BRIEFING
Learning from serious incidents in NHS acute hospitals

A review of the quality of investigation reports   June 2016

Introduction

"Is it safe?" is one of the five questions CQC asks on every inspection of health and social care services in England. We have found many good and outstanding services over the past three years, and yet, safety continues to be our biggest concern. One of the most common issues we find is the way that organisations investigate, communicate and learn when things go wrong.

We wanted to get a better understanding of these issues, so we decided to carry out a review of a sample of serious incident investigation reports. We also wanted to test a method that we could use in our inspections and identify ways that we could help to encourage improvement.

Our review included a sample of 74 investigation reports from 24 NHS acute hospital trusts, representing 15% of the 159 acute trusts in England at the time of this review. We used an assessment framework based on NHS England's Serious Incident Framework and associated guidance, templates and tools (further information about how we carried out this review is included in the appendix).

Many of our findings are not new, but they echo many of the issues raised by the Public Administration Select Committee in March last year; the Government's response in July 2015; and the Parliamentary and Health Service Ombudsman's report in December 2015. They also provide further evidence of the need for a step change in the way that serious incidents are investigated and managed in the NHS.

This briefing provides a summary of our findings, linked to five opportunities for improvement:

1. **Prioritising serious incidents that require full investigation and developing alternative methods for managing and learning from other types of incident.**

2. **Routinely involving patients and families in investigations.**

3. **Engaging and supporting the staff involved in the incident and investigation process.**

4. **Using skilled analysis to move the focus of investigation from the acts or omissions of staff, to identifying the underlying causes of the incident.**

5. **Using human factors principles to develop solutions that reduce the risk of the same incidents happening again.**

These issues raise important questions about how we now work together across the system to align expectations and create the right environment for open reporting, learning and improvement. The development of the new Healthcare Safety Investigation Branch and the move of the National Patient Safety team from NHS England to NHS Improvement provides a timely opportunity for us to come together to develop a shared definition of good practice and agree how we will work together to support and encourage improvement.

FIVE OPPORTUNITIES FOR LEARNING

1. Prioritising serious incidents that require full investigation and developing alternative methods for managing and learning from other types of incident

In a third of the reports we reviewed, it was not clear how the incident being investigated met the criteria for a full investigation under the Serious Incident Framework.

Over 13,000 serious incidents were reported and investigated in NHS acute trusts in 2014. The Serious Incident Framework guidance states that providers should prioritise incidents that require a full root cause analysis (RCA) according to their available resources and that "if an organisation states that all incidents that led to harm must be investigated using RCA, the organisation must ensure there are enough staff with the expertise and resources to do this".

Good practice

We found two near misses that were investigated appropriately.

One case involved a mis-calculation of paediatric medication. The other involved administering a drug for general anaesthesia to a patient who was having a surgical procedure that should have been commenced under local anaesthetic.

In both cases, staff quickly identified the error and the patients suffered no lasting harm. Nevertheless, the two trusts identified the potential for learning and made good attempts to identify the underlying human factors.

Our review suggests that in the absence of other agreed and potentially more proportionate responses, trusts often see the formal investigation process as the only available option for learning from incidents resulting in harm.

We saw a number of investigation reports of the most frequently reported types of incident, such as patient falls (10) and pressure ulcers (6) that took a long time to complete and contained lengthy chronologies. Many of them did not result in clear conclusions or recommendations that could be expected to reduce the likelihood of the incidents happening again. There were also examples that contained no information to explain how the impact or outcome for the patient aligned with the serious incident criteria.

The serious incident guidance suggests that "where an organisation has identified widespread risk and has undertaken (or is undertaking) a multi-incident investigation…. consideration should be given to whether resources could be better used on the delivery of improvement work rather than initiating another investigation".

We concluded that some of the incidents we reviewed would have benefitted from alternative approaches, using less complex but more efficient ways to address the needs of the patient(s) and to identify any mitigating actions that could prevent the incidents happening again.

