

Broken trust: making patient safety more than just a promise

HC 1444

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About us

The Parliamentary and Health Service Ombudsman (PHSO) makes final decisions on complaints that have not been resolved by the NHS in England, UK government departments and other public organisations.

When we investigate, we gather all relevant information from the person who made the complaint and the organisation they are complaining about. This will include relevant clinical records and information, such as a complaint file. We may get advice from experienced clinical professionals who are specialists in particular areas of care. We weigh up all the evidence impartially to reach a decision. In cases we uphold, we can make recommendations to put things right for the individuals involved.

We share insight from our casework to help improve public services and complaint handling. This includes highlighting failings in systems and failures to follow guidance if complaints show there is a need for further learning.

Foreword from the Ombudsman

‘This must never happen again.’ That phrase is uttered every time an NHS scandal hits the papers. But as we saw in the similarities between inquiries into maternity services in East Kent and Morecambe Bay seven years earlier, lessons are not always learned. It is as vital as ever that my Office continues to call for action to improve learning, accountability and, ultimately, safety.

The last ten years have seen significant activity from policymakers to improve patient safety. We have the NHS Patient Safety Strategy and welcome the introduction of the Patient Safety Incident Response Framework, which recognises the complexity of systems and the risks to staff and patients of a blame culture.

And yet, it is clear from the analysis of our most serious patient safety cases through this report that there is a gaping hole between best practice policy and consistent real-life practice. We may have a very sophisticated understanding of how to prevent patient safety incidents and avoid compounding harm for patients, families and staff when things do go wrong. But our evidence suggests that, on the ground, this is regrettably not always implemented.

Sadly, but perhaps inevitably, mistakes will happen in a complex health system that relies on human judgement. But every time my Office rules that a patient died in avoidable circumstances, it means that incident was not adequately investigated or acknowledged by the Trust. It also means staff, patients and their families had to go through an unacceptably long and painful process to make sure action was taken to address shortcomings and justice was achieved for the patient.

In this report, we consider the reasons for the continued failures to accept mistakes and take accountability for turning learning into action and improvement. We pose questions on how to embed an honest, open and unafraid culture in our healthcare system that supports staff and patients to challenge and learn.

Complex systems need robust regulation and oversight to recognise good practice and identify poor systems. When regulation and oversight work well, they also serve to keep people safe from harm. We need to see less fragmentation of the patient safety landscape. This report will have failed if it prompts the creation of yet another patient safety body or initiative. What we need is a streamlined system that works together, with real leadership from Government.

But the biggest threat to patient safety is a system at breaking point. In this report, we recognise that the NHS itself can only go so far in improving patient safety. We need to see concerted and sustained action from Government to make sure NHS leaders have the tools to prioritise the safety of patients and are accountable for doing so. This means getting past politics to put patient safety at the very top of the agenda.

Rob Behrens CBE

Parliamentary and Health Service Ombudsman

Executive summary

There have been significant developments in patient safety over the last decade. But there is a concerning disconnect between increasing activity and progress made to embed a just and learning culture across the NHS. Recognising the challenging operational context for the NHS, this report draws on findings from our investigations. It asks what more must be done to close the gap between ambitious patient safety objectives and the reality of frontline practice.

We identified 22 NHS complaint investigations closed over the past three years where we found a death was – more likely than not – avoidable. We analysed these cases for common themes and conducted in-depth interviews with the families involved.

What we found

We found that the physical harm patients experienced was too often made worse by inadequate, defensive and insensitive responses from NHS organisations when concerns were raised.

When we looked at the direct causes of harm, we identified four broad themes of clinical failings leading to avoidable death:

- failure to make the right diagnosis
- delays in providing treatment
- poor handovers between clinicians
- failure to listen to the concerns of patients or their families.

We also looked at the further harm – sometimes called compounded harm – that happens when families, who have already experienced the devastating consequences of losing a loved one, try to understand what has happened but are met with a poor response from NHS organisations. We identified several factors that contribute to compounded harm:

- a failure to be honest when things go wrong
- a lack of support to navigate systems after an incident
- poor-quality investigations
- a failure to respond to complaints in a timely and compassionate way
- inadequate apologies
- unsatisfactory learning responses.

Our recommendations

Recognising the complexity of the issues identified, and the lack of easy solutions, our recommendations focus on two areas.

1. Accountability for a robust and compassionate response to harm, which supports learning for systems and healing for families

The Patient Safety Incident Response Framework (PSIRF) offers a new approach to patient safety investigations. It holds great promise but needs to be accompanied by sufficient monitoring and better support for families. We recommend that:

- Integrated care boards, with oversight from NHS England, should closely monitor the impact of the PSIRF to identify any negative consequences of the new flexibility it offers, which gives Trusts more autonomy to decide when a patient safety investigation is needed. This should include paying special attention to the balance of patient safety investigations versus other learning responses in Trusts (or service areas of a Trust) where there are poor Care Quality Commission (CQC) ratings for safety and leadership, or where other national bodies have raised concerns (recommendation 1).
- As part of their quality monitoring role, the PSIRF executive lead on each Board should look at any discrepancies between local and PHSO investigations, or other independent investigations, and make sure the Board discusses them. This should include where local investigations did not take place, or did not find that things went wrong, but PHSO or another independent oversight body later identified failings (recommendation 2).
- The Department of Health and Social Care and NHS England should further scrutinise the lack of compliance with duty of candour. They should review the operation of duty of candour to assess its effectiveness and make recommendations for improvement (recommendation 3).
- The Department of Health and Social Care should commit to funding further independent advocacy to support harmed patients, families and carers when they raise concerns or look for answers after an incident (recommendation 4).

2. Evidencing that patient safety is a top Government and NHS priority

NHS leaders and frontline staff need to be in no doubt of the priority placed on patient safety. But patient voice and leadership for patient safety are fractured. Political leaders have created a confusing landscape of organisations, often in knee-jerk reaction to patient safety crisis points. The Healthcare Safety Investigation Branch (HSIB), the Patient Safety Commissioner, PHSO, NHS England, NHS Resolution and at least a dozen different health and care regulators all play important roles in patient safety. But there are significant overlaps in functions, which create uncertainty about who is responsible for what. The Government must consider the case for streamlining some of these functions, for the benefit of people who use the NHS, their families and carers. This is not about reducing investment in patient safety. It is about creating a system that is coherent and easier to navigate, based on evidence and engagement with patients, families, NHS staff and leaders. We recommend that:

- The Department of Health and Social Care should commission an independent review of what an effective set of patient safety oversight bodies would look like. The review must include meaningful engagement with NHS leaders, staff, patients and families (recommendation 5).

Patient safety must be a consistent priority over the long term. It must not be subject to changes of emphasis or importance each time there is a new minister or leadership change in the NHS. We recommend that:

- The Government should seek cross-party support for commitments to embedding patient safety and the culture and leadership needed to support it as a long-term priority (recommendation 6).

It is not possible to prioritise patient safety while avoiding difficult decisions about the workforce the NHS needs. Patient safety will always be at risk in environments that are understaffed and where staff are exhausted and under unsustainable pressure.

Tackling workforce shortages goes beyond political decisions about resourcing. It is about making the NHS a place where people want to work and stay because they feel valued, not just because it is a vocation. We must break down the false dichotomy between the interests of patients and staff, recognising that a system that does not treat its workforce with humanity and compassion will struggle to extend these qualities to patients and families.

We recognise the Government has promised to publish a new NHS workforce strategy. At the time of writing, this is expected 'shortly'. But for this to properly address the underlying causes of NHS staffing pressures, it needs cross-party consensus. In a sector where it can take nearly two decades to train a consultant doctor, a workforce strategy will only succeed if there is support from across the political spectrum, and far beyond one parliamentary term.

We recommend that:

- The Government should urgently produce its long-awaited long-term workforce strategy, with cross-party support, to increase the numbers entering and staying in the workforce across clinical and non-clinical roles. This strategy must:
 - include independent, evidence-based and fully costed projections of future workforce requirements
 - include detailed plans for training and recruiting new staff, retaining staff already working in the NHS and attracting those who have left to return
 - take account of the mix of different professional skills required, rather than just total numbers in the workforce, and how existing professional skills can be deployed where they are most needed (recommendation 7).

