Parliamentary and Health Service Ombudsman

A review into the quality of NHS complaints investigations

where serious or avoidable harm has been alleged

EMBARGOED COPY Not to be published in any form before 00:01hrs on Tuesday 8 December 2015.

Contents

The images used in this report are not representative of any person or particular individual and are used for illustrative purposes only.

Introduction

When things go wrong with NHS care, it can have devastating consequences for patients and their families. People want answers, to understand what happened and why, and to know that action is being taken to prevent the same thing happening again to others.

But our research has cast a question mark over the current ability of NHS organisations to conduct effective investigations where it is alleged that someone may have been harmed, or died, avoidably. We have found that NHS trusts are not always identifying patient safety incidents and are sometimes failing to recognise serious incidents. When investigations do happen, the quality is inconsistent, often failing to get to the heart of what has gone wrong and to ensure lessons are learnt.

As part of our review of the quality of NHS investigations, we asked: how successful are NHS organisations, particularly acute trusts, at determining what went wrong and why? Are lessons being learnt and applied, not just across departments but across organisations and localities? Is appropriate action being taken and if not, why not? What can be done to improve how local investigations are conducted and delivered so that more people are not subjected to the same errors time and time again?

This report explains the findings of our research, highlights the issues we have identified, and sets out the action we believe needs to be taken to improve the quality of NHS investigations.

About complaints investigations, serious incidents and patient safety incidents

More than 80% of the complaints we receive are about NHS care and treatment, many involving avoidable harm.

Avoidable harm spans everything from minor to moderate harm, to unexpected or avoidable death and incidents that may cause widespread public concern resulting in a loss of confidence in healthcare services. Where the consequences of these failures to patients, families and carers, staff or organisations are so significant or the potential for learning is great, cases should be investigated as serious incidents[1].

Generally, the complaints we see are about incidents of avoidable harm. These could be classed as patient safety incidents; cases where minor or moderate harm has occurred. Four out of five of the cases we reviewed were investigated as patient safety incidents as opposed to serious incidents.

As an Ombudsman's service, we believe that whether or not the event was significant enough to warrant being labelled a serious incident or a patient safety incident, people have a right to know that their complaint has been taken seriously and investigated thoroughly. Indeed, we expect trusts to be measuring and improving people's experience of complaining by using *My Expectations*[2] when assessing the performance of their complaints service and to what extent this is meeting the needs of the public.

How we approached this

We reviewed 150 NHS complaints investigations where avoidable harm or death was alleged. We were interested to learn about the quality of complaints investigations; did these NHS investigations get to the root cause? Were the findings evidence based? We also spoke to six different trusts; we wanted to know what the challenges were to conducting these types of investigation and where there might be opportunities to improve the system. Finally, we surveyed over 170 NHS complaints managers to provide additional insight into the issues and brought together an advisory group to test our findings.

---

1 Serious incidents are defined as "*unexpected or avoidable death, unexpected or avoidable injury resulting in serious harm - including those where the injury required treatment to prevent death or serious harm, abuse, Never Events, incidents that prevent (or threaten to prevent) an organisation's ability to continue to deliver an acceptable quality of healthcare services and incidents that cause widespread public concern resulting in a loss of confidence in healthcare services*." NHS England (March 2015) *Serious Incident Framework*. Available at https://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incidnt-framwrk-upd.pdf

2 PHSO (Nov 2014) *My Expectations: a user-led vision for raising concerns and complaints*. Available at: http://www.ombudsman.org.uk/__data/assets/pdf_file/0008/28817/My-expectations-for-raising-concerns-and-complaints-summary-leaflet.pdf

What we found

1. The process of investigating is not consistent, reliable or good enough.

We found that 40% of investigations were not adequate to find out what happened. Not only are trusts not identifying failings, they are also not finding out why the failings happened in the first place. For example, trusts did not find failings in 73% of cases in which we found them, and in over a third of cases where failings were found, trusts did not find out why something went wrong. This is in marked contrast to the perception of 91% of NHS complaints managers who were confident an investigation could find out what had gone wrong.

Serious incidents are not being reliably identified by trusts; we judged 28 of the cases we looked at to be serious enough to lead to a serious incident investigation, but only 8 had been treated as such by the NHS. Identification often relied on either clinicians to spot an incident or on a central risk team flagging incidents. It was clear from our visits to trusts that not all had reliable processes in place, contrary to the perception of complaints managers; 96% stated there was both a process and trigger to help identify a serious incident at their trusts.

We found wide variation between and within trusts in terms of how patient safety incidents are investigated. Perhaps more worrying, is a distinct absence of shared investigatory principles. How a case is investigated is subject to the individual investigator.

We are concerned that there is no national guidance for patient safety incident investigations which make clear:

- who should investigate and how independent of events they should be;
- the level of training an investigator should have for any particular type of investigation;
- broad requirements for the specific evidence needed. For example, statements, interviews or independent clinical reviews;
- how investigations should be independently quality assured;
- what general outcomes any good investigation should aim to achieve.

Worryingly, medical records, statements and interviews were missing from almost a fifth of investigations making it even harder for trusts to arrive at what went wrong and why. Organisations that provide care should not lose sight that it is patients, carers and families who are often at the heart of these investigations. They need to be involved in a meaningful way if investigations are to answer their questions. All of this has a huge impact on patients and families at the centre of any investigation. Our results show that in 41% of cases, complainants were given inadequate explanations for what went wrong and why. The two cases opposite highlight the tragic impact poor quality investigations can have on families and those raising complaints, and why it's important that lessons are learned.

Case study

A one-day-old baby received a blood transfusion to treat severe jaundice. Tragically, serious errors were made in delivering the transfusion resulting in Baby F's collapse, which led to permanent brain damage. Although a serious incident investigation was carried out, it was done so by a close colleague of the paediatrician in charge that day.

