Care Quality Commission

Opening the door to change

NHS safety culture and the need for transformation

DECEMBER 2018

About the Care Quality Commission

Our purpose

The Care Quality Commission is the independent regulator of health and adult social care in England. We make sure that health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.

Our role

We register health and adult social care providers.

We monitor and inspect services to see whether they are safe, effective, caring, responsive and well-led, and we publish what we find, including quality ratings.

We use our legal powers to take action where we identify poor care.

We speak independently, publishing regional and national views of the major quality issues in health and social care, and encouraging improvement by highlighting good practice.

Our values

Excellence – being a high-performing organisation

Caring – treating everyone with dignity and respect

Integrity – doing the right thing

Teamwork – learning from each other to be the best we can

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Claire's story

Claire (not her real name) describes the effect of experiencing a wrong-site surgery.

"I was experiencing a tremendous amount of pain due to sciatica, and had a procedure to relieve this. It resulted in the surgeon injecting the wrong side. This was recognised immediately and as I was awake during the procedure he was able to ask me if he could do the right side, so it was rectified straight away. It was classed as a Never Event as it was a 'wrong-site surgery'.*

"Looking back, I can see the circumstances that led to the incident. I noticed that when people were doing checklists before the procedure they were interrupted quite a lot. I had one checklist with a nurse who was interrupted by an anaesthetist, who was then interrupted by a surgeon.

"I offered to give feedback to the trust… and I was invited to have a chat. Everyone listened and took a lot of notes. The manager of orthopaedics was very adversarial and wouldn't accept any of it – there was clearly an issue between them and the rest of the surgical team, and it was really uncomfortable. Some of the things they said also indicated that they had productivity targets to meet as a priority.

"One of the obvious things that was picked up during the investigation was volume – they were getting too many cases through the door, all with multiple appointments. The system felt fractured.

"When you have a poor experience, the amount of trust you have in the system declines – you ask whether you want to expose yourself to that again. The incident didn't impact my life personally that much – I was just pleased that the problem was solved and neuropathic pain was gone.

"[However,] the clinical governance lead was very attentive – they seemed committed to safety and stopping the poor experience, and that it was the circumstances that caused the incident rather than the person.

"Following the incident, the trust moved this sort of procedure to day surgery, so the second time I went in, it was a brilliant experience. The department felt more coordinated, less busy, staff seemed happier, and it was a smoother experience.

"Personally, I feel culture is just one part of the issue. It comes back to having a system of penalising staff. The assumption is that there's been 'wrongdoing' rather than mistakes – and puts blame on frontline staff, rather than further up the chain."

*Note: *the Never Event status of the type of incident used in this example is temporarily suspended, as the supporting clinical guidance for preventing such incidents is currently under review. The revised classification details will be reinstated in due course.*

Foreword

There has been much focus on the safety of NHS care over recent years and there is unquestionably a strong commitment across the service to make the care of patients as safe as possible.

Our inspections of NHS trusts have identified safety culture as a key concern and this study of the reasons for the recurrence of Never Events shows us that while the commitment to safety is indeed strong, trusts remain in the dark when it comes to up-to-date understanding of the principles of safety both within and outside the NHS, and have limited capacity to keep staff in touch with current best practice. Without specific patient safety expertise in each trust, the risk is that organisations will not have the necessary tools and knowledge to change the culture of safety in the NHS.

Never Events are patient safety incidents. They are only a very small proportion of the approximately two million reported patient safety incidents and approximately 21,500 serious incidents reported in 2017/18 in England's NHS. What sets Never Events apart is that they are believed to be wholly preventable by the implementation of the appropriate safety protocols. Despite this preventability, the number of Never Events has not fallen. About 500 times each year we are not preventing the preventable. That means that around 500 patients are suffering unnecessary harm. This failure to reduce

the number of Never Events is sending us an important message.

The occurrence of a Never Event is thought to tell us something important about the patient safety processes in the service where it happens. There is undoubtedly some truth in this, but as we have carried out this review it has become increasingly clear to us that our failure to reduce the toll of Never Events tells us something fundamental about the safety culture of our health care.

We brought together healthcare staff with experience of managing safety issues and safety experts from other safety critical industries. We were struck by how differently health care thinks about safety compared with other industries. The other safety critical industries speak of their work as "high risk" and this informs everything they do. Safety alerts are implemented effectively and consistently; an