The Department of Health and Social Care should write to the Health and Social Care Select Committee and the Public Administration and Constitutional Affairs Committee within six months of the publication of this report to provide an update on progress against recommendations 3, 4, 5, 6 and 7.

NHS England should write to the Health and Social Care Select Committee and the Public Administration and Constitutional Affairs Committee within six months of the publication of this report to provide an update on progress against recommendations 1 and 3.

Introduction

It is ten years since the landmark Francis Inquiry into failings of care at Mid Staffordshire NHS Foundation Trust. The final report identified a system that should have picked up on appalling deficiencies in quality and safety of care, but ‘failed in its primary duty to protect patients and maintain confidence in the healthcare system’.¹ The report also argued that a fundamental culture shift was needed, to make sure ‘the patient is put first day in and day out.’²

The Francis report was a wake-up call for healthcare systems. In the decade that followed, the patient safety landscape has undergone significant change. Globally, there has been greater recognition of the importance of safety science in healthcare and a strategic approach to patient safety. In 2020, patient safety was included as one of the five priorities of G20 Health Ministers, and 2021 saw the publication of the World Health Organisation Global Patient Safety Action Plan.

The NHS developed an NHS Patient Safety Strategy in 2019, with an updated version expected this year. The strategy has a vision to save 1,000 lives and £100 million per year and has seen some concrete successes in specific areas, such as improved care of premature babies and reductions in prescribing opioids (pain-relieving medicines that have a serious risk of addiction).³ This year, the NHS will roll out the Patient Safety Incident Response Framework (PSIRF), marking a major change in the approach to recording and learning from patient safety incidents. There are also plans to expand the roll-out of medical examiners to provide independent scrutiny of the causes of deaths. This should provide answers for bereaved relatives and help NHS organisations to learn and improve the care of future patients.

On issues of transparency, there is now a legal duty of candour requiring organisations to be honest with families when they make mistakes. And there are freedom to speak up guardians to give staff a route to report patient safety issues in each hospital. There is greater recognition of the insights that patients, families and carers hold, with a Patient Safety Partner role set up to use these insights in managing patient safety.

¹ Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry: Executive summary (February 2013).

² As above.

³ Statistics on impact shared with us by the Patient Safety Strategy team. Improved care of premature babies through optimal cord management (delaying cutting the cord after a baby is born) has saved up to 417 lives since 2020. There have been up to 347 lives saved over two years and 2,152 fewer cases of short-term harm each year, as a result of fewer people with chronic pain being prescribed long-term opioid pain relief compared to 2021. (Figures calculated in March 2023.)

Following the recommendation of the Independent Medicines and Medical Devices Safety Review, the role of Patient Safety Commissioner has been created to amplify the views of patients in relation to medicines and medical devices.

There has also been an important transition to a more widespread understanding of patient safety as a systems issue. As the NHS Patient Safety Strategy recognises, failings in care often result from systems and processes that allow errors to happen, rather than from people who lack the skills to care, or who deliberately cause harm. The national conversation around patient safety now focuses on learning, rather than seeking to blame individuals. And it recognises the huge complexity in healthcare processes, which means to understand when things go wrong, we must look at all the environmental and organisational factors that affect behaviour at work, not just the specific incident. This approach is now supported by the work of HSIB, drawing out national safety recommendations from its investigations.⁴

It is clear there is no shortage of programmes, policies, new initiatives and roles to try to reduce instances of avoidable harm. But there is a disconnect between the increasing levels of activity and consciousness about patient safety and the level of progress we see on the frontline. The statistics about patient harm remain stark. There are an estimated 11,000 avoidable deaths every year in the NHS due to patient safety failings, with thousands more patients seriously harmed.⁵ Behind these numbers are the stories of individuals and their families and friends, whose lives have been shattered as a result of avoidable harm.

There is a well-recognised ‘implementation gap’ – the difference between what we know improves patient safety and what is done in practice.⁶ Overcoming this represents a huge challenge. The NHS is an incredibly complex and sometimes fragmented system, making it challenging to embed changes to working practices and cultures. The structural changes brought in by the 2022 Health and Care Act offer the potential for better collaboration at a regional and local level through Integrated Care Systems and place-based partnerships. But such structural change brings the risk of disruption as local leaders divert attention to building new organisations and relationships. There is also good reason to be concerned about the prospects for reducing avoidable harm when attention is focused overwhelmingly on throughput, and the people and systems that make up the NHS are under growing pressure.

We know there is a long way to go to embed working cultures that can learn and improve in response to failings in some parts of the NHS. In the latest NHS Staff Survey, nearly 40% reported they did not feel safe to speak up about anything that concerns them in their organisation. More worrying still, less than half of staff felt confident their organisation would address their concern.⁷

⁴ From October 2023, HSIB will become the Health Services Safety Investigations Body (HSSIB), an independent public body under the Health and Care Act 2022, with its own ‘safe space’ for confidential investigations. The CQC will host HSIB’s maternity programme.

⁵ NHS England and NHS Improvement (July 2019), ‘The NHS Patient Safety Strategy: Safer culture, safer systems, safer patients’.

⁶ Patient Safety Learning (April 2022), ‘Mind the implementation gap: the persistence of avoidable harm in the NHS’.

⁷ NHS Staff Survey 2022: National results briefing, March 2023.

In clinical safety specifically, more than a quarter of staff did not feel secure raising concerns about unsafe clinical practice and nearly 40% did not feel confident their organisation would address their concern about unsafe practices. These two measures have worsened in the last two years.⁸ This polling is a reminder of the gap between the ‘learning not blaming’ vision of national strategies and the day-to-day experience of frontline NHS professionals.

Concerns about progress in patient safety need to be considered against a backdrop of intensifying workforce pressures, creating further risks. Latest data from NHS England shows there are more than 8,000 doctor vacancies and more than 40,000 nursing vacancies across the NHS.⁹ The CQC, in its latest State of Care report, said that ‘continuing understaffing in the NHS poses a serious risk to staff and patient safety, both for routine and emergency care’.¹⁰

The latest data from the British Social Attitudes Survey shows the cracks are growing. Although the British public remain committed to the founding principles of the NHS as a universal service, funded by taxation and provided free at the point of contact, public satisfaction with the service is now at just 29%. This is seven percentage points lower than the year before and the lowest level since the survey began in 1983.¹¹

The NHS cannot wait any longer. Nor can the people who use it or work in it. We must see urgent action and sustained commitment to address the root causes of problems that result in patient harm.

About this report

Recognising this challenging context, we have developed this report to share learning from our investigations into complaints about serious avoidable harm in the NHS.

Our intention is not to further demoralise NHS staff and leaders at a time of extreme pressure. We recognise that the vast majority of NHS staff are highly motivated to provide excellent care and never intend to cause harm. And we know that involvement in patient safety incidents can be traumatic for staff too.¹²

The Ombudsman has a unique position in the patient safety landscape. We investigate impartially and do not take sides or speak on behalf of patients or clinicians. Our role is to objectively and independently understand what happened. Where we find failings, we make recommendations for learning to improve services and protect patients. The cases we see highlight persistent clinical failings and, perhaps even more importantly, persistent failure to respond to patients and families in a compassionate way when they raise complaints.

⁸ NHS Staff Survey 2022: National results briefing, March 2023.

⁹ NHS Vacancy Statistics, England, April 2015 - December 2022, Experimental Statistics.

¹⁰ CQC (October 2022), State of Care 2022, Summary.

¹¹ The Kings Fund (March 2023), Public satisfaction with the NHS.

¹² See, for example, research outlined in BMJ (2015), ‘Supporting “second victims” is a system-wide responsibility’.

This report builds on the detailed and extensive work of countless others over the past ten years. In recognition of that, we have engaged with policymakers, oversight bodies, regulators, professional bodies and advocacy organisations to test and refine our conclusions and recommendations.

By analysing the unique evidence of complaints we have investigated, we have identified two sets of findings. First, we reflect on common themes that emerge when clinical failings have led to avoidable harm. Despite the diversity in the cases we looked at – some involving babies a few days old, others older adult patients; situations that progressed in a matter of hours and others over a number of years – there are issues that come up repeatedly.