We considered that Baby F's collapse was avoidable and requested the trust carry out a review to find out why things went so seriously wrong. The trust acknowledged the investigation was a review of notes only, and clinical staff were not interviewed or asked to provide written statements.

It took three years for Baby F's parents to get a proper explanation for what happened to their baby, adding to their distress.

Case study

Mr M, a 36-year-old father, was taken to accident and emergency with sudden, severe chest pain. Medical staff suspected a heart attack however further tests revealed Mr M may have suffered a tear to the wall of his heart.

After being admitted to a medical ward, Mr M was later discharged with a possible blockage in the bowel with further investigation of his abdomen planned. The following day, Mr M collapsed and lost consciousness. Attempts at resuscitation failed and Mr M died.

Our investigation concluded had a CT scan taken place, Mr M would have been transferred for surgery giving him an 80% chance of survival. No serious incident investigation was conducted and two complaints meetings failed to give the family the answers they needed, despite a list of questions being submitted by the family in advance.

The hospital refused to provide an 'expert view' on whether the doctors' actions were appropriate, adding to the injustice and distress felt by the family.

2. Staff do not feel adequately supported in their investigatory role

There is no national, accredited training programme to support investigators and/or complaints staff in their role. Cultural issues can often be a barrier to getting to the heart of why something has happened.

Common reasons cited during our visits to trusts included a lack of respect; not being provided with protected time to investigate, and the lack of an open and honest culture despite the introduction of the duty of candour in November 2014.

Our visits suggest inequity in terms of who can lead different types of investigations. Our visits revealed that serious incident investigations would often be led by a named investigator with training; all other investigations which fell short of the serious incident criteria could be led by an 'appropriate person'.

Ultimately, staff need to be equipped and empowered to carry out investigations otherwise trusts risk adding to the distress felt by individuals and missing opportunities to make essential service improvements as the following case illustrates.

Case study

Ms G was concerned about changes to her breast and was referred by her GP to a breast clinic. An ultrasound scan led to a diagnosis of mastitis. At a follow-up appointment, a different breast specialist made the same diagnosis. When Ms G missed a follow-up appointment three months later, she was discharged from the breast clinic.

Fourteen months later, Ms G was diagnosed with incurable, advanced breast cancer that had spread to her bones, liver and brain. We found that the secondary cancers were allowed to develop because she had been misdiagnosed and that the two letters she had received confirming mastitis gave her false reassurance. We also found that the trust failed to fully investigate, and did not acknowledge the extent of the failings or the impact on Ms G.

The trust later acknowledged that it should have instigated a serious incident investigation when Ms G was diagnosed with cancer and had it done this, it could have considered learning and service improvements much sooner.

The trust identified a skills gap for staff responsible for investigating complaints, and developed and commissioned a complaint handling course with a local university; complaints management would now become part of their individual appraisals. The trust also established a quality approval process for complaints.

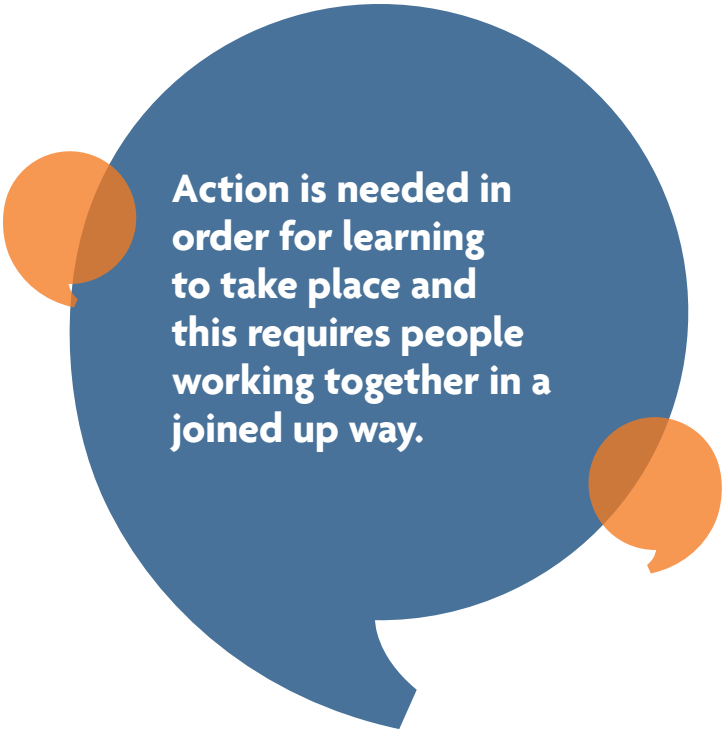
3. There are missed opportunities for learning.

Many complain because they do not wish the same thing to happen to somebody else. Therefore it was worrying to find that 25% of complaints managers were unsure that sufficient processes existed to prevent a recurrence of an incident, and a further 10% believed sufficient processes were not in place.

The impact of poor quality investigations that do not trigger a serious incident is felt most significantly by individuals and their families. However, it also results in missed opportunities to learn and make the relevant service improvements as the case opposite illustrates.

Action is needed in order for learning to take place and this requires people working together in a joined up way. NHS complaints managers, who are responsible for providing explanations to families and ensuring learning takes place, need to be joined up with clinical staff who are often tasked with leading patient safety incident investigations.

Our findings demonstrate that divisions within hospitals often work in isolation to each other; learning from investigations appears to be trapped in high level meetings; and learning across organisations often relies on goodwill and personalities rather than any established processes or mechanisms. Our advisory group reported that cross organisational learning tends to be led by the willing few rather than something that is a widespread practice across the NHS.



Case study

Mr D, a 77-year-old man, was admitted to A&E and seen by a junior doctor who suspected the cause of his symptoms was sepsis, a severe infection. He was not seen by a doctor for two-and-a-half hours, and antibiotics were then not given until two hours after they were prescribed.

