Parliamentary and Health Service Ombudsman

Broken trust: making patient safety more than just a promise

HC 1444

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.

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 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 Events[28] – 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.

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.

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 rection 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 rights 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.

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    - **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).**

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