In some of the reports in our sample the investigation template had been used to document reviews that were carried out to determine whether care had resulted in an 'avoidable' or 'unavoidable' outcome. Rather than being carried out to inform learning, they often read more like case note reviews and concluded that no action could have been taken to prevent the poor outcome.

One report was about an incident that related to the professional behaviour of a member of staff. This one should have been managed through the organisation's human resources or people management departments rather than the patient safety incident investigation processes.

2. Routinely involving patients and families in investigations

Only nine (12%) of the reports in the sample included clear evidence that the patient or their family had been involved in the investigation.

The Serious Incident Framework states that "the needs of those affected should be a primary concern for those involved in the response to and the investigation of serious incidents". The guidance recommends that the investigation report should clearly set out the action that was taken to respond quickly and efficiently to the needs of the patient and their family, and to provide the support, information and answers that they require.

Very few reports in our sample recorded the impact and outcome of the incident for the patient or set out how this was managed through additional care or support. Only nine reports (12%) clearly indicated any involvement of the patient or family in the investigation. As a result, reports showed a lack of perspective from the patient or their family on the incident.

- Most reports (88%) included some indication that the patient or their family had been informed of the incident.

- Just under half (36 reports) stated that patients or families were kept informed about the investigation.

- Only 27 reports (36%) included any evidence that the patient or their family had been offered a chance to discuss the report.

- 32 reports (43%) stated that the patient would be offered a copy of the report. However, very few of these recorded that a copy had actually been sent to the patient or their family.

We cannot conclude from our sample that patients and families were not informed or involved, but the reports did not clearly demonstrate that people were involved in line with the expectations of the current guidance and investigation reporting templates.

Good practice

A report of an investigation of an obstetric incident stated "On [date] the on-call consultant met with [the patient] and family for clinical review and to answer questions. The consultant also explained to [the patient] and family that a formal investigation was to take place. A designated family liaison person has been assigned to [the patient] as per the 'Being Open Policy'. A meeting took place with [the patient] and the family liaison personnel on [date]. Support for [the patient] and family was provided and remains on-going with follow up arranged."

3. Engaging and supporting the staff involved in the incident and investigation process

Only 29 (39%) of the reports we reviewed included evidence of interviews with members of staff who were involved in, or who had a perspective on the incident.

When an incident has serious consequences for a patient and their family it can also have a profound effect on the staff involved and the teams in which they work. While it is clearly a priority to manage the immediate needs of the patient and their family, it is also important to support members of staff who may be affected by the incident.[1]

The majority of the investigation reports in our sample (58 reports) included a section which stated that staff had been supported after the serious incident was identified. However, in many cases trusts used a standard phrase that was repeated in each report that we reviewed, irrespective of the impact on the individual member of staff involved.

It was more common for investigation reports to record that staff had provided written statements rather than being interviewed. This was the case in 46 reports (62%) in our sample.

Twenty-one reports (28%) provided no evidence of staff either being interviewed or providing written statements.

Sixteen reports (22%) showed that there had been some opportunity for the staff involved in the incident to take part in the investigation by reviewing the incident as a group. While this may not always be appropriate, it is sometimes a good way of identifying key problem areas and any deviation from expected or usual care processes. This requires skilful handling to create a non-threatening and honest environment.[2]

Data from the 2015 NHS staff survey shows that 86% of staff in acute hospitals felt encouraged by their organisation to report errors, near misses and incidents and that 44% agreed that their organisation treats staff who are involved in an error, near miss or incident fairly. However, nearly a third of respondents said they "neither agree nor disagree" in response to the latter question, which may suggest a lack of confidence in their organisation's culture and treatment of staff.

The report of the Public Administration Select Committee concluded that a "culture of defensiveness and blame, rather than a positive culture of accountability, pervades much of the NHS." The serious incident guidance recommends using the Incident Decision Tree (IDT) tool "to promote fair and consistent staff treatment within and between healthcare organisations".

Good practice

"The Midwives concerned have been supported by their Supervisors of Midwives, line manager and Operational Matron. The Student Midwives were also supported by their mentors, senior staff on [the unit], Supervisors of Midwives, Operational Matron and their University tutor. Head of Services and manager for surgery were informed of the incident and the need for staff members involved in the care of Patient [x] to be supported. An informal de-brief occurred with the staff involved following the incident and a further formal de-brief was arranged for [x] where all staff involved in the care of Patient [x] were invited".