Despite stepping up his treatment, Mr D died two days later. Concerns were raised by close family about the timeliness of Mr D's treatment and whether his death could have been avoided. In response to the complaint raised, the trust outlined chronological events using clinical records only.

Had a complaints investigation been done thoroughly, the trust would have found that clinical staff failed to recognise the severity of Mr D's illness, that he was not seen by a doctor for more than two hours, observations were not taken regularly and that a serious incident should have been triggered.

Our investigation concluded that the hospital missed an opportunity to give him the best chance of recovery by failing to give him more timely treatment.

What needs to change?

In April 2016, a new Independent Patient Safety Investigation Service (IPSIS) will be established. Through a combination of exemplary practice and structured support to others, IPSIS has the opportunity to make a decisive difference to how the NHS improves the way it investigates in the future.

We therefore call upon IPSIS and the NHS more broadly, to consider how the following recommendations can be implemented:

1. IPSIS and NHS England should consider how the role of NHS complaints managers and investigators can be better recognised, valued and supported. This includes working with others to develop a national accredited training programme.

2. To support all investigations to be carried out to a consistent and high quality, IPSIS should develop and champion broad principles of a good investigation. The emphasis should be on building capability and capacity at a local level whilst also allowing for flexibility and proportionality.

3. IPSIS should work with others to lead, inspire and share learning from its own investigations in order to improve the capability of the local NHS. This includes demonstrating to organisations how they can take what they have learned from one investigation and apply it not just across divisions within a hospital, but across organisations too.

4. Trusts should demonstrate to their boards that they have clear objectives both for their organisations and their staff to be open and honest, learn from investigations, and resolve complaints. Boards should be using *My Expectations* to assess to what extent local complaints services are meeting the needs of people who use the service.

5. The Department of Health and NHS England should work with IPSIS to make clear who has accountability for conducting quality NHS investigations at a national and local level. The different roles of organisations that provide care, commissioners, regulators including NHS Improvement, should be clearly outlined.

We believe that taken together, these changes will result in tangible improvements to the quality of local investigations. Although our report is a snapshot in time, it raises doubts over the ability of trusts to reliably identify when something has gone seriously wrong and why. Without this capability, trusts will continue to miss opportunities to learn and make service improvements.

As the stories in our report highlight, this is leading to tragic consequences for the people and families who are directly affected, and raises questions about whether the same preventable mistakes will not be repeated. There is some way to go before the NHS can be confident in the quality of local NHS investigations.

We look forward to playing our part in supporting improvements. As a first step, we will commit to disseminating our findings and will be sending copies of this report to the boards of each NHS trust across England.

Headline figures and insight

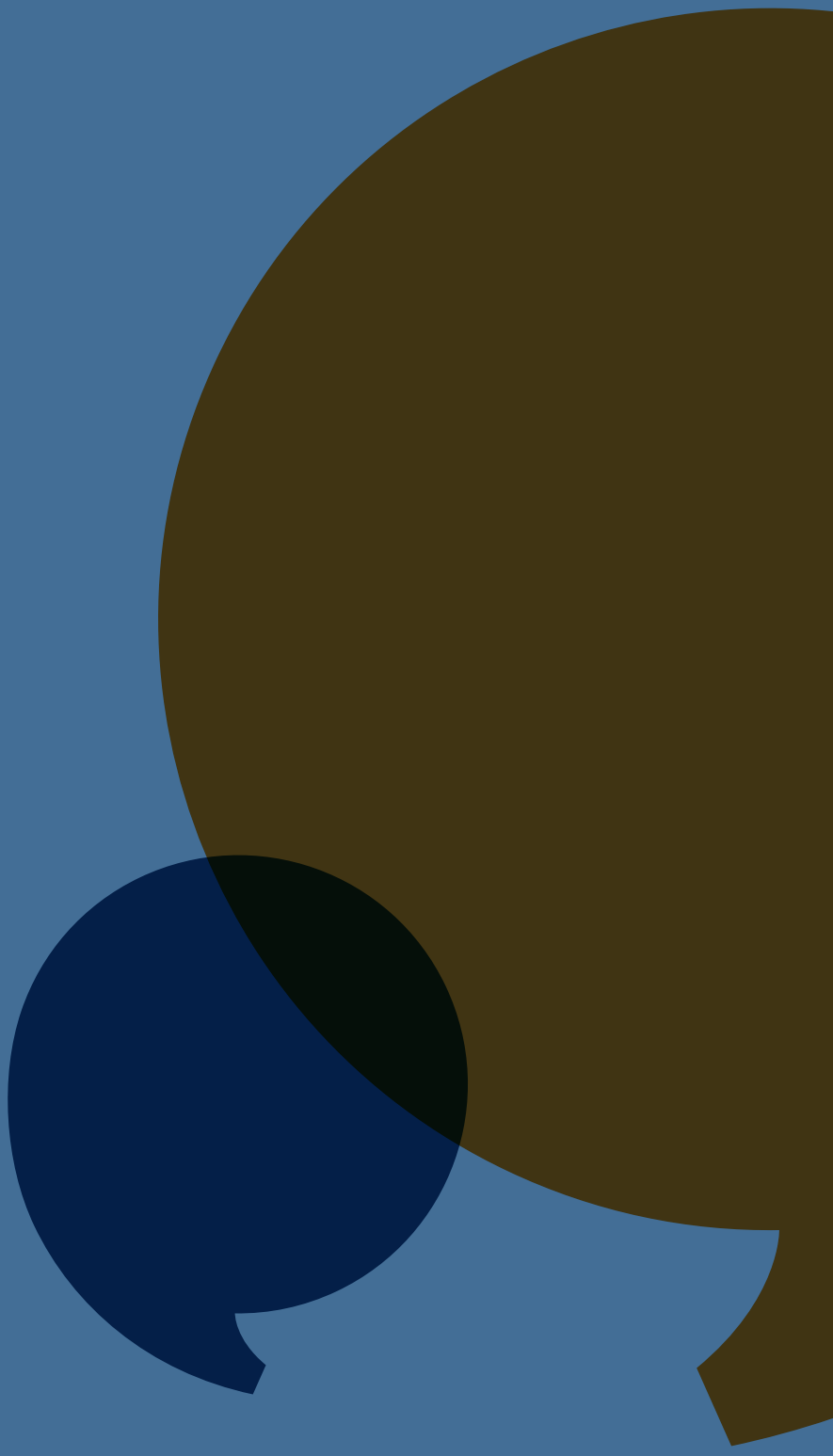
The evidence that we collated is attached to this report in annexes B to E. This shows variation in the quality of investigations of patient safety incidents, and provides comprehensive evidence about what is going wrong in the system. This evidence is summarised here.