Second, we look at the additional harm – sometimes called compounded harm – that happens when families, who have already experienced the devastating consequences of avoidable harm, try to understand what has happened to their loved ones but are met with a poor response from NHS organisations.

In the final section, we suggest the wider changes needed to see the improvements that patients, families and clinicians deserve when it comes to serious avoidable harm.

How we developed this report

To develop this report, we undertook a qualitative analysis of over 400 detailed health complaint investigations from the past three years. We identified 22 cases where someone had died and we found that the death was – more likely than not – avoidable. We know that relatively few families, having been through a local complaints process while dealing with their own grief, will feel able to keep going and bring their case to us. So these 22 cases are a significant sample of what is likely to be a much bigger problem.

In these cases, we found that the patients would not have died if they had received the right care and treatment at the right time. This happened mainly in inpatient settings in NHS acute trusts, including emergency departments, intensive care units (ICUs) and general medical wards.

We analysed the cases in more detail to develop the themes in this report. We conducted four interviews with families who brought the cases to us, to hear from them directly about their experience of raising concerns with Trusts. We supplemented this with a review of secondary literature on patient safety to put our evidence in context.

Words we use in this report

Throughout this report, we use **clinical failings** to refer to clinical care and treatment that a patient should have received but did not receive.

We use **avoidable harm** to refer to clinical harm that a patient suffers because they did not receive the right care and treatment at the right time.

Our casework evidence on avoidable harm

Clinical failings leading to avoidable harm

Patient harm is a global phenomenon¹³ that happens everywhere patient care takes place. Over 1.25 million staff in the NHS¹⁴ have 1.5 million patient interactions every day,¹⁵ so it is inevitable that mistakes will happen. But, despite improvements over the last ten years, the estimated number of 11,000 avoidable deaths every year is shocking.

After analysing the 22 cases where we found that a death was avoidable, we identified four broad themes of clinical failings leading to avoidable harm:

- failure to make the right diagnosis
- delays in providing treatment
- poor handovers between clinicians
- failure to listen to the concerns of patients or their families.

Failure to make the right diagnosis

In more than half of the cases we looked at, we found that a failure to diagnose directly led to or significantly contributed to the avoidable death of a patient. In these cases, the right diagnosis could have been made at the right time. If this had happened and the correct treatment had been provided, it is likely the patient would not have died.

A range of factors and circumstances can lead to clinicians not making the right diagnosis at the right time, especially when a patient's condition is complex or critical. In our casework analysis, failures to make the right diagnosis were mainly the result of:

- not seeking more senior or specialist input where that would be appropriate
- not observing or monitoring someone at regular enough intervals to recognise deteriorating health or new issues
- failings in imaging, such as failing to follow up on an unexpected finding.¹⁶

¹³ Bennett, S. A. (2020), 'Avoidable deaths in Britain's National Health Service - A systems-thinking informed analysis using data garnered from government agencies, representative bodies, private canvassing and public inquiries'. *International Journal of Healthcare Technology and Management*, 18 (1–2), pp. 95–110.

¹⁴ NHS Workforce Statistics - December 2022.

¹⁵ The King's Fund (October 2022), *Activity in the NHS*.

¹⁶ For a more detailed analysis of failings in imaging, see our 2021 report, 'Unlocking Solutions in Imaging: working together to learn from failings in the NHS'.

In one case we looked at, the patient's National Early Warning Score (NEWS score)¹⁷ showed he was very unwell and should have been reviewed by a more senior clinician with the knowledge and experience to diagnose and treat him while his condition was getting worse. The Trust should have asked for an urgent review by a more senior clinician, but this did not happen. When the patient's condition got worse, the Trust delayed asking for an urgent review, and there were further delays in reviewing the patient. This meant the Trust failed to recognise the patient had sepsis and did not give him the right treatment. The patient suffered a cardiac arrest (when the heart stops pumping blood around the body) and died.

We identified the importance of appropriate and timely senior input in our report on sepsis, 'Time to Act', noting that 'the skills necessary for early identification of patients at risk of severe sepsis are high level and develop with long experience'.¹⁸ It is concerning that a decade after this report, and following huge efforts to improve the early recognition and treatment of sepsis, we still see these kinds of failings.

¹⁷ NEWS is the National Early Warning Score designed to standardise the assessment of and response to acute illness. It combines scores along six physiological measures: respiration rate, oxygen level, blood pressure, pulse rate, level of consciousness or new confusion and temperature. It was updated in 2017 and NEWS2 is endorsed by NHS England as the early warning system for use in all secondary care and ambulance services.

¹⁸ PHSO (2013), 'Time to Act', p. 43.

Case study: failure to diagnose pulmonary embolism

- A man contacted an out-of-hours GP service because he had been suffering from shortness of breath for over a month and had a fever. The GP diagnosed a chest infection and prescribed steroid medication.
- The patient's family called for an ambulance the same evening because his breathlessness had started to get worse. The ambulance crew arrived and took him to hospital.
- The patient's observations showed a fast heart rate, raised rate of breathing and a low level of oxygen in his blood. Staff gave him a nebuliser and his oxygen levels improved.
- A doctor reviewed the patient. An X-ray did not show any concerns. The doctor diagnosed pneumonia, prescribed antibiotics and decided not to admit the patient.
- The following day, a GP visited the patient at home and prescribed an inhaler. They suggested the patient should return to the hospital.
- Later that day, the patient's family called an ambulance because they were concerned about his condition. When the ambulance arrived, the patient was conscious but short of breath.
- The patient suffered a cardiac arrest and the paramedics tried to resuscitate him. Unfortunately, they could not do so and the patient died. The cause of death was a pulmonary embolism (a blocked blood vessel in the lungs).
- We found the doctors failed to follow the relevant guidance when they reviewed the patient at the hospital.
- The clinical signs the patient presented suggested a pulmonary embolism was the likely cause of their breathlessness, high heart rate, high respiratory rate and low oxygen. Doctors should have arranged a specific blood test, but this did not happen. Instead, the patient was sent home without the right treatment.
- The doctors made a diagnosis of pneumonia (inflammation of the lungs) but the chest X-ray results showed the patient's lungs were clear and there was no evidence of blood tests to confirm a diagnosis of infection.
- We found it likely the patient would have survived had he received the right treatment after the doctor reviewed him. This would likely have led to the diagnosis of pulmonary embolism and successful treatment with the right medication.¹⁹

¹⁹ In its report on the diagnosis of pulmonary embolism in emergency departments, HSIB identified a safety risk in missed diagnosis and treatment of pulmonary embolism, given its atypical symptoms: HSIB (2022), 'Clinical decision making: diagnosis of pulmonary embolism in emergency departments'.

We spoke to the patient's mother who described her and her family's experience of seeing the patient die at home:

● 'My son came home with absolutely no information whatsoever ... He should have been in hospital, he should have been on a ward. He died in his bedroom and I had to hear it ... My grandson was in the room next door with me and he heard him die too. It's not something that you would want for anybody.'

Failing to observe or monitor someone at regular enough intervals can result in missed opportunities to recognise deteriorating health or new issues. In one case we looked at, a man was admitted to the Trust's emergency department with chest pains. His condition got worse in hospital but staff did not carry out observations to monitor him as frequently as they should have done. This resulted in a missed opportunity to notice the patient's health getting worse due to sepsis and to involve critical care. It delayed the diagnosis and treatment of sepsis for over ten hours. We found that if the patient had been monitored at appropriate intervals, it is likely his worsening health would have been identified, he would have received treatment for sepsis and, more likely than not, he would have survived.

In another case, a mental health Trust did not observe a long-term inpatient as frequently and as closely as it should have done. The woman attempted to harm herself in a way that could have led to her death on two occasions. Staff managed to stop her from harming herself both times. The Trust should have updated the risk assessment to include actions to reduce any risks and minimise harm, including risks posed by ligature points (anything that could be used to attach a cord, rope or other material for the purpose of self-harm). The following day, the patient was found unresponsive and died because of a hypoxic brain injury (when the brain does not get enough oxygen). We found that if the Trust had observed the patient more closely and frequently and taken action to address ligature points, it was unlikely the suicide attempt would have been completed. If the patient had been monitored more frequently, it is likely there would have been the opportunity to intervene in time and prevent the woman's death.

