NHS England and NHS Improvement, has established a pilot to examine how the implementation of all the HSIB's national recommendations could be monitored, the potential resources required and information that may aid future evaluation. The National Patient Safety Committee's draft report on the pilot is currently undergoing review and is expected to be finalised this year.*
>
> *Responsibility for monitoring the implementation of the maternity safety recommendations made by the HSIB rests with individual National Health Service trusts. The HSIB works closely with trusts on addressing emerging themes from the investigations and has quarterly review meetings where trusts provide feedback on the actions being taken to implement the recommendations. The HSIB will raise any immediate concerns to the Department and NHS England and NHS Improvement via governance and assurance meetings."*[54]

We appear to have no system of oversight in this area, no way of verifying that organisations are implementing safety recommendations from HSIB and no assessment of the effectiveness of actions to address the underlying causes of harm. This applies for actions are addressed to a specific organisation or where recommendations are made to the wider healthcare system more broadly.

Further to HSIB safety recommendations, there also appears to be a lack of clarity around the patient safety insights and learning drawn from their safety observations. It is not clear that there is any formal framework on a national level to consider these. It appears that these points are expressed in reports but then fall straight into the implementation gap, reliant on individuals or organisations deciding whether to consider any action at all. We consider this is far too ad-hoc an approach.

While HSIB plays an important role in investigating and uncovering serious patient safety issues, beyond the organisation promoting its own work, there appears to be a lack of a system-wide approach to sharing its findings and recommendations. This is coupled with a clear implementation gap, with a lack of means by which to assess this in a meaningful way.

Recommendation 2: HSIB reports and their recommendations need system-wide commitment and resources, with effective and transparent performance monitoring to ensure that their recommendations translate into action and improvement.

3. Prevention of Future Deaths reports

When a patient dies because of avoidable harm, it is crucial that we learn and where possible implement changes to ensure that others are not similarly harmed. The findings and recommendations of Coroner's Prevention of Future Deaths (PFD) reports can play a key role in this, helping to identify what went wrong and the actions needed to prevent a similar incident taking place in future. This does not just apply to the Trust in which the death

occurred, as learning may often be applicable beyond this organisation for wider system learning.

Table 6: Prevention of Future Deaths reports

There is a statutory duty for coroners to issue a PFD report to any person or organisation where, in the coroner's opinion, action should be taken to prevent future deaths.[55]

The report must state the coroner's concerns and that in the coroner's opinion action should be taken to prevent future deaths. The report need not be restricted to matters causative (or potentially causative) of the death in question. The report must be sent to a person or organisation who the coroner believes has power to take such action. These reports are made publicly available on the Coroners Tribunals and Judiciary website with the organisations involved having a duty to respond within 56 days.

As with the work HSIB however, a significant gap emerges when it comes to the implementation of these reports' recommendations.

At an organisation level, how these reports are responded to appears to vary from trust to trust.[56] Nationally, there is no structured process for monitoring the implementation of safety recommendations contained in a PFD report. There is an open question about who is held accountable if the actions requested are not fully implemented, or if the response taken is ineffective. It is difficult to assess how healthcare providers go about this as there appears to be no specific system to monitor this.

There is also a barrier to sharing patient safety learning from PFD reports. Reports can often cover issues that may be applicable beyond the Trust where the death occurred. In some cases, these reports are sent to the organisation involved and a national body, such as the Department of Health and Social Care or the National Institute for Health and Care Excellence. While such organisations must formally respond, there is no set process for them to disseminate any guidance or changes that may result from this or report back on whether action has been taken.

Also, a Trust may take action to respond to the coroner's recommendation on a safety issue, which satisfies the coroner to the point where they feel that it is no longer necessary to issue a PFD report. In these cases, unless the Trust proactively shares this learning directly, the recommendation and action taken to address it may simply be lost, meaning the same incident could occur at another Trust in future.[57] In other cases the coroner may not recognise a point of wider learning and therefore may not send this to a national body who could potentially share this across the healthcare system.