Insight	Evidence	Our recommendation
The process of investigating as it stands is not consistent, reliable, or good enough.	40% of investigations were not adequate to find out what had happened. 19% of investigations had relevant evidence (medical records, statements and interviews) missing when they were conducted. Trusts did not find failings in 73% of cases in which we found them. Trusts did not find out why things went wrong in 36% of cases where they found failings.	To support all investigations to be carried out to a consistent and high quality, IPSIS should develop and champion broad principles of a good investigation. The emphasis should be on building capability and capacity at a local level whilst also allowing for flexibility and proportionality.
Serious incidents are not being reliably identified by trusts, and there exists wide variation between trusts, and within trusts, in terms of how patient safety incidents are investigated.	Out of the 150 cases we reviewed, 28 were judged by us to be serious enough to lead to serious incidents, but only 8 were reported as such. We found that identification often relied on either clinicians to spot an incident or on a central risk team flagging incidents.	

Insight	Evidence	Our recommendation
There is a lack of shared investigatory principles - how a case is investigated depends on the individual investigator.	There is no national guidance on patient safety incident investigations that sets out who should investigate and how independent they should be, level of training required, requirements for evidence needed, quality assurance, and general outcomes for good investigations.	To support all investigations to be carried out to a consistent and high quality, IPSIS should develop and champion broad principles of a good investigation. The emphasis should be on building capability and capacity at a local level whilst also allowing for flexibility and proportionality.
Poor quality investigations only increase the distress to the person who is complaining and their families.	In almost a fifth of investigations medical records, statements and interviews were missing, making it difficult for trusts to arrive at what went wrong and why. In 41% of cases inadequate explanations were given to complainants for what went wrong and why.	
Staff do not feel adequately supported in their investigatory role.	There is no national, accredited training programme to support investigators and/or complaints staff in their role. During our visits to trusts, staff cited a lack of respect, not being provided with protected time to investigate, and the lack of an open and honest culture as barriers to getting to the heart of why something has happened. There is inequity in terms of who can lead different types of investigations. We found serious incident investigations would often be led by a named investigator with training; all other investigations not meeting serious incident criteria could be led by an 'appropriate	IPSIS and NHS England should consider how the role of NHS complaints managers and investigators can be better recognised, valued and supported. This includes developing a national accredited training programme. Trusts should demonstrate to their boards they have clear objectives, both for their organisations and their staff, to be open and honest, learn from investigations, and resolve complaints. Boards should be using My Expectations to assess to what extent local complaints services are meeting the needs of people who use the service.

Insight	Evidence	Our recommendation
There are missed opportunities to learn.	25% of complaints managers were unsure that sufficient processes existed to prevent a recurrence of an incident. A further 10% of complaints managers believed sufficient processes were not in place.	IPSIS should work with others to lead, inspire and share learning from its own investigations in order to improve the capability of the local NHS. This includes demonstrating to organisations how they can take what they have learned from one investigation and apply it not just across divisions within a hospital, but across organisations too. The Department of Health and NHS England should work with IPSIS to make clear who has accountability for conducting quality NHS investigations at a national and local level. The different roles of providers, commissioners, regulators including NHS improvement, should be clearly outlined.

Annexes



Annex A: Our approach and the evidence we gathered

We gathered evidence about the quality of NHS investigations through four strands of work: a review, a survey, visits to trusts, and an advisory panel.

The review

In January 2015 we completed an initial review of 150 of our cases that involved a complaint about avoidable harm or death. The aim was to establish whether trusts' own handling and investigation of these types of cases are adequate to identify and deal with failings in care or a serious incident. Our investigators answered a series of questions about the quality of the NHS' original complaint investigations, and the evidence that the trusts had relied upon in coming to their decisions.

The survey

In March 2015, we sent a survey about the investigation processes in relation to complaints about patient safety incident to 171 complaints managers in all acute trusts in England. The purpose of the survey was to understand their processes, and gain insight into best practices and areas for improvement. We asked closed questions and gave staff the opportunity to provide qualitative comments. The survey was anonymous. There were 104 responses after a three-week period. This equates to a response rate of 61%.

The visits

We visited acute trusts across the country, including small trusts, large trusts, trusts that had been performing well, and also those that had recently been in special measures. We asked the trusts questions about how they investigate allegations of a patient safety incident and how their complaints process is set up to investigate and learn from complaints. We spoke to a wide variety of staff including directors of nursing, complaints managers, complaints staff, divisional leads, and governance leads. We used the information from these visits to validate and add depth and context to the information that we obtained from the survey and the review. We also looked to find examples of good practice.

Advisory group

Once we had gathered evidence from the review, the survey and the visits, we convened an advisory group. The advisory group was made up of organisations and individuals with a special interest in patient safety incident investigations. We discussed our findings with the advisory group, whether what we found fits with their experience and how our work fits into the wider landscape. All members of the advisory group said that our evidence resonated with their experience.