We spoke with the patient's sister who told us the Trust did not manage to keep her sister safe:

● 'It was supposed to be a place of safety and it clearly wasn't. My sister shouldn't have died in the hospital.'

Case study: failure to carry out repeat risk assessments

- A patient went to a Trust's emergency department with a swollen left hand. The patient had cellulitis (a bacterial skin infection that causes swelling) and gout (a build-up of uric acid causing swelling in the joints).
- The Trust admitted the patient to the hospital and considered their risk of developing venous thromboembolism (VTE, a condition that happens when a blood clot forms in a vein).
- The Trust decided there was no risk and did not carry out any further risk assessments. Staff treated the patient, which included elevating their arm and giving them antibiotics.
- A couple of days later, the patient started experiencing chest pains and tightness in their chest. The Trust carried out an electrocardiogram (ECG, a test to check the heart's rhythm and electrical activity) and provided medication. Later that day, the patient became sick and collapsed.

- The doctor planned to move the patient to a bed with more monitoring. But, before this could happen, the patient suffered a cardiac arrest. The Trust resuscitated the patient and gave them medication to break down blood clots.
- After this, the patient remained stable for a short time during which they were moved to the intensive care unit. Sadly, their condition did not improve and they died that evening. The Trust carried out an autopsy which confirmed the cause of death as a pulmonary embolism (blockage of a lung artery).
- We found the Trust failed to carry out a full assessment of the patient's risk of developing VTE, and then failed to reassess them 24 hours later as outlined in NICE guidance. It missed two opportunities to provide appropriate and timely treatment to prevent a pulmonary embolism.
- Had the Trust given the right treatment on time, it is more likely it could have prevented the pulmonary embolism and avoided the patient's death.

Delays in the treatment response

Our casework shows that serious harm can be caused by delays in providing treatment. In our analysis, we found that these delays often relate to:

- a diagnosis being made but then not being acted on properly or quickly enough
- not acting quickly enough on observations.

In one of the complaints we looked at, the Trust appropriately and quickly diagnosed a woman with vasculitis (inflammation of the blood vessels). Vasculitis is a condition that needs urgent treatment. But the Trust did not prescribe the medication needed for another 16 hours after the diagnosis. After prescribing the medication, the Trust did not give it to the patient for another 11 hours. The Trust significantly delayed giving the patient the life-saving treatment she needed for 27 hours. Our investigation found the patient could have survived if she been given the correct medication in time. It is more likely than not that her death could have been avoided.

When there is evidence that a patient's health is getting worse it is vital to respond quickly, but we found instances where this did not happen. For example, in a case where the on-call doctor did not attend when requested to, we found that the way they were contacted (via a 'bleep') did not include information about the urgency of the request. The Trust explained the system does not give any sign of urgency unless the doctor is being called to attend a cardiac arrest. Our investigation report highlighted that this is a problematic system because it does not allow clinicians to prioritise their patients' needs. We argued that it undermines the benefits of a warning system like NEWS if clinicians are not meaningfully empowered to act quickly in response.

This is a well-known issue. It is highlighted, for example, in a recent national investigation report by HSIB on recognising and responding to critically unwell patients. The report notes that early warning scores ‘can place a high demand on medical staff and the current escalation protocols may not be achievable owing to a task versus resource mismatch’.²⁰ Clearly, monitoring is only useful if there are enough staff to respond when deterioration is detected.

Case study: failure to provide timely sepsis treatment

- A patient went to hospital for a hysteroscopy (a procedure to examine the inside of the womb).
- The procedure was completed without incident and the plan was for her to stay in hospital to be monitored.
- After being transferred to the ward, she felt unwell. Staff carried out assessments to examine her symptoms. The results showed abnormal blood tests, including a very low white blood cell count.
- The patient was referred to and reviewed by the emergency medical response team. The doctors considered sepsis as one of several possibilities for explaining the clinical findings. But they thought this was unlikely so they did not prescribe antibiotics.
- The patient was transferred to the acute medical unit for closer monitoring. The doctor who reviewed her recommended an immediate dose of antibiotics.
- Unfortunately, she did not receive the antibiotics until four hours later. Her health deteriorated significantly in that time.
- This delay in receiving antibiotics meant the patient did not receive timely treatment for sepsis in line with the NICE sepsis guidance.
- Staff performed a CT scan (a computerised tomography scan, which creates detailed images of the inside of the body) the following morning. They prescribed another dose of antibiotics, reviewed the patient and transferred her to the intensive care unit to receive medication to support circulation.
- The patient’s condition did not improve. Doctors explained to her family they could give no further treatment and started end of life care. Sadly, she died that evening.
- We found that the delays in starting antibiotic treatment and admitting the patient to the intensive care unit (to support her circulation) significantly affected her chances of survival.
- If the Trust had done what it should have done, it was more likely that the patient would not have died.

²⁰ HSIB (2021), ‘Recognising and responding to critically unwell patients’.

Poor handovers

Good communication between clinicians and appropriate handover between teams is an essential part of patient safety. General Medical Council guidance²¹ to doctors, for example, stresses the importance of working collaboratively, communicating effectively and sharing information between teams. Equally, the Nursing and Midwifery Council Code of Practice highlights the need to maintain effective communication and keep health and care professionals informed when sharing the care of individuals, to 'preserve the safety of those receiving care'.²² This includes the need for timely and appropriate handovers between teams. Research has identified that transfers into or out of intensive care units and when information has to be communicated to other teams during a critical care stay can be risk points for patient safety incidents.²³

In almost half of the cases we analysed, we found failings in communication between different clinicians and teams. In one case, for example, we could not find any evidence that the Trust followed a clear and coordinated clinical management plan when a man in his seventies attended the Trust's emergency department with a twisted bowel. We found that poor communication between teams contributed significantly to the Trust failing to take urgent action to reduce the risk of bowel perforation. When investigating another case, we could not find evidence of a documented handover between teams. This meant we could not understand what actions the Trust had taken at the time to make sure the patient continued to receive adequate care.

²¹ General Medical Council, 'Domain 3: Communication partnership and teamwork', Good medical practice.

²² Nursing and Midwifery Council, The Code.

²³ Thomas, A.N., and MacDonald, J.J. (2016), 'Patient safety incidents associated with failures in communication reported from critical care units in the North West of England between 2009 and 2014'. *Journal of Intensive Care Society*, 17 (2), pp. 129-135.

Case study: failure to diagnose and lack of handover between teams

- A patient went to a Trust's emergency department after an out-of-hours GP told them to call 999. The patient said they had a racing heart, felt generally unwell and had pain in their forearms.
- The Trust carried out a series of checks and found them to be within normal limits. The doctor prescribed an antibiotic and discharged the patient.
- A few days later, the patient was admitted to a medical assessment unit after a GP referral for a respiratory opinion.
- A consultant reviewed them and noted they might have a blood clot and fluid around the lung.
- The consultant requested a troponin test (a blood test that can help assess heart damage), echocardiogram (a scan to look at the heart and nearby blood vessels) and repeat ECG, and prescribed a blood-thinning injection to treat the suspected clot.
- Another doctor reviewed the patient and considered a pleural effusion (when excess fluid builds up in the space between the lungs and the chest wall) rather than a blood clot. Staff gave the patient antibiotics and drained the fluid around the lung. The following day, the doctor noted the patient's symptoms were improving.
- A couple of days later, a consultant respiratory physician noted that the patient had aching pain in both arms, breathlessness and difficulty breathing when lying down. They reviewed the test results and considered the patient had congestive heart failure (when the heart cannot pump blood around the body properly), which was probably secondary to a recent heart attack.
- The consultant asked for an ECG and troponin test and prescribed medication. They left instructions for staff to triage the patient as a cardiology patient and arrange an ECG to check the heart's rhythm and electrical activity.
- The next day, the patient was moved to a ward and nurses noted that a doctor needed to do a medical review, including reviewing the ECG results.
- Sadly, the patient died the next day after suffering a cardiac arrest.
- We found multiple failings in relation to the patient's care.
- The Trust had not carried out the troponin test and echocardiogram the first time a consultant requested them, and staff did not act on early warning observations when they should have alerted a doctor.
- There was evidence of a heart attack in the ECG results, but this did not get an urgent medical review. And no medical review was carried out after the patient was transferred to the ward.