Another factor that frustrates wider learning is that although these PFD reports are published online, they are not easily searchable or sharable. It is difficult to proactively draw out common themes, actions and response, highlighted in a recent thematic analysis of these reports published in the *Journal of Patient Safety And Risk Management*.[58] These limitations have also been recognised by the National Institute for Health Research School of Primary Care, who have now funded a separate website aimed at tracking and systematically analysing the information from PFD reports.[59]

Further to this, it is not clear that NHS England and NHS Improvement currently undertake any central trend analysis or review to draw out common themes that may be applicable to all organisations, in the same way that the HSIB does when it publishes its investigation reports.

We currently lack assurance that safety recommendations arising from Coroners reports do not simply fall through the gaps in the system, resulting in preventable incidents of avoidable harm recurring.

Recommendation 3: The Coroner's Prevention of Future Deaths system needs to be improved so that recommendations for patient safety improvements and organisational responses to the reports can be easily accessed. Processes need to be in place to provide assurance that learning from causal factors of avoidable deaths is captured consistently and the insight from these cases is disseminated and acted upon across all healthcare organisations.

4. When patients and families take legal action

When a serious incident in healthcare results in a clinical negligence claim, the processes around this can often provide an opportunity to understand what went wrong and the actions needed to prevent harm reoccurring. Such insights may often be applicable beyond the organisation in which the incident took place and provide a point for wider system learning.

NHS Resolution, the body responsible for providing expertise to the NHS on resolving concerns and disputes, identifies this as part its role. It publishes guidance on learning from clinical negligence claims and thematic reviews on specific areas of its work, such as *Learning from suicide-related claims* in 2018.[60] [61] While this work is important and commendable, there exists a significant implementation gap in this area regarding the learning which we draw from litigation processes.

Table 7: NHS Resolution

NHS Resolution is an arm's-length body of the Department of Health and Social Care. It is responsible for providing expertise to the NHS on resolving concerns and disputes fairly, sharing learning for improvement and preserving resources for patient safety.[62] It describes its key functions as:

1. Claims Management.
2. Practitioner Performance Advice.
3. Primary Care Appeals.
4. Safety and Learning.

Its fourth function is aimed at supporting "Claims Management service members to better understand their claims risk profiles to target their safety activity while sharing learning across the system".

As the system currently operates, when clinicians are contacted as experts on litigation cases by a representative from the NHS Resolution 'Panel of Solicitors', as part of this process they are asked to feedback for any general points of learning to be shared across the NHS.

While this is a valuable approach in principle, in practice Patient Safety Learning has heard concerns from both clinicians and lawyers that their feedback has not been shared widely or acted on for improvement. We have contacted NHS Resolution about this process, who

have said that the primary way these general points of learning are fed back into the system is:

- Through their members – these are shared with NHS Resolution member organisations on individual cases, which can be used to subsequently inform their own organisational clinical governance and patient safety processes.
- For wider learning – these inform NHS Resolution's in-depth reviews and studies on specific subject areas.

NHS Resolution have advised us that due to the nature of the information involved in clinical negligence cases, for a combination of privacy, personal sensitivity, and legal reasons they are limited in the ways they can share these insights for learning and improvement.

While there is a degree of complexity involved with sharing such insights more widely, this still means we are missing an enormous and valuable opportunity to extract significant system-wide learning that could improve patient safety. These insights could be used to rapidly share information and opportunities for learning, and enable the Department of Health and Social Care, NHS England and NHS Improvement, CQC, HSIB, the incoming Patient Safety Commissioner's in England and Scotland, and others to identify emerging patient safety trends/concerns.

In its current form, we fail to fully utilise and implement learning from these processes, and we consider that this is an area that requires further review and action.

Recommendation 4: NHS England and NHS Improvement and NHS Resolution need to work together to improve the process for identifying the causal factors of unsafe care identified through litigation, ensuring this can be disseminated widely and acted on to improve patient safety.

5. Patient complaints

Complaints made about healthcare are potentially a powerful source for learning about avoidable harm. Shortfalls in the quality and safety of care that result in a complaint can present an opportunity to identify where problems have occurred in existing processes and procedures, enabling remedial action to be taken to prevent their reoccurrence. Learning from feedback from patients, including formal complaints, can help to identify both issues local to an organisation and those with wider applicability across the healthservice.