You can read a summary of the evidence we gathered in Annexes B to E of this report.

After we had collated all the evidence, we analysed it against the existing applicable standards: the *Ombudsman's Principles of Good Administration* and *Good Complaint Handling*, *My Expectations*, the *Duty of Candour*, and the *Complaints Regulations*. We considered whether what we had found suggested that the NHS was falling short of those standards when conducting a patient safety investigation following a complaint. We looked at whether the culture, systems and processes that were in place were robust enough to allow those standards to be met.

Annex B: The review - summary

Introduction

We undertook this review because our casework tells us that there is a wide variation in the quality of NHS investigations into complaints that patients have suffered serious avoidable harm. We completed this in January 2015 and the aim was to establish whether the NHS complaints process is acting adequately as a safety net to identify and deal with failings in care and patient safety incidents. We also looked for features of good practice.

Methodology

We identified and considered 288 cases about the NHS in England that we investigated in 2014. In each of the 288 cases a patient, or relative, alleged that they had suffered avoidable harm because of NHS treatment. Out of those cases, we identified 150 that raised issues of serious avoidable harm or death at acute trusts. The focus of our review was to look at the features and quality of the NHS investigation into the allegation, rather than the result of our subsequent investigation. We therefore did not discriminate between cases that we had upheld or not upheld.

Our investigators reviewed the case file for each of the 150 cases. They answered a series of questions[3] about the quality of the trust's original investigation into the complaint and the evidence that the trusts had relied on in coming to their decisions.

The questions were:

- Was the allegation of avoidable harm or avoidable death?
- What was the nature of the alleged avoidable harm?
- What was the main alleged clinical failing leading to avoidable harm or avoidable death?
- Which specialism was complained about?
- Was a serious incident investigation carried out?
- Do you consider that it should have been?
- Did the organisation understand and investigate the complaint put to it?
- Was the complaints investigation carried out by appropriate staff?
- Did the organisation communicate adequately with the complainant?
- Did the organisation have access to the relevant clinical records?
- Was there a review of the care and treatment by appropriate clinical staff?
- If yes, was the review done by a clinician not involved in the patient's care?
- Were key staff interviewed?
- Were key staff asked to provide a written statement?

[3] The criteria for the questions were informed by, but not confined to, the requirements of the *Serious Incident Framework*.

- Was any relevant evidence missing or not considered?
- Were the investigation findings reasonable and based on evidence?
- Did the organisation give the complainant an adequate explanation of what happened and why?
- Did the organisation find failings relating to avoidable harm or death?
- If yes, did the organisation find out why things went wrong?
- If failings were found, did the organisation take action to ensure patient safety?
- How long did the investigation take?
- Was the investigation adequate or inadequate?
- Was the complaint upheld or not upheld by us?

What we found

Our initial review bore out our premise that the NHS complaints process does not adequately address complaints about avoidable harm. Out of the cases we reviewed, over one third of investigations into allegations by patients, or their relatives, were not good enough to identify if something had gone seriously wrong.

We found that one third of investigations did not have reasonable conclusions that were based on evidence, and did not reliably identify when something had gone wrong.

Equally we found that, even when investigations did identify failings, the trusts did not always try to find out why something had gone wrong, or take remedial action.

In our review, 14 investigations (9%) found failings relating to avoidable harm; however, our subsequent investigations identified failings relating to avoidable harm in 52 cases (35%). Furthermore, in only 9 of the 14 cases did the trust try to find out why something had gone wrong, and in only 10 of the cases did the trust take action to try to make sure patients were safe in the future.

In the majority of cases the trusts had access to the relevant clinical records, and in 56% of investigations written statements were obtained and 38% involved interviewing key staff. In 90% of cases a review of the clinical care was carried out, but only 52% of cases involved an independent clinical review. In almost a fifth of cases we found that relevant evidence was missing from the trust's investigation. Some of the reasons that our investigators gave for this included that evidence had been given orally, and not documented; interviews or written statements, although considered necessary, were not obtained, and some clinical records could not be obtained.

We looked at the features of the investigations that we considered adequate, and those we considered inadequate. There was no significant difference in the adequate or inadequate groups in how frequently the trusts obtained written statements, interviewed staff, or obtained independent clinical reviews.

However, 71% of complaints that should have triggered a serious incident investigation were not identified as such. The 20 cases that should have been classified as a serious incident included: complaints about missed opportunities to survive; delays in providing medication and fluids that could have contributed to death; problems administering blood transfusions, leading to adverse consequences, including brain damage; and unexpected deaths. We found that for these 20 cases:

- 9 did not obtain written statements;
- 9 did not interview key staff;
- 7 did not either obtain written statements or interview key staff;
- 4 had evidence missing;
- 4 did not obtain a clinical review; and
- 6 of the 16 clinical reviews carried out were not independent.

Given the seriousness of these complaints, we considered that, even if the trusts did not recognise that these cases should have been classified as a serious incident, they should have followed a more thorough investigation process.

In addition to how trusts investigated the complaints, we also looked at how they communicated with complainants. Having reviewed the complaints files, we considered that in 27% of cases the trusts did not communicate adequately with the complainants. The reasons they gave for this include: delays in the complaints process; infrequent contact with complainants; and not keeping complainants updated about the progress of the investigation. We also found that in 41% of cases the trusts did not provide complainants with an adequate explanation of what happened and why.

Annex C: The survey – summary

Introduction

In March 2015, we sent a survey about the way complaints about patient safety incidents are investigated to complaints managers in all acute trusts in England, 171 in total. The purpose of the survey was to understand the trusts' processes, and gain insight into best practices and areas for improvement.

What we found

The survey asked closed questions and gave staff the opportunity to provide qualitative comments. Feedback was anonymous.
We received 104 responses after a three-week period, which is a response rate of 61%.

Below is a breakdown of the key results by question.