- If the Trust had made a timely diagnosis and given appropriate treatment, there would have been an improved chance of the patient surviving. It missed an opportunity to provide potentially lifesaving treatment. It was more likely than not that the patient's death was avoidable.
- We found that communication with the patient's next of kin was flawed and incomplete, and there were failings in the Trust's complaint handling that caused them distress and frustration.

Failure to listen to the concerns of patients and their families

Listening to patients and their families is a vital part of providing good quality care and treatment that puts the patient front and centre. In our casework, we identified a small number of cases where failures to listen to the concerns of patients and their families had a clinical impact.

For example, a man who was admitted to hospital with abdominal pain raised concerns with clinical staff on multiple occasions about his care and treatment. During our investigation we found evidence that he was concerned he did not feel well enough to leave the hospital. Despite this, the Trust still considered him well enough to go home and discharged him on the same day. Two days later, he returned to hospital and died shortly after being admitted due to gastric aspiration (where vomit enters the larynx and lungs). Our investigation found that the Trust should have carried out an urgent CT scan, which would have led to the patient having lifesaving surgery.

In another example, a complainant described how he had to persuade staff to admit his mother after she had attended the Trust's emergency department multiple times. During our investigation, we found evidence that staff doubted the patient's symptoms and failed to appreciate the serious nature of her condition. Understandably, this was upsetting for the complainant who could see that his mother was very unwell. The complainant's mother died after having a stroke in hospital. This could have been avoided if she had been diagnosed correctly and treated during an earlier admission.

Summary

The themes we have identified around clinical failings are wide-ranging but will be very familiar to anyone with experience in patient safety. The caseworkers who worked on these cases observed that they reflect the types of issues we see in most of our health casework, not just those that resulted in the most serious possible outcome of a patient's avoidable death.

Although a lot can be done to reduce clinical harm and improve patient safety, and certain incidents can be prevented entirely with the right processes, systems and cultures in place, it is unrealistic to expect that all clinical errors and omissions can be eliminated. But it should always be possible to respond well, with compassion, and in a way that shows learning and accountability when avoidable harm has happened. In the next section we look at the evidence from our casework about the impact on families when this does not happen.

The ongoing impact of clinical harm: compounded harm to families

All too often in our casework, we see families who have already experienced the devastating consequences of avoidable harm suffer further distress because of the response they get from healthcare organisations. This additional harm that people experience when interactions following patient safety incidents feel closed and defensive is known as 'compounded harm'.²⁴ Researchers have recognised the impact of compounded harm, 'especially when people feel unheard or invalidated'.²⁵

Although the idea of compounded harm is not new, it is often neglected in the process of understanding the impact of avoidable serious harm. In this section, we look at evidence of compounded harm in our casework. We highlight the experiences of families who brought cases to us, as they described it during our interviews with them.

When we looked at our casework, we identified the following scenarios that are likely to contribute to compounded harm:

- failure to be honest when things go wrong
- a lack of support to navigate systems in the aftermath of an incident
- poor-quality investigations
- failure to respond to complaints in a timely and compassionate way
- inadequate apologies
- unsatisfactory learning responses.

A failure to be open and honest when things go wrong

The duty of candour requires organisations to be open and honest with patients as soon as possible after they realise something has gone wrong. But we know from our casework that this duty is not always met. In one example, we found the Trust did not disclose the contradictory opinions it had received from different reviewers when determining whether a delay to an operation had resulted in avoidable harm. We judged that this review should have triggered action under the duty of candour, but there was no evidence the Trust had considered its responsibilities to inform the family.

In a case where a baby died after antibiotics were not given quickly enough, we found the Trust had not properly equipped its staff to acknowledge what had gone wrong. Important details about the sequence of events and the nature of the infection were not given to the parents until seven weeks after their son died. Staff even discussed deleting a recording made during a meeting when the parents temporarily stepped out of the room, because they realised what they had said might get the Trust into difficulty. This complete failure of transparency created understandable mistrust and worsened the pain and distress of the family in their grief.

²⁴ This term features in the Patient Safety Incident Response Framework guidance on engaging with and involving families, patients and staff following a patient safety incident.

²⁵ Wailling, J., Kooijman, A., Hughes, J., and O'Hara, J. (2022), 'Humanizing harm: Using a restorative approach to heal and learn from adverse events'. *Health Expectations*, 25 (4), pp. 1192-1199.

Duty of candour

The underlying principle of the duty of candour is that when something goes wrong in the provision of health and care services, patients and families have a right to receive a meaningful apology and explanations for what happened as soon as possible.

The statutory duty of candour was introduced in 2014 in regulations to the Health and Social Care Act 2008.

Regulation 20 puts a legal duty on health and social care to be open and transparent with people using services and their families. It sets out actions that providers must take when a 'notifiable safety incident' happens. Notifiable safety incidents:

- are unintended or unexpected
- happen during the provision of an activity the CQC regulates
- are incidents that – in the reasonable opinion of a healthcare professional – could, or already appear to have, resulted in death or severe or moderate harm to the person receiving care.

As soon as a notifiable safety incident has been identified, organisations must act promptly and are expected to:

- tell the relevant person, face-to-face, that a notifiable safety incident has taken place
- say sorry
- provide a true account of what happened, explaining what is known at that point
- explain what further enquiries or investigations will take place
- follow up by providing this information and the apology in writing, and giving an update on any enquiries
- keep a secure written record of all meetings and communications with the relevant person.

The CQC regulates compliance with the statutory duty of candour. Organisations must have clear policies and procedures in place and make sure staff understand their responsibilities. The CQC also expects senior managers to show they have a safe culture where staff feel able to speak up and are supported to carry out the duty of candour. Failure to comply with the duty can result in enforcement activity ranging from warning or requirement notices to criminal prosecution.

Lack of support to navigate systems in the aftermath of an incident

All our interviewees spoke about the difficulties they had in knowing how to raise concerns about what happened to their family member. A lack of information was a common experience. One complainant explained: ‘we didn’t get any information in regards to letting them [the Trust] know about our experience, how we felt about my mum’s care; all of that was sorted by me and I didn’t get any family support either. I literally did it all by myself’.

Another commented:

● ‘Nobody gave me any information at all. I went online and googled what to do and that was it. Nobody gave me any advice on how to complain, on what to say, or anything like that.’

We also heard some concerns about a lack of independent advice, if it came from the same organisation where the incident took place:

‘I feel like it was a very distressing situation, there was no sort of advice around the complaint. I first complained to PALS which work in the hospital. I don’t actually think that this is a good way for patients to complain about the hospital because the people they complain to work within the hospital.’

Where complainants were able to access independent advocacy services, this was a positive experience:

● ‘I did find an organisation that supported me called POhWER, they were really helpful. I was really upset and distressed and the first lady was very patient with me, very kind, very helpful, she told me the steps to complain. Then that lady left and they gave me another advocate and she was also really helpful ... she read every single page with me, and she literally held my hand all the way through the process. So the advocates were helpful, but in regards to the hospital, there was no help from them.’

Local authorities have a statutory duty to fund independent NHS complaints advocacy. This type of advocacy is provided by trained, professional advocates who can give information, signposting and support with the complaints process. Professional advocacy can be a source of valuable information and guidance, and a way of supporting complainants through what can be a long and difficult process, although emotional or psychological support is not part of the role of professional NHS complaints advocates.

As we highlighted in ‘Making Complaints Count’, NHS complaints advocacy services are limited to helping people navigate the NHS complaints process. Complaints advocacy providers cannot give advice on the clinical parts of a complaint or other processes a complainant might be involved in or considering, such as coroner inquests or making a claim.²⁶

²⁶ PHSO, Making Complaints Count, p. 32.