However, despite this potential as a source of patient safety insight, too often in healthcare these processes are viewed in a negative light or as a threat, with points for learning and improvement falling through the implementation gap.[63] This is an issue that comes up repeatedly when conducting investigations into major patient safety scandals.

The public inquiry into the Mid Staffordshire NHS Foundation Trust highlighted this issue, noting concerns that the Trust did not have a culture of listening to patients, along with inadequate processes for dealing with complaints. It stated that in the complaints that were responded to that "identifying issues and learning lessons" was not given a high enough priority.[64] The Inquiry made several specific recommendations aimed at creating an effective approach to handling patient complaints, which it described as:

> *"Patients raising concerns about their care are entitled to: have the matter dealt with as a complaint unless they do not wish it; identification of their expectations; prompt and thorough processing; sensitive, responsive and accurate communication; effective and implemented learning; and proper and effective communication of the complaint to those responsible for providing the care."*[65]

Concerns about the failure of complaints processes to identify patient safety issues was also highlighted several years later by the IMMDS Review. It pointed to concerns about the complaints system as a whole, noting it was "both too complex and too diffuse" to promptly identify safety issues arising from a medication or device.[66] In common with the Mid Staffordshire Inquiry, the Review also noted serious concerns about patients not being listened to and the consequences this had for deterring future reporting:

> *"Dissatisfaction with how the system has responded to complaints, sometimes multiple, about named clinicians and individual Trusts has been a common thread throughout our engagement with those affected. If complainants feel their complaints are being disregarded unfairly they, and others, will be discouraged from reporting their concerns and the system's culture of denial and resistance to acknowledging mistakes will continue unchallenged."*[67]

Further to this, the Independent Review of Maternity Services at the Shrewsbury and Telford Hospital NHS Trust, published in 2022, provides yet further evidence of complaints processes in the NHS failing patients. It highlighted concerns about a lack of senior oversight of complaints, an absence of transparency and dismissal of patient concerns. It raised specific concerns about a lack of learning from these processes, stating that:

> *"There is no evidence available that the Head of Midwifery, Director of Midwifery and Clinical Director were ever advisory on complaint responses before they were sent to the Trust's Patient Experience Team for the then CEO's signoff. Neither is there any evidence, that complaint themes and trends were analysed and used proactively to improve the service. Even in the latter years of the review period it was unclear what structure was in place for answering complaints and where the accountability lies."*[68]

In response to this evidence that the existing patient complaints processes are not as effective as they should be and too often do not result in learning or improvement, there has been a recognition and acknowledgement of the need to change this.

In the wake of the Mid Staffordshire Inquiry, a Government commissioned review of NHS hospital complaints, co-chaired by Ann Clwyd MP and Tricia Hart, made a number of recommendations for change in complaints handling and procedures.[69] More recently the Parliamentary and Health Service Ombudsman (PHSO) have been piloting a new NHS Complaints Standards, which place a strong emphasis on senior leaders regularly reviewing what learning can be taken from complaints and how this can be used to improve services.[70] It sets out four criteria that define what an effective complaint handling system looks like:

1. Welcome complaints in a positive way
2. Is thorough and fair
3. Gives fair and accountable responses
4. Promotes a just and learning culture

While these principles are positive and admirable, the implementation gap in this area of patient safety has persisted despite many previous recommendations with similar aspirations, such as those from the Mid Staffordshire inquiry, as they have simply not been translated into change on the ground. The PHSO's new standards, model procedure and guidance is currently being piloted at several sites and is due for rollout across the NHS in

2022. It is vital that the full rollout is effectively overseen, monitored, and evaluated if these aims are truly going to result in a move towards a complaints system and effectively seizes on the insights and learning from complaints processes to improve patient safety.[71]

Recommendation 5: The introduction of the new NHS Complaints Standards needs to be closely monitored, with clear guidance for organisations on how to implement this and clarity on who is responsible for this within the organisation. This should be accompanied by public transparent reporting by organisations on the rollout of the new standard, allowing for consistent monitoring and comparison.