1. *Does your trust's complaint team follow different investigation processes for complaints of avoidable harm, in comparison to other complaints?*
    - Just under a tenth of respondents did not know whether they have different processes in place for avoidable harm complaints.
    - Out of the remaining respondents, approximately half follow a different investigation process for complaints about avoidable harm.
2. *In your opinion, do you think that improvements are required in the complaints process to adequately investigate allegations of avoidable harm?*
    - No respondents selected that 'a lot of improvements' were required to their complaints process.
    - However, over half (53%) stated that 'some' improvements were required.
    - 47% felt 'no improvements' were needed.
3. *If a complaints investigation identifies that something has gone wrong with the care provided, do you feel that there is an adequate process at your trust to find out why things went wrong?*
    - The majority (91%) felt that there is an adequate process at their trust to find out why things went wrong.
4. *If a complaints investigation identifies that something went wrong with the care provided, do you feel that your trust has a sufficient process to prevent the same mistakes happening again?*
    - In contrast to the previous question, only 6 in 10 respondents felt that their trust has sufficient processes in place to prevent mistakes happening again.
    - Over a quarter of respondents were 'unsure', with over a tenth stating their trust did not have sufficient processes in place.

5. *Is there a process at your trust to identify a serious incident?*

- The majority of respondents (96%) said that there is a process to identify a serious incident at their trust.

6. *Is there a process for your complaints team to trigger a serious incident once the complaint has been identified as requiring one?*

    - As in the previous question, the majority of respondents (96%) said that there is a process to trigger a serious incident.

7. *In your opinion do you consider that the complaints process at your trust can identify and trigger a serious incident when necessary?*

    - The majority of respondents (92%) felt their trust's processes can identify and trigger a serious incident when needed.

8. *Has your trust signed up to NHS England's safety campaign?*

    - Just over half of respondents said their trust has signed up to this campaign.
    - However, 45% of respondents said their trust had not.

Qualitative statements

Respondents were asked to offer ideas for improvements to complaint-handling processes. These centred on the following themes:

- Better training (for complaints teams, as well as others in trusts);
- Being more open, and creating a culture of openness;
- Better engagement between divisions and cross-department collaboration when investigating a complaint, so that people can learn from complaints;
- National guidelines and nationwide consistency (as it was felt that current complaints regulations are outdated);
- Greater ownership of the complaint and taking responsibility for actions relating to it, and for sharing any learning from it;
- Better resources; more time, money, and appropriate manpower;
- Involving more independent opinions in the complaints process;
- Greater focus on quality and consistency of the trust's responses; and
- Auditing the effectiveness of the actions taken.

We also asked respondents to share experiences about serious incident processes at their trust. They raised issues about decisions and processes being out of the complaint team's hands, meaning that staff in the complaints team had less influence in decisions. However, it was noted that things that worked well include:

- Sharing complaints and what is learned from them with other teams;
- Deciding the importance and urgency of complaints;
- Close working with other teams, for example, weekly meetings;
- Clear and consistent processes to deal with the complaint; and
- Having personnel involved who have experience of investigating and handling complaints.

Annex D: The visits – summary

Introduction

In April and May 2015, we visited six acute trusts[4] across the country. These included smaller acute trusts, large trusts, trusts that had recently been in special measures, as well as trusts that had been performing well. We asked the trusts questions about how they investigate allegations of avoidable harm and how their complaints process is set up to investigate and learn from complaints. We spoke to a wide variety of staff, including directors of nursing, complaints managers, complaints staff, divisional leads, and governance leads.

We used the information from these visits to validate or highlight gaps in the information that we obtained from the survey and the review. We also looked to find examples of good practice.

Below is an overview of the feedback we received from these six trust visits.

What we found

We were made to feel welcome, and generally, trust staff spoke to us openly about the complaints process and their approach to investigating allegations of avoidable harm. The staff we spoke to were keen to improve the system.

We have not quantified how many trusts provided certain responses. This is because we only spoke to six trusts and this, therefore, cannot be representative of all trusts. However, themes did emerge. Equally, the information we gathered helped validate the information we had already collected.

The themes we looked at:

- **How the complaints teams and process is structured:**

  Often the complaints teams do not, structurally, sit with the governance teams, but within the nursing directorate. This means the governance and complaints systems run in parallel. The complaints teams tend to liaise with complainants and deal with minor complaints, but do not investigate patient safety incidents. Generally we found that the complaints teams sent complaints about patient safety incidents to the division where the complaint arose to be investigated by clinical staff within that division.

  However, one of the trusts we talked to was in the process of changing its approach, and its complaints team (who are lay people) will be investigating patient safety incidents. This is unless the complaint has already been reported on the relevant patient and risk management software (Datix) and investigated within the division.

  We did not find any consistency about who would be investigating the complaint, and the level of training of investigators. Some trusts had a list of trained investigators within the divisions. Other trusts did not necessarily use trained investigators, but said that incidents were investigated by 'the appropriate person'.

[4] The trusts provided information anonymously.

Another variation we found was that in some trusts a trained investigator would investigate a serious incident, but anyone could investigate a patient safety incident that did not meet the criteria of a serious incident. Trusts also told us that investigators did not necessarily have time in their working week to do the investigations, but had to do this in addition to their clinical or managerial workloads.

The complaints staff we spoke to were all keen to resolve complaints and were persistent in following them through to the end. In some trusts, it appeared to be personalities and persistence that was improving the complaints and investigations process, rather than the investigations process itself. The majority of trusts were open in telling us that they did not feel they had a culture of openness.

- **Investigation process (patient safety incidents)**

  In general, we found that complaints staff speak to the complainants and agree the scope of the investigation, and then pass the investigation over to the division where the patient safety incident occurred. However, one trust was starting to use complaints staff to investigate patient safety incident that did not meet the criteria for serious incident. Complaints teams generally told us that when they received a complaint about a patient safety incident they would cross reference it on the trust's logging system - most commonly Datix - and if the incident was not already reported they would report it. Different trusts said there were different levels of reporting of patient safety incidents by clinical staff on Datix before the complaint was raised.