The benefit of access to advocacy is something the Harmed Patients Alliance recognised in a recent report. It said: ‘well-advised and supported people are more likely to take an active part in investigations without suffering compounded harm’, as well as being better able to take part ‘in a meaningful way in a patient safety investigation under the Patient Safety Incident Response Framework (PSIRF)’.²⁷

Poor-quality investigations

Organisations should provide clear, evidence-based explanations in response to concerns, provide reasons for their decisions, and consider the impact of any failings. We routinely see Trusts fail to accept errors or the extent of what has happened and its impact. In most cases where we found a death was avoidable, the Trust had not conducted a serious incident investigation. And there were no instances of Trusts themselves reaching the same conclusion as our investigation that errors in care led to the death of the patient. Because we use evidence that organisations would have had access to, it is reasonable to expect those organisations should also have been able to identify these errors.

In one case, after delaying its response by a whole year, the Trust responded to a complainant about her mother’s death by summarising what was said in a local resolution meeting (a meeting between the Trust and the complainant). We saw no evidence that the Trust conducted a full investigation into the complainant’s concerns or attempted to address them in any detail. In another case, there were contradictions in the Trust’s written responses and inaccuracies in its account of the care and treatment provided to the complainant’s wife, who had died of a brain tumour. The Trust provided two responses a year apart. The first response accepted there was a delay in identifying that the tumour was growing, while the second response explained events differently.

Some investigations are not as thorough as they should be and crucial parts are missed out. For example, a case in which a senior house officer failed to attend when beeped was a significant moment in understanding failures in care and treatment. But the senior house officer was not interviewed as part of the serious incident investigation that followed. Nursing staff were asked to give statements, but the senior house officer was not. This meant the Trust was unable to explain why there was a delay in responding to the bleep and missed an opportunity to understand the context of the failing. This added to the distress felt by the patient’s partner, who was left with no answers to this important part of the incident.

In some instances, we found the Trust identified the clinical failings correctly but the local investigation failed to consider the impact of them. In one case, the Trust carried out an investigation and correctly identified the clinical failings that led to a mother’s death from sepsis. It made an action plan for improving process, which showed it aimed to learn from the incident, but it did not consider the impact of the failings, which was that the patient’s death would not have happened if they had received the right treatment at the right time. In another case, the Trust initially refused to accept that it should have identified clear abnormalities on an X-ray and did not believe this represented a missed diagnosis.

²⁷ Harmed Patients Alliance (2022), Signpost to Nowhere, p. 4.

Trusts can sometimes use comorbidities (when someone has more than one, often chronic or long-term, disease or condition at the same time) to minimise the impact of any failings or omissions. For example, in a case where there was a significant delay in giving antibiotics, the Trust said the patient's history of cardiac problems and low blood pressure would have limited the patient's response to sepsis. But our critical care advisor said this was not supported by the information available. Examples like these suggest an ingrained defensiveness and lack of curiosity about the causes of harm, which is sadly still prevalent in some Trusts.

Case study: failure to make the right diagnosis and poor-quality investigation

- A patient with a long-standing autoimmune disease went to a Trust's emergency department with symptoms including dizziness, poor balance and blurred vision. The Trust kept the patient overnight for further investigations.
- A doctor carried out a brief initial assessment of the patient and noted they looked unwell and pale. Later in the evening, a nurse took blood samples for testing and examined the patient using a MEWS score (Modified Early Warning Score, an early warning system based on clinical observations). This was recorded as 1.
- The Trust transferred the patient to the acute medical unit to wait for a full medical assessment.
- Later in the night, a doctor assessed the patient and noted nystagmus (involuntary flickering eye movements) in addition to earlier symptoms including blurring of vision and dizziness.
- The doctor made a working initial diagnosis of dehydration. The doctor started a care plan to continue with IV fluids, to monitor IV fluids in and urine out, and to refer the patient to the ophthalmic team if the visual changes did not improve with rehydration.
- Afterwards, the nursing team noted further heart rate increase and that the patient had not passed urine since they went to the acute medical unit. The Trust recorded a MEWS score of 4 – 1 for the increased heart rate and 3 for the lack of urine output.
- The patient told the doctor who attended for review that they were unable to pass urine. The patient was catheterised for urine drainage, which eased their discomfort.
- The following morning, a family member reported a rapid change in the patient's condition. They were concerned about the patient becoming drowsy and unable to speak. This prompted the immediate escalation of their treatment.
- Tests and scans were ordered to try to identify the underlying cause of the change. Shortly after, the patient's condition suddenly got worse and they eventually lost consciousness.

- The CT head scan results showed signs of hydrocephalus (fluid pressure in the brain caused by a blockage stopping fluid from draining out of the skull) and a bleed on the brain. The patient was immediately transferred to the nearest Regional Neurosurgical Department for surgery to relieve the pressure and stop the bleed.
- Despite having two operations to try saving their life, sadly the patient never regained consciousness and died a few days later.
- The surgeon's notes show they found a growth in the brain during surgery, which caused the hydrocephalus and eventually had also been the source of a bleed on the brain.
- We found several failings in the care the Trust gave the patient.
- We found a failing to complete a full neurological assessment and order a CT head scan in response to signs of nystagmus noted by the doctor at the acute medical unit. Although the nystagmus was identified correctly, the doctor missed the significance.
- This led to a missed opportunity to diagnose and treat the patient's condition and potentially avoid their death.
- We found there was failure to make sure the MEWS score was monitored hourly following the MEWS score of 4 being recorded.
- We also found that the Trust's complaint investigation failed to identify and address these issues, which added to the distress and grief suffered by the patient's family.

The Patient Safety Incident Response Framework (PSIRF)

The PSIRF is being rolled out across the NHS, with a deadline for implementation of autumn 2023. While this is too recent to be relevant to the cases in this report, it represents the future for the approach to patient safety in the NHS.

What the PSIRF is changing

The PSIRF replaces the Serious Incident Framework. Unlike the Serious Incident Framework, it is not an investigation framework that prescribes what to investigate (although there are still circumstances where a patient safety investigation will be mandatory: incidents meeting the ‘learning from deaths’ criteria; Never Events²⁸ – safety events that are ‘wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers’; deaths of patients detailed under the Mental Health Act (1983) or where the Mental Capacity Act (2005) applies).

Instead, the PSIRF promotes a range of system-based approaches for learning from patient safety incidents. This includes alternatives to an investigation such as a multidisciplinary team review and a ‘swarm huddle’ – when staff gather to quickly analyse what happened immediately after an incident and decide how to reduce future risks.

The PSIRF is intended to be more flexible, allowing organisations to tailor their response to patient safety so that it is relevant for their contexts and the populations they serve. This flexibility will allow organisations to focus resources on where they can really make an impact, rather than having to always conduct an investigation where that might not lead to new learning or create change. The framework represents a move away from root cause analysis and towards approaches that look at the wider system and human factors.

Under the framework, NHS organisations need to develop a plan and a policy outlining how they will respond to patient safety incidents. There is a focus on compassionate engagement with patients and families, with specific guidance on how to do this well.

In terms of oversight, the framework requires a PSIRF executive lead on each NHS Board, as well as an integrated care board lead who will work with providers on their responses to patient safety. The suggestion is that oversight focuses more on collaborative working and collecting qualitative data, rather than requiring lots of quantitative measures. As stated in the guidance, it ‘focuses on engagement and empowerment rather than the more traditional command and control’.²⁹

Who the PSIRF applies to

The PSIRF is a contractual requirement under the NHS Standard Contract so it will be mandatory for acute, ambulance, mental health and community healthcare providers. This includes maternity and all specialised services. Primary care providers (for example, GPs) may adopt the PSIRF but are not required to at this stage.

²⁸ NHS (2018), ‘Never Events policy and framework’.

²⁹ NHS England, Patient Safety Incident Response Framework supporting guidance: Oversight roles and responsibilities specification, August 2022.

Failure to respond to complaints in a timely and compassionate way

As we are the final stage for unresolved complaints in the NHS, we usually expect people to complain to the organisation they are unhappy with first. This gives the organisation the chance to look into the concerns and, where needed, put things right. We frequently see examples of unacceptable and unreasonable delays in responding to complaints, and failures to keep families informed and updated about the progress of their case. These delays and failings in communication often cause more distress and frustration for complainants and their families at a difficult time.