6. Incident reports

A comprehensive approach to incident reporting is a crucial improvement tool in all safety-critical industries, alongside an open culture that supports the importance of this.[72]

In the NHS, a key part of this is incident reports from individual organisations which are subsequently gathered and collated in the National Reporting and Learning System (NRLS). As noted earlier, NHS England is currently in the process of replacing this with its new Learn from patient safety events (LFPSE) service. This is being developed for use by patients and the public; while a public reporting facility does currently exist, it is not widely known, used nor do there appear to be reports published from this.

Table 8: National Reporting and Learning System

The NRLS is a central database of patient safety incident reports.[73]

It was set up in 2003 by the National Patient Safety Agency, following the example set in other safety-critical industries like aviation and nuclear power.[74] It is a single national system for receiving incident reports from healthcare providers across the country, allowing patient safety for patterns, trends, and risks to be identified at a national level.

Most incidents are reported locally via risk management systems, providing the opportunity for local use before submission to the NRLS. From this system national patient safety alerts can be generated, requiring action to be taken by healthcare providers to reduce the risk of death or disability.

There is a separate incident reporting process regarding suspected side effects to medicine and medical devices, the Yellow Card scheme. This is operated by the Medicines and Healthcare products Regulatory Agency (MHRA), allowing voluntary reporting of problems by the public and healthcare professionals.

Table 9: The Yellow Card scheme

The Yellow Card scheme, run by the MHRA, can be used to report safety concerns in regard to:

- Medicines.
- Vaccines.
- Blood factor and immunoglobulin products.
- Herbal or complimentary therapies such as homeopathics.
- Medical devices.
- E-cigarettes including their refill containers (e-liquids).

The intention is that this system acts as an early warning for safety issues that may require further investigation. Reports are entered into a specialised database which the MHRA can then use to analyse reports and identify emerging safety issues that may require further investigation.[75]

While these two systems provide, in theory, the means to gather patient safety insights and learning to inform improvement, questions are often asked as to how effective they are in reducing avoidable harm.

While incident reporting can provide a crucial tool for learning and improvement, there have been difficulties transferring this process from other safety-critical industries to healthcare, as noted by Dr Carl Macrae:

> *"…in translating incident reporting into healthcare from aviation, what was largely missed was that, in airlines and other industries, the rapid detection and resolution of safety issues depend on a deeply embedded and widely distributed social infrastructure of inquiry, investigation and improvement"*[76]

He notes that in healthcare much focus has been primarily on building the infrastructure for incident reporting systems and the inputs but less on the learning and outputs, that we have tended to "collect too much and do too little".[77]

The recently published report into cases of maternal and neonatal harm at Shrewsbury and Telford Hospital NHS Trust highlighted some of most serious problems incident reporting can encounter in the NHS. Despite the Trust having full reporting processes in place, the quality of investigations following these were poor and did not lead to learning and improvement. In its findings, the report noted that an external review by the Royal College of Obstetricians and Gynaecologists found that:

> *"… there was no culture of shared learning, that the RCAs often focused on the wrong issues, lacked system wide actions and focused instead on non-specific actions such as 'share report widely' and 'learn from events'. There was no documentation that action plans were completed and recommendations often focused on individuals, rather than recommendations for system changes."*[78]

Cultural issues can form a significant barrier to the effective use of incident reporting systems. One of these issues is that reporting is often misused as a form of reprimand or threat, leading one of the reporting systems most used in the UK, Datix, coming up time and time again as a verb with the threat "I'm going to Datix you".[79] This can act as a detriment of reporting incidents for learning and action if involvement with this, or inclusion in a report, is associated with fear, retribution and blame.