  The larger trusts told us that it can be difficult to obtain clinical records, whereas the smaller trusts found this less of a barrier. Trusts that had an electronic records system said they were better able to get access to clinical records.

  Some trusts relied on statements and did not interview staff because they said interviews were too difficult to arrange. Trusts also reported poor quality written statements and having to keep going back to the clinicians to get the information they needed.

  Some trusts said that clinicians were unwilling to review their colleagues' work, which made getting an independent clinical review difficult. However, the majority of trusts could get clinical reviews from within the division where the incident occurred for patient safety incidents, and some sought reviews from different divisions for serious incidents, but there was no consistent approach to this. Trusts' complaints staff reported difficulties in challenging clinical opinions. Generally, external clinical reviews were only sought for serious incidents and larger trusts found it easier to get an independent clinical review. Trusts reported difficulty in obtaining independent clinical reviews where the speciality was rare and the number of clinicians working in that field at that trust was limited.

It was generally reported that doctors were more unwilling or slower to provide opinions and statements than nurses. Trusts considered that where the complaint response was quality assured by staff not involved in the care, this introduced an element of independence.

We found variation in whether trusts dealt with serious incidents, and patient safety incidents that did not meet the serious incident criteria, in the same way, or whether they approached them differently.

Equally, we did not find consistency in how the investigations were approached. Some trusts had a root cause analysis (RCA)[5] template that the investigators followed, and others simply said that the investigator would choose how to approach the investigation on a case-by-case basis. The process and approach also differed between divisions within the same trust. Trusts generally expected the investigator to analyse the information and uncover why things went wrong.

We found that complaints teams tended to have a weekly meeting with the divisions where the complaint arose to discuss progress of outstanding investigations, and this helped the complaints team manage the process.

- **Governance**

  We found, in general, that divisional leads quality assured the investigation reports, which were then quality assured by various senior managers and the chief executive. We were told that when a lot of people were in the quality assurance chain the process was longer and harder. This is because staff would tailor the write-up of the investigation and/or response to suit an individual's style, and it would then go to a different individual who would have a different personal preference about writing style. Trusts considered that the quality assurance chain introduced an element of independence. The complaints teams also quality assure responses before they are sent out and will query the complaint response if it does not answer the question, or is not written in plain English.

  Trusts told us that complaints and patient safety incident/serious incident investigations were discussed at regular governance and senior management/ board meetings. Trusts reported a move towards better identification of trends of where things are going wrong. Trusts reported that senior management gave complaints priority. Trusts also told us that governance and/or auditing of any changes that were implemented is an area that needs improvement.

[5] A methodology in which steps are taken to identify, and tackle, the root causes of any errors or failings identified as the result of an investigation, in seeking to prevent them from recurring.

- **Communication**

  Trusts reported that since the *Duty of Candour* requirements came out in November 2014 they inform patients more reliably about patient safety incidents. Trusts all reported that they have improved how they respond to complaints, and are aiming to give complainants clearer explanations of what happened and why. Trusts also reported that they explained, in their responses, what improvements had been put in place as a consequence of the complaint. Some trusts reported that local resolution meetings with complainants helped communication, and others said that written responses worked well.

- **Implementation and learning**

  The majority of trusts said that the investigator was responsible for drawing up action plans for learning from a complaint. Usually the heads of division will sign off an action plan once the investigator has drawn it up. Trusts told us that not all investigations (even upheld ones) resulted in an action plan.

  Trusts also told us that an area they needed to work on was sharing with staff what had been learned from complaints and investigations. They said that patient safety incidents and investigations were discussed at high level governance meetings, and that learning was cascaded down through matrons to ward staff. However, there was inconsistency in how this translated into changes in delivering clinical care.

  Trusts also said that monitoring and auditing any changes was an area that needed improving, and there did not appear to be any robust processes in place to make sure this happened. Trusts said that the culture around learning from complaints and patient safety incidents needs to improve. Trusts also told us that it is difficult to achieve cross-divisional or trust-wide learning, as currently divisions appear to work as isolated units.

- **Serious incidents**

  Trusts did not have a consistent process to identify a serious incident. They told us that, often, these had not been reported before a complaint was raised. They also told us that clinicians in some trusts use their experience to 'spot' serious incidents, whereas other trusts had a central risk team that flagged serious incidents.

  It is more likely that serious incidents are investigated by a trained RCA investigator who will use an RCA investigation template, but this is not guaranteed. Again there is no set process to investigate these complaints. Some trusts follow the same approach for patient safety incidents and serious incidents, and others do not.

- **Barriers**

  Trusts told us that the barriers they face are:

  - Difficulty getting access to clinical records;
  - Problems contacting staff who have moved;
  - The use of temporary staff, which makes it harder to identify and track people;
  - The challenging pace and scale of work;
  - Poor interpretation of the available evidence;
  - Lack of a system for learning from complaints;
  - Lack of a culture of openness; and
  - A culture where doctors who do not accept it when complaints staff and investigators challenge them about their statements or reviews.

- **Areas for improvement**

  Trust staff suggested these areas for improvement:

  - Create a check list for complaints team to help them identify if a complaint should be reported as a serious incident..
  - Train complaints staff in investigation skills.
  - Standardise processes for investigating patient safety incidents that do not meet the serious incident criteria, and use of an RCA template, irrespective of whether the issue was raised by a health professional or as a complaint.
  - Better collaboration across the divisions when investigating and learning from patient safety incidents and complaints.
  - Better ownership and dissemination of learning and action.
  - More resources, including appropriately trained staff.
  - Better consistency and quality of investigation reports.
  - Better and more consistent monitoring of the effectiveness of action plans/change.
  - More thorough, but not unnecessarily cumbersome, quality assurance processes.
  - Senior acceptance of changing culture in respect of openness.
  - Buddying system with different trusts for clinical reviews.
  - Cross trust learning methods such as the National Patient Safety Agency (NPSA) or Medicines and Healthcare Products Regulatory Agency (MHRA)[6] alerts could help share learning across the country.
  - Creation of a pool of national clinical advisers to review cases.
  - More consistent national guidelines (we were told that the new serious incident guidelines are cumbersome).