Case study: failings in care and poor complaint handling

- A patient with bipolar disorder (a mental health condition that affects your moods) attended a hospital's emergency department by ambulance, due to shortness of breath they had been experiencing for a few days.
- Staff arranged a chest X-ray and diagnosed inflammation of the lungs. This inflammation caused impaired oxygen absorption which resulted in respiratory failure. This resulted in low oxygen levels causing the patient to be confused and agitated.
- The patient was admitted to the intensive care unit and prescribed antibiotics and continuous positive airway pressure (CPAP, a type of breathing support).
- A few days later, the patient could breathe without respiratory support and maintain oxygen levels. The consultants considered the patient to be medically stable and transferred them to a ward.
- A couple of days later, the patient had a cardiac arrest. The doctors resuscitated the patient and transferred them back to the intensive care unit.
- Staff carried out an electrical brain wave test, which showed irreversible brain damage. A neurology assessment also confirmed that recovery was unlikely.
- The consultant decided to withdraw critical care support. The patient died later that week. The cause of death was recorded as severe hypoxic brain injury (when the brain does not get enough oxygen) and cardio-respiratory arrest (loss of breathing and heart function).
- We found that staff failed to observe the patient as frequently as they should have. If this had happened, they may have recognised the patient's health deteriorating earlier and called for senior medical input before the cardiac arrest happened.
- We also found the Trust failed to provide planned, focused, one-to-one care for the patient during their time on the ward. If the Trust had provided one-to-one care, staff would have identified the patient's cardiac arrest much sooner.


- If this had happened, it is likely the patient would have been resuscitated without suffering the irreversible brain damage that led to their death. It is likely the patient's death could have been avoided.
- We also found failings in the way the Trust handled the complaint.
- When the patient's daughter complained, the Trust took over six months to arrange an initial meeting to discuss it and failed to provide a written response.
- Before we began our investigation, we asked the Trust to provide a written response. It agreed to do this by the end of the following month but did not provide it until a year later. This meant the complainant only received a response to her complaint about her mother's death two years after complaining to the Trust.

In one case, a man who complained about the death of his wife from a brain tumour had to wait two years for the Trust to conclude its investigation.

In interviews we conducted, complainants described the process of trying to resolve their complaint with Trusts as 'long and torturous', 'a long, dragging sequence of events' and 'very lengthy and distressing'.

Often, Trusts will explain that the complaint department was understaffed or dealing with high staff turnover. We know from previous research that complaint handlers in the NHS may not be sufficiently empowered or trained to resolve a complaint.³⁰

Treating complainants with dignity and compassion is an essential part of resolving a complaint, but we found instances where organisations failed to do this. For example, in one of the complainant interviews, a mother whose son died of a pulmonary embolism told us:

 **'At some point a doctor from the Trust phoned my [other] son to tell him that his brother would have died anyway and there was really no point in carrying on with this.'**

The same complainant told us she felt the Trust 'just weren't interested. It was over, it was done with, and they didn't want to know'.

In another interview, the complainant told us their first meeting with the Trust took place in the same ward where her mother had recently died.

³⁰ PHSO (2020), 'Making Complaints Count: Supporting complaints handling in the NHS and UK Government Departments'.

The complainant said this was so insensitive to her and her family that ‘it felt cruel’. The same complainant told us she did not feel like the Trust was interested in what she had to say:

‘I didn’t think they were interested. I felt like my mum had passed away and so it wasn’t a concern for them. It was almost like, you know, she’s gone now and that was it.’

NHS Complaint Standards

We are committed to supporting and improving frontline complaint handling. We developed the NHS Complaint Standards to support organisations to provide a quicker, simpler and more streamlined complaint handling service. The Standards apply to NHS organisations in England and independent healthcare providers that deliver NHS-funded care.

The Standards have a strong focus on:

- early resolution by empowered and well-trained people
- all staff, particularly senior staff, regularly reviewing what learning can be taken from complaints
- how all staff, particularly senior staff, should use this learning to improve services.

The Complaint Standards are based on ‘My Expectations’, which sets out what patients want to happen when they make a complaint about health or social care services.³¹ The Standards and the guidance modules describe how staff can meet those expectations.

We worked with 11 pilot sites and over 70 ‘early adopters’ across the NHS in 2021-22 to help test how the Standards, supporting materials and training can support frontline complaint handling.

Feedback from the pilot has been overwhelmingly positive, with NHS staff telling us the support on offer will make a real, practical difference and promote consistency. Throughout 2023, we will be working to embed the Standards across the NHS.

Inadequate apologies

Guidance from NHS Resolution makes it clear that apologising is not an admission of fault or liability.³² The same guidance highlights that organisations must make meaningful apologies when things go wrong. It states that a meaningful apology ‘is vital for everyone involved in an incident, including the patient, their family, carers, and the staff that care for them’.

³¹ PHSO (2014), ‘My expectations for raising concerns and complaints’.

³² NHS Resolution, ‘Saying sorry’: ‘The Compensation Act 2006 states; “An apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty”’.

But we still see organisations that fail to give a genuine apology. Organisations may say sorry and accept that failings happened, but it is rarer that they offer a clear and unreserved apology that shows they have understood the impact of those failings on the patient. In 'Making Complaints Count', we identified how a culture of defensiveness can result in staff feeling like they are not allowed to say sorry. Advocates also told us they often see organisations send apology letters that say 'I'm sorry if you felt that...' rather than offering a sincere apology.³³

In one case, the apology letter repeated that the Trust had been asked to accept the failings we found, but it did not go on to do this. Instead, it referred to what the Ombudsman 'felt', which suggests a lack of acceptance of our findings and the learning they offer. The apology letter did not accept responsibility for what happened or even refer to the patient or the fact that they died. In another case, we considered that the Trust's apology letter did not accept that its failings led to avoidable serious harm. In its first apology letter to the complainant, the Trust only apologised for the complainant having 'had cause to raise concerns'. It was clear the Trust did not accept responsibility and had not apologised for the impact of the failings. It was only after repeated contact with the Trust on the content of the apology letter that it gave the complainant an unreserved apology for the avoidable serious harm it caused to the patient.

One complainant told us that after our investigation they felt the 'Trust finally had to accept that they had got it wrong'. But they also said:

● 'I don't think that they did it with a good grace. I think it was just a formula ... They weren't sorry that they'd done it, they were sorry they'd been caught.'

Unsatisfactory learning responses

Most complainants want assurances that something is being done to prevent the same mistakes from happening again. In our recent research on motivations for complaining, 93% of respondents said 'ensuring that others don't face the same issues in the future' was either very important or important in their decision to complain.³⁴ Similarly, in our interviews with complainants, they all said part of the reason why they complained was to make sure the same thing does not happen to other patients, families and carers.

Being able to show that learning has happened is vital if families are to feel their complaint has achieved its purpose. Responses that do not feel meaningful can leave families feeling badly let down and frustrated.

While we do see good examples of thorough action plans, we frequently see less robust responses. These are a missed opportunity for learning from avoidable serious harm and taking action to prevent it from happening again. In one case, we had to follow up multiple times to make sure we were satisfied with the proposed action plan. The Trust did not plan to audit its proposed new processes, so there would be no way of knowing if they were effective.

³³ PHSO (2020), Making Complaints Count, p. 14.

³⁴ PHSO (2023), Outreach Research.

In one interview, the complainant told us:

● ‘I knew that all the things they said they were going to implement to change things, wouldn’t change the way the ward was operated and the way nurses behaved, or the way that the actual patients on the ward felt. It was all just more rules, and probably just more bits of paper for the nurses to fill in, but not translating to an effect on the ward.’

Another complainant told us:

● ‘I don’t believe they’ve learned one lesson.’

It is clear that, far from being a process that promotes learning and provides resolution and healing, the response to families following an incident frequently creates further harm and distress. This is completely unacceptable. Reducing compounded harm must be an urgent priority for everyone working to improve patient safety.