Another cultural problem is the persistence of blame culture in parts of the NHS, resulting in a reluctance to report incidents, with staff concerned that they will not be treated fairly. This problem was highlighted in the recently published results of the NHS Staff Survey Results 2021, with over 160,000 of members of staff who responded not able to say that they would feel secure raising concerns about unsafe clinical practice.[80] In a closely related question of whether respondents felt safe to speak up about anything that concerns them in their organisation, 38% of respondents (approximately 240,000 members of staff) felt they could not say this was the case.[81]

NHS England and NHS Improvement is currently preparing to reform incident reporting with the creation of a new Patient Safety Incident Response Framework (PSIRF), outlining how providers should respond to patient safety incidents and how and when a patient safety investigation should be conducted.[82] Recognising the need to reform the current approach to improve patient safety, and the implementation gap between investigating unsafe care and applying the learning for improvement, it has stated that:

> *"We know that organisations are struggling to deliver good quality investigations that consistently support the reduction of risk. As a result, opportunities to reduce patient safety incidents can be missed."*[83]

It states that the new approach being taken by PSIRF's:

> *"… refocuses systems, processes and behaviours on delivering a sustained reduction in risk, rather than simply applying a reactive, bureaucratic process that too often does not lead to change."*[84]

PSIRF is being introduced in a phased approach: first supporting several 'early adopter' systems of healthcare providers and commissioners to do so and then using their experiences to inform its wider implementation across the NHS.

While the approach is commendable, a recent evaluation pilot highlighted concerns regarding the availability of training and investigation methodology.[85] This complex and NHS wide change needs to be well led and resourced to achieve its aims. Patient Safety Learning are working with its partners to monitor the implementation of PSIRF and assess the effectiveness of its ambition to close the 'implementation gap' from investigation and reviews of local incidents of avoidable harm. We will be reviewing with interest how the implementation of PSIRF is being supported monitored and evaluated against its ambitious aims to ensure that incident investigation and other sources of insight leads to action for improvement and the reduction of avoidable harm.

Turning to the Yellow Card Scheme, the IMMDS Review raised serious concerns about the effectiveness of this in preventing avoidable harm. In describing how the healthcare system struggles to identify medication and device safety issues, it said:

> *"For decades there has been something known as the 'Yellow Card' system through which clinicians, and indeed patients, can report suspected adverse reactions to treatment. But it is clear that there is gross under-reporting, and our complaints systems are both too complex and too diffuse to allow early signal detection."*[86]

While noting improvements had made to the Yellow Card scheme to improve its accessibility, the report noted that this remained "not well recognised or routinely used" and not simply among patients, but also among healthcare professionals. Considering this criticism, the Government and MHRA have both outlined ongoing work and plans in place improve the Yellow Card scheme.[87]

While incident reporting can be a vital source of learning and insights, the limitations in our current systems and how we follow up on incidents makes it difficult for us to comprehensively translate the data we collect into practical patient safety improvements. We think there are huge opportunities to use real time performance data, using Artificial Intelligence and other approaches, to proactively capture insights into the causes of avoidable harm, insights the NHS and from patients that can provide feedback on clinical performance and the safety in use of medical devices and drugs.

Recommendation 6: NHS England and NHS Improvement and the MHRA must ensure that the development of the new PSIRF and changes to the Yellow Card scheme have a core focus on learning for action and improvement to tackle the implementation issues highlighted in this report.

Common themes

Having considered these six areas where the policy implementation gap undermines our ability to translate patient safety insights and learning into practical improvements, several common themes emerge:

a) Absence of a systemic and joined-up approach

Across each of these areas there is a lack of coordination in how we respond to incidents of avoidable harm in healthcare and the insights and learning that emerge from them.

To take the example of public inquiries and reviews, in the absence of processes to track the implementation of their recommendations, we see both the Government and NHS time and time again respond through separate processes to individual reports that highlight similar systemic patient safety issues. Recurring themes include a blame culture deterring incident reporting and speaking up about safety issues, failure to listen to and dismissal of patient concerns and a lack of engagement by the organisation/s leadership in patient safety. Despite these common threads however, responses to these reports often appear to be dealt with in isolation, rather than considered as part of this wider context.

In a recent example of this, the Government's response to the Paterson Inquiry (published in February 2020) and the IMMDS Review (published in July 2020) were conducted through separate processes, which differed considerably, without reference to each other. While these concerned quite different medical interventions, they also featured significant common patient safety themes around failing to listen and learn from patients after incidents of harm, failing to learn from complaints and gaps in patient safety leadership.