---

[6] The MHRA regulates medicines, medical devices and bloods for transfusions in the UK.

Annex E: Advisory group - summary

Introduction

In June 2015 we held a meeting with an advisory group to discuss our findings, how what we had found resonates with their experience, and how our work fits into the wider landscape. The advisory group was made up of organisations and individuals with a special interest in complaints investigations, patient safety incidents and serious incidents. The advisory group comprised Peter Walsh (Action Against Medical Accidents), Chloe Peacock (Healthwatch), Brian Toft (Coventry University), Denis Wilkins (CORESS), Donna Forsyth (NHS England), Nikki Pitt (Department of Health), Maria Dineen (Consequence UK), Carol Brennan (Queen Margaret University), Paula Mansell (Care Quality Commission) and Umesh Prabhu (Wrightington, Wigan and Leigh NHS Foundation Trust). Paula Mansell and Umesh Prabhu were unable to attend the advisory group meeting and therefore we met with them separately to capture their views. All members of the advisory group said that our evidence resonated with their experience.

Key areas

At the advisory group discussions, we identified key areas for improvement: those most in need of change; and those areas which, if changed, would have most impact on improving investigations. We also identified that culture and leadership are crucial to improving the following areas:

- **Staff**

  The advisory group considered that it would be useful for investigators to have a skills and competency framework.

  Skills that were seen as important to such a framework include:

  - Facilitation;
  - Analytical;
  - Project and multi-project management;
  - Time management;
  - Interviewing;
  - Research, including content mapping[7] and affinity mapping[8];
  - Active oral and written communication, which is empathetic and non-judgemental.

  The advisory group also considered that investigators should have enough seniority to carry things through, and have a sound knowledge of a range of investigation and human factors[9] methodologies.

  The group felt that training for investigators should be accredited, and those that provided the training should be able to show evidence of competency and compliance with national requirements in their training packages.

---

[7] A tool used to map content to the needs of service users or the organisational goals.

[8] A tool used to group information and ideas together according to them having a shared relationship.

[9] The process of understanding what factors will affect how people think, behave and act.

In addition, they felt that a senior level champion (a named person) in each trust, for example, a head of profession, at board level could oversee the training of staff conducting investigations.

The advisory group suggested that a buddying, leadership and mentorship pool within and across clinical care group communities could be developed to aid training and share experience.

- **Consistent process**

  The advisory group felt that the patient and family that had made the complaint should be involved at every stage to manage expectations and to provide information for the investigation. They also felt that the patient and/or family should be able to have access to a source of independent advice and support.

  They said that consideration should be given to standardising the investigation process across the NHS. This may include alignment of complaints investigations into patient safety incidents and serious incidents investigations, so that all investigations are subject to the same process, albeit the size, complexity and terms of reference of the investigation could change. For this to happen, the advisory group said that the complaints team and governance may need to sit and work together.

  The advisory group noted that the NPSA had developed an investigation template, but this is not used routinely. It was hoped that the new clinical incident investigation unit (IPSIS) would consider how to make sure that a template is used consistently. This may include considering how any template would match the skills and/or competencies of investigators, so that staff have the knowledge to use the template.

  The advisory group also considered that commissioners could be involved in ensuring independence in the investigations process. Clinical commissioning groups, or a group of trusts, could develop a pool of investigators who can share resources and reciprocate help by giving independent views. Equally a group of people who would challenge the investigation process could be set up.

- **Learning and monitoring**

  The advisory group agreed that the term 'learning' needed to be clearly defined.

  The theory of the use of legislation versus education to spread what is learned from complaints across the NHS was discussed. That is, do trusts need someone external to the system to motivate and make changes happen (for example, legislation and/or policy changes backed up by penalties for non-compliance), or whether training, empowering staff, and making changes to the culture would result in change.

The group felt that the possible blocks to improving learning from complaints (both across and within trusts) were:

- 160+ trusts all approach this differently and they do not always talk to each other;
- Limitations on resources, although it was felt that a potential solution to this would be to involve the third (charitable) sector;
- They felt that there have been opportunities to build a more collaborative culture and it may not have happened because:
  - People are not always willing to share (in order to prevent bad press or the need to be the best independently);
  - There was a risk to organisations' reputations;
  - People do not want to relinquish control;
  - People work in isolated groups;
  - There tends to be a coalition of the willing - those who would naturally engage with this do, and the remainder do not.

The advisory group considered leadership to be the key to a supportive learning environment by:

- Using a public forum to discuss patient safety incidents where staff can make public pledges;
- Involving staff in finding solutions;
- Working together;
- Listening to staff at all levels; and
- Encouraging staff at all levels to speak up, and bring down the hierarchy.

Many of the advisory group members thought that the solution, therefore, was to use the benefits of both legislation and encouraging collaboration and partnership. Together these methods may result in:

- Empowerment of clinical teams;
- Legislation and accountability as the backstop if individuals or organisations are unwilling to learn; and
- Harnessing good practice and inviting people to tell and/or share their stories.

Parliamentary and Health Service Ombudsman

Tel: 0345 015 4033

Fax: 0300 061 4000

Email: phso.enquiries@ombudsman.org.uk

www.ombudsman.org.uk

Follow us on

If you would like this report in a different format, such as DAISY or large print, please contact us.