Our recommendations

The issues we have identified are complex. They reflect the fact that healthcare is a web of interactions, behaviours and processes, underpinned by deeply ingrained cultures. If there were readily available, easy solutions to tackle clinical failures and end compounded harm, they would have been implemented long ago.

Facing up to this complexity, we have focused on two themes in our recommendations.

1. Accountability for a robust and compassionate response to harm, which supports learning for systems and healing for families

Our casework shows that many local investigations are not good enough. It cannot be right that in so many instances, the Ombudsman finds errors that the Trust has not identified at an earlier stage. The gap between the findings of local investigations and the findings of our investigations suggests how defensive some NHS cultures can be. In some Trusts, there is still an embedded lack of curiosity about what has happened and what can be learned.

It is important to recognise that our evidence base is just one snapshot in a much bigger picture. We understand that few people will have the energy to keep going and bring their case to the Ombudsman, having been through the trauma of grief, an investigation and a complaints process. This means what we see through our casework is likely to be the tip of the iceberg.

We must improve investigation quality and practices so they aid learning and promote healing, rather than adding to compounded harm. The HSIB has done important work to upskill NHS staff in best practice investigation methodologies, and the PSIRF is an excellent framework to take this even further. There is a lot to welcome in the framework's systems-based approach and emphasis on compassionate engagement.

While we want to endorse the approach the PSIRF outlines, we need to be realistic about how far there is still to go. There is a gap between the welcome rhetoric in PSIRF guidance documents and the defensive behaviours from some NHS leaders we still see in our casework, as evidenced in this report.

The additional flexibility the PSIRF offers (giving Trusts more autonomy to decide when a safety investigation is needed) might present a risk that Trusts with poor cultures do not carry out safety incident investigations when they should. This possibility is not acknowledged in the PSIRF oversight guidance. Rather, the emphasis on 'proportionate responses' focuses more on making sure unnecessary investigations are not conducted if they would repeat old ground or would not lead to learning.

The PSIRF needs to be accompanied by sufficient monitoring and support for families.

We recommend that:

- **Integrated care boards, with oversight from NHS England, should closely monitor the impact of the PSIRF to identify any negative consequences of the new flexibility it offers, which gives Trusts more autonomy to decide when a patient safety investigation is needed. This should include paying special attention to the balance of patient safety investigations versus other learning responses in Trusts (or service areas of a Trust) where there are poor CQC ratings for safety and leadership, or where other national bodies have raised concerns (recommendation 1).**
- **As part of their quality monitoring role, the PSIRF executive lead on each Board should look at any discrepancies between local and PHSO investigations, or other independent investigations, and make sure the Board discusses them. This should include where local investigations did not take place, or did not find that things went wrong, but PHSO or another independent oversight body later identified failings (recommendation 2).**

The PSIRF recognises that genuine apologies are critical to avoid compounded harm. As we found in cases we analysed, apologies are often still not good enough and duty of candour is not always implemented as it should be. It is unacceptable that Trusts still fail in this duty nearly a decade after it was introduced. Again, this is symptomatic of a defensive culture in some Trusts. Duty of candour is the right policy, but it needs more attention and monitoring.

We recommend that:

- **The Department of Health and Social Care and NHS England should further scrutinise the lack of compliance with duty of candour. They should review the operation of duty of candour to assess its effectiveness and make recommendations for improvement (recommendation 3).**

We welcome the model of family engagement outlined in the PSIRF. But we know that, for the foreseeable future, it will continue to be very challenging for families affected by safety incidents to navigate the complex NHS landscape when they raise concerns and seek answers. They are often very aware of the power imbalances in dealing with professionals who are familiar with the processes and systems that they are coming to for the first time. In this context, advocacy is an essential service, not a 'nice to have'.

While there is a statutory duty for local authorities to commission NHS complaints advocacy, these services are often limited to helping people navigate the NHS complaints process. As we noted in 'Making Complaints Count', there are concerning gaps in access to more specialist services that may be important for families affected by patient safety incidents.

We recommend that:

- **The Department of Health and Social Care should commit to funding further independent advocacy to support harmed patients, families and carers when they raise concerns or seek answers after an incident (recommendation 4).**

2. Evidencing that patient safety is a top Government and NHS priority

The right patient safety framework is not enough on its own to drive change. NHS leaders and frontline staff need to be in no doubt of the priority placed on patient safety.

In some ways it is strange that this should need emphasis: patient safety is about the NHS' core purpose to do no harm. But there are clear signs that patient safety is not prioritised at the moment, however much rhetoric there is to suggest otherwise.

First, we are becoming too used to seeing repeated failings. This is especially stark in maternity services. In his inquiry in East Kent, Bill Kirkup acknowledged the disappointing familiarity of the findings to those he made in Morecambe Bay seven years earlier. The fact that inquiries many years apart find the same failings is met with dismay, but not always outrage or even surprise. There is almost an acceptance that this is 'how things are'. This inertia undermines the difficult work underway to change cultures and manage patient safety more effectively.

Second, political leaders have created a confusing landscape of organisations, often in knee-jerk reaction to patient safety crisis points. HSIB, the Patient Safety Commissioner, PHSO, NHS England, NHS Resolution and more than a dozen different health and care regulators all play important roles in patient safety. But there are significant overlaps in functions, which create uncertainty about who is responsible for what. This means patient safety voice and leadership are fractured. This is not due to a lack of dedication and professionalism from those tasked with championing patient safety. The problem is structural.

The Government must consider the case for streamlining some of these functions, for the benefit of people who use the NHS, their families and carers. This is not about reducing investment in patient safety. It is about creating a system that is coherent and easier to navigate, based on evidence and engagement with patients, families, NHS staff and leaders. We recommend that:

- **The Department of Health and Social Care should commission an independent review of what an effective set of patient safety oversight bodies would look like. The review must include meaningful engagement with NHS leaders, staff, patients and families (recommendation 5).**

Patient safety must be a consistent priority over the long term. It must not be subject to changes of emphasis or importance each time there is a new minister or leadership change in the NHS. We recommend that:

- **The Government should seek cross-party support for embedding patient safety and the culture and leadership needed to support it as a long-term priority (recommendation 6).**

Third, it is not possible to claim to prioritise patient safety while avoiding difficult political decisions about the workforce the NHS needs. Patient safety will always be at risk in environments that are understaffed and where staff are exhausted and under unsustainable pressure. No matter how effective the safety systems and process, it is not possible to run a safe service without the right numbers of staff. Many patient safety commentators draw parallels between the NHS and aviation. In aviation, a plane would not take off without the right number of staff, with the right skills, who have had enough rest, support and training to be able to operate safely.

Tackling workforce shortages goes beyond political decisions about resourcing. It is about making the NHS a place where people want to work and stay because it is somewhere they feel valued, not just because it is a vocation. We must break down the false dichotomy between the interests of patients and staff, recognising that a system that does not treat its workforce with humanity and compassion will struggle to extend these qualities to patients and families.

We recognise the Government has promised to publish a new NHS workforce strategy. At the time of writing, this is expected 'shortly'. But for this to properly address the underlying causes of NHS staffing pressures, it needs cross-party consensus. In a sector where it can take nearly two decades to train a consultant doctor, a workforce strategy will only succeed if there is support from across the political spectrum, and far beyond one parliamentary term.

We recommend that:

- **The Government should urgently produce its long-awaited long-term workforce strategy, with cross-party support, to increase the numbers entering and staying in the workforce across clinical and non-clinical roles. This strategy must:**
 - include independent, evidence-based and fully costed projections of future workforce requirements
 - include detailed plans for training and recruiting new staff, retaining staff already working in the NHS and attracting those who have left to return
 - take account of the mix of different professional skills required, rather than just total numbers in the workforce, and how existing professional skills can be deployed where they are most needed (recommendation 7).

The Department of Health and Social Care should write to the Health and Social Care Select Committee and the Public Administration and Constitutional Affairs Committee within six months of the publication of this report to provide an update on progress against recommendations 3, 4, 5, 6 and 7.

NHS England should write to the Health and Social Care Select Committee and the Public Administration and Constitutional Affairs Committee within six months of the publication of this report to provide an update on progress against recommendations 1 and 3.

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