If we are to effectively act on and implement the wide-ranging changes needed to improve patient safety, we need to ensure that the healthcare system's responses to serious patient safety failings do not simply focus on the latest report into avoidable harm. It is important that the Department of Health and Social Care considers recommendations that have been made by and accepted in the past, avoiding making the same recommendations without considering why change has failed to happen. Currently it is far from clear that inquiries and reviews where there are overlapping patient safety themes are being looked it in a coordinated fashion. The healthcare system needs to understand and address the barriers for implementing recommendations, not just continually repeat them.

b) Poor systems for sharing learning and acting on that learning

Another consistent theme across these different areas of the implementation gap is poor or absent systems to share patient safety insights and learning.

Too often when effective solutions are found to prevent avoidable harm there is simply a lack of means by which these are shared more widely. This gap between learning and implementation means that while we may we know what improves patient safety, this information can often remain siloed in specific organisations and health care systems, resulting in patients continuing to experience harm from problems that have already been addressed by others.

This is notable in the case of recommendations from coroners' reports, where there is no structured process for widely sharing the action taken to implement of safety recommendations contained in a PFD report beyond the organisation in question. This manifests itself in a different way in regards to cases where patients and families take legal action. While there are thematic reviews stemming from these cases and sharing learning, local learning and actions in response to incidents may often not be extracted from these processes and shared widely, with legal reasons cited as a barrier preventing this.

In the case of HSIB reports, while there more developed systems to share learning and insights in place, there are significant gaps. This is true of formal recommendations but is particularly pertinent when considering HSIB's safety observations. While theses may provide useful points of learning and improvement there appears to be no system to disseminate or act on these, beyond them being published towards the end of numerous patient safety reports.

In the absence of effective systems to share learning, and with gaps in existing systems, it becomes sadly inevitable that healthcare system continues to fail to learn from our mistakes and the same incidents of avoidable harm reoccur. As a result of this we not only do not always share knowledge of new risks and concerns, but also miss opportunities to learn from good practice. In some cases, organisations may have innovative responses to coroners or HSIB recommendations which improve patient safety. But without the mechanisms to share how this work is done, this knowledge can remain trapped within organisations.

Both our failures to share learning from mistakes and examples of good practice point to a wider challenge – we struggle in healthcare to share more generally, whether as a result of cultural resistance or simply a lack of capacity. At Patient Safety learning we recognise this issue and through our work have developed *the hub*, an online platform for patients, clinicians, managers, and health and social care system leaders to share learning about safety practice and performance.[88] However we also need the NHS to have better routes to share insights and knowledge for learning from avoidable harm and improvement.

c) Lack of system oversight, monitoring, and evaluation

In each of the six areas outlined in this report there is a clear problem of the overall healthcare system lacking the ability to monitor and evaluate the effectiveness of patient safety recommendations.

The recommendations of some inquiry reports are monitored, however for others the timeframes and progress associated with these are at best opaque. We just do not know whether action is being taken and how effective it is. As noted by the National Audit Office, there is no central means for tracking or monitoring whether recommendations have been implemented.[89]

Considering patient complaints, there are significant variations amongst different hospitals concerning how they report on complaints, in terms of the data provided publicly, and what they do in response to these complaints. A recent report by Healthwatch England highlighted the difficulty this creates in analysing whether learning on patient safety issues raised from patient complaints translate into learning and practical improvements:

> *"Earlier this year, we asked hospital trusts a series of questions about their handling of complaints through a Freedom of Information request. In total we had responses from 120 trusts, with 78% telling us that they publish outcomes or learning taken from complaints. Worryingly, we were only able to find evidence of report on learning from complaints for 38% of trusts. This shows that although trusts may believe they are demonstrating learning, this information is not actually accessible to the public."*[90]

In the case of recommendations from coroners' PFD reports and HSIB reports, organisations have a duty to respond within a specific timeframe. However, once their response has been provided, the implementation of any changes is the responsibility of the organisation themselves and is not monitored. There are no means by which to verify their implementation or assess their effectiveness.