However, only four investigation reports (three were from one trust) in our sample documented the use of the IDT (or any other tool) to ensure that staff were treated fairly as part of the investigation process. In one of the four cases, the use of the tool was incorrectly applied to the incident as a whole, rather than to an individual staff member. In another, the tool was applied to the patient rather than to a member of staff.

4. Using skilled analysis to move the focus from the acts or omissions of staff to identifying the underlying causes of the incident

Very few reports in our sample included clearly documented evidence of a well structured methodology and analysis leading to identification of key causal factors.

The Serious Incident Framework endorses the use of the tools and templates in the NPSA's RCA resource centre. These tools support the skilled analysis required to undertake a systematic investigation that looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which the incident happened. The reports we looked at showed little evidence that the recommended tools had been used.

The guidance in the framework states that organisations need a central team of experts in all types of risk and that staff who lead an investigation, or take part in an investigation team, will need an in-depth understanding of the investigation methodology and should be able to apply the tools and techniques in a variety of settings.

We found only six reports (8%) showed evidence of a clearly structured methodology that identified:

- the key issues to be explored and analysed
- the contributory factors and underlying system issues
- the key causal factors that led to the incident.

Sixty-one per cent (45) of the reports included entries under the heading of 'contributory factors', but there was very little evidence that the key issues had been analysed to identify the underlying system or environmental factors that allowed things to go wrong. Too many reports concluded that the actions of staff were the 'key causes' of the incident, with conclusions such as "the causal factors in the incident arise from failure to follow trust policy and procedures."

Often, reports did not include any evidence to show that the reasons behind the failure to comply had been fully explored. We assessed that nearly 75% (54 reports) had unanswered questions or unexplained issues, leaving the focus on staff acts or omissions.

5. Using human factors principles to develop solutions that reduce the risk of the same incidents happening again

Organisations that nurture a fair and just culture support and encourage their staff to share their learning and focus on addressing the causal factors that allowed things to go wrong. Research and human factors principles tell us that safety solutions that reduce the risk of the same incidents happening again are designed around a number of factors. These include:

- Designing tasks and processes to minimise dependency on short-term memory and attention span.
- Standardising processes and equipment, where relevant.
- Resisting reliance on policies and protocols as task aids; and that
- Retraining staff is not always the right solution.[3]

Good practice

One investigation identified a number of key causal factors that led to an incorrect drug being administered in theatres; these included the following issues:

- Similar looking bottles being kept next to each other in the cupboard, increasing the possibility of selecting the wrong one.
- A new data collection system causing distraction to the staff as they were asked for information during the drug administration.
- New charts, which may have mitigated the risk, had not been rolled out to all theatres.

Although the investigation reports in our sample included recommendations, many of them focused on reminding staff to follow or review agreed processes, or to be more vigilant. This included an example where an individual member of staff was required to undergo a period of supervised practice when it was the organisation's safety processes that had failed to detect an equipment failure.

Our review assessed whether it was clear from the report how the recommendations had reduced the risk of incidents happening again. In 26 of the 74 reports (35%) there was a positive response, indicating that our reviewers could see how the suggested recommendations and actions could reduce the risk of recurrence even if the investigation methodology was not clear. The quality of these 26 reports was better than most and they generally included some evidence of an investigative methodology.

Only 21 reports (28%) followed the investigation guidance and recorded a risk assessment following the investigation and the planned actions.

Good practice

We saw only a few examples where the recommendations could be linked to the analysis of key causal factors, including the design of equipment, environment and procedures, which could prevent the incidents happening again, for example:

- Wristbands for patients with swabs purposely left in situ.

- Colour coding introduced for particular specimen handling.

- Change in environment for specific task to minimise risk of interruption.

- Changing the design of theatre trays to prevent microvascular clips falling through the holes.