Frustration at this process can be seen in reports from coroners' who express concerns that they are seeing deaths occur in similar circumstances without action being implemented to address these issues. Commenting in a PFD report into the death of a patient who fell five times during a hospital stay, Coroner Caroline Saunders noted in her matters of concern that:

> *"During the inquest I was presented with an action plan, however this is not the first action plan I have been presented with (in very similar circumstances) and sadly I am not convinced that this plan will prevent future deaths for the following reasons. The policies referred to above have been in place for several years. I am informed that although there is bespoke documentation training, all staff are trained in falls risk assessment from the time they are in nurse training. Therefore, it is not a lack of understanding or policies which have caused these failures."*[91]

In the case of HSIB reports, there is no existing system of oversight, no way of verifying that organisations are implementing safety recommendations from HSIB and no assessment of their effectiveness. As noted in the recent response to a parliamentary question by Jeremy Hunt MP, this is being explored by the National Patient Safety Committee, but at this time no firm proposals have been produced.

In many cases, we simply lack the tools to measure what action is being taken to implement the recommendations or to assess their impact in reducing avoidable harm in healthcare. This must be an urgent action for the NHS leadership.

d) Unclear patient safety leadership

The three themes above all feed into a broader issue, the weakness in system-level leadership for patient safety. This is not a new problem, previously identified in a 2018 report by the CQC, *Opening the door to change*, which stated:

> *"Arm's-length bodies, including CQC, royal colleges and professional regulators, have a substantial role to play within patient safety, but the current system is confused and complex, with no clear understanding of how it is organised and who is responsible for what."*[92]

At a national level in England, the approach is fragmented with no clear lead body. Different aspects of patient safety are monitored and overseen by the National Patient Safety Team in NHS England, the Healthcare Safety Investigation Branch, the CQC and the MHRA. There are separate regulators in Northern Ireland, Scotland, and Wales, all with patient safety responsibilities. This landscape will be further complicated with the creation of independent Patient Safety Commissioners in England and Scotland and the recently announced new Special Health Authority for Independent Maternity Investigations.[93]

While there are undoubtedly reasons for this division in roles and responsibilities, persistent and new threats to patient safety are rarely neatly contained within a single domain or part of the UK. In this complex governance environment, there is no obvious central point that can identify and coordinate the response to the policy implementation gaps highlighted in this report.

In February 2021 the Government established a National Patient Safety Board, whose membership includes officials from the Department of Health and Social Care, NHS England and the CQC. Its role is set out in its Terms of Reference as:

> *"Programme Board to ensure key leaders and stakeholders are collectively involved in the development and progress of the NHS Patient Safety Strategy and the policy areas where there is a significant patient safety element, including maternity, complaints and clinical negligence cost reduction, as outlined in annex A. The Board will identify gaps and ensure collective action across Government to reduce barriers to the delivery of patient safety via collaboration, partnership and prioritisation across organisations and work programmes with joined up, forward looking planning."*[94]

While this could potentially become a nascent central body for coordinating patient safety activity across the system, it is unclear to the extent to which it is likely to do so. It is currently not publicly promoted and there is little transparency around its activities and remit with no agendas, reports or minutes from its meetings currently published. Its role also appears focused solely on healthcare in England.

Another national body that exists is the National Quality Board. Formed in 2009, it:

> *"… champions the importance of quality and drives system alignment of quality across health and care on behalf of NHS England and Improvement, NHS Digital, the Care Quality Commission, the Office of Health Promotion and Disparities, the National Institute for Health and Care Excellence, Health Education England, the Department of Health and Social Care, and Healthwatch England."*[95]

Its minutes and agendas are published in the public domain; however, it does not appear to have a remit to oversee the insights from inquiries, reports, and other sources of learning nor the performance management of recommendations to ensure learning and improvements for the reduction of avoidable harm.

With this fragmented approach to patient safety leadership, the Secretary of State for Health and Social Care currently lacks the levers and means to address the implementation gap outlined in this report and cannot with confidence assure current and prospective patients patient safety is being placed at the core of healthcare

Patient safety as a systems issue

Despite the growing recognition of the need to make significant improvements to patient safety, and the hard work of many people involved in the sector, avoidable harm continues to persist at an unacceptable rate, fed by its systemic causes. Patient Safety Learning believes that to address this we need to think and act differently, making a transformation change in our approach to patient safety.

Patient safety is typically seen as a strategic priority. This sounds important, but it means that, in practice, health and social care decision-makers will weigh (and inevitably trade-off) the importance of patient safety against other priorities, like finances, resources or efficiency.

We believe that patient safety is not just another priority: it is core to the purpose of health care. Patient safety should not be negotiable.

In doing this we need to address the underlying system causes of avoidable harm. In our report, *A Blueprint for Action*, underpinned by systemic analysis and evidence, we identify six foundations of safe care for patients and these practical actions to address them:[96]

1) **Shared Learning** - organisations should set and deliver goals for learning, report on progress and share their insights widely for action. It is not enough to say, 'we've learned from incidents of unsafe care', we need to see action for improvement and impact.

2) **Leadership** - we emphasise the importance of overarching leadership and governance for patient safety. This is not just about governance; it is about behaviours and commitment too.

3) **Professionalising patient safety** - organisations need to set and deliver high standards for patient safety These need to be used by regulators to inform their assessment of whether organisations are doing enough to prevent avoidable harm and assess whether they are safe.

4) **Patient Engagement** - to ensure patients are valued and engaged in patient safety, at the point of care, if things go wrong and for redesigning health care for safety.

5) **Data and Insight** - better measurement and reporting of patient safety performance, both quantitative as well as qualitative.

6) **Just Culture** - all organisations should publish goals and deliver programmes to eliminate blame and fear, introduce or deepen a Just Culture and measure and report progress.

Bridging the implementation gap

What does taking a systems approach, and placing patient safety as part of the purpose of health and social care, mean for tackling the implementation gap?

There is no silver bullet, the system-wide change we need detailed above goes far beyond the specific areas of concern highlighted in this report. We need to place patient safety and staff safety at the heart of our healthcare system. This also applies to all parts of the system,

including Integrated Care Systems set to become new statutory bodies from July 2022. We need everyone, politicians, policymakers, patients, families and communities, clinicians, managers, system and professional regulators, researchers and academics, and health and social care system leaders involved in this effort.

We are calling the Government, parliamentarians, and NHS leaders to take action to address the underlying causes of avoidable harm in healthcare and inviting them to engage in a system-wide debate about how healthcare can reshape its approach to learning and safety improvement. We also detail specific recommendations relating to the areas of the implementation gap highlighted in this report, which we hope can form part of a public discussion.

We will be writing to leadership organisations outlining these recommendations and welcome responses from them on our proposals.

Recommendations

1. **Patient safety inquiries and reviews need system-wide commitment and resources, with effective and transparent performance monitoring to ensure that the accepted recommendations translate into action and improvement.**

2. **HSIB reports and their recommendations need system-wide commitment and resources, with effective and transparent performance monitoring to ensure that their recommendations translate into action and improvement.**

3. **The Coroner's Prevention of Future Deaths system needs to be improved so that recommendations for patient safety improvements and organisational responses to the reports can be easily accessed. Processes need to be in place to provide assurance that learning from causal factors of avoidable deaths is captured consistently and the insight from these cases is disseminated and acted upon across all healthcare organisations.**

4. **NHS England and NHS Improvement and NHS Resolution need to work together to improve the process for identifying the causal factors of unsafe care identified through litigation, ensuring this can be disseminated widely and acted on to improve patient safety.**

5. **The introduction of the new NHS Complaints Standards needs to be closely monitored, with clear guidance for organisations on how to implement this and clarity on who is responsible for this within the organisation. This should be accompanied by public transparent reporting by organisations on the rollout of the new standard, allowing for consistent monitoring and comparison.**

6. **NHS England and NHS Improvement and the MHRA must ensure that the development of the new PSIRF and changes to the Yellow Card scheme have a core focus on learning for action and improvement to tackle the implementation issues highlighted in this report.**

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