CONCLUSION

Investigating incidents that have led, or could lead to, harm is an important feature of the safety systems and processes that we expect to see in organisations that are committed to openness and transparency, learning and improvement.

Provider organisations have primary responsibility for making sure that their staff have the skills, capacity and support they need to carry out good quality investigations. They should have access to external expertise when needed, and opportunities to contribute to wider improvement initiatives when incidents may not warrant a formal investigation but where learning and solutions are needed to reduce the risk of them happening again. Trust boards must ask themselves if their investigations are making a difference and leading to improvement.

CQC also plays an important role, but we are just one part of a complex system in which many of our partners, including NHS Improvement, NHS England and commissioning organisations, also have an important role in leading and supporting improvements in safety.

The new Healthcare Safety Investigation Branch will also be established this year and is expected to become a centre of best practice.

This creates an ideal opportunity for us all to come together to agree a shared set of expectations, and to agree how we can develop and coordinate our respective roles and responsibilities in a way that can best support local organisations and encourage improvement.

Together, we have an opportunity to work together and agree:

- Which incidents are sufficiently serious that they should continue to be investigated formally against the Serious Incident Framework, and what other approaches there should be to learn from incidents that may not warrant a full and formal investigation, including where there are multiple or repeated incidents.

- What more we, or others, can do to support hospitals to develop the capacity and capability that is required, to encourage them to embed good investigative practice into their wider approach to learning and improvement, and to make sure that patients and their families are informed and involved, in line with the Duty of Candour.

- How we can encourage improvement across the wider health and social care sector and support other types of services, including new models of care, many of which may have less advanced safety systems and processes than the acute hospital sector.

APPENDIX: How we carried out the review

We reviewed 75 serious incident reports from 24 acute hospital trusts in total. This sample represented 15% of the total 159 acute hospital trusts in England at the time of undertaking this review. One report that didn't meet the criteria for a serious incident investigation was removed from our sample before analysis as it related to a human resources issue.

To reduce the burden on trusts, the sample was selected from the incident investigation reports already submitted by trusts as part of CQC's inspection process (included in provider information returns). The investigation reports in the sample related to incidents that had occurred between April 2013 and October 2014.

From the trusts that had submitted reports to CQC, we selected a sample with a representative distribution across CQC's Intelligent Monitoring priority bandings (as at January 2015) and geographical regions. We also reviewed the most recent inspection ratings for each trust in the sample (as at July 2015) to check whether the ratings for the trusts in our sample were representative of the ratings of all the acute trusts that had submitted serious incident investigation reports to CQC at the time.

For each hospital in the sample, we selected at least three recent investigation reports. This provided information about:

- The consistency and robustness of an organisation's application of safety systems, such as safety infrastructure, training, 'Being Open', staff support, trust oversight.

- The overarching quality assurance and sign-off processes as part of a commitment to learning from incidents.

- Whether a good investigation is due to a single good investigator or rather part of a positive safety culture.

The review was carried out by a small team of three CQC staff and four Specialist Advisers - all of whom had experience in undertaking investigations and/or assessing their quality. Workshops were held to ensure consistency in relation to the review process and interpretation of the review tool. A small pilot was undertaken, followed by feedback on the use and consistency of the tool and judgements made by the review team. Reviews were also benchmarked to ensure consistency of judgements.

The assessment framework used for this review was produced using current guidance, tools and templates available on the NHS England website, including:

- The Serious Incident Framework March 2013, which was the guidance in place when trusts carried out the investigations in the review.

- The revised Serious Incident Framework March 2015, to identify the impact of changed guidance on the findings of the review.

- The guidance, tools and templates available in the RCA resource centre http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/.

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1 Edrees H, Federico F, "Supporting clinicians after medical error", *British Medical Journal* 2015; 350 doi: http://dx.doi.org/10.1136/bmj.h1982, 15 April 2015

2 Guide to investigation report writing following Root Cause Analysis of patient safety incidents www.npsa.nhs.uk/nrls.

3 Leape LL, Berwick DM, Bates DW, "What practices will most improve safety?" Evidence-based medicine, JAMA 288(4): 501–7. PMID: 12132984, published 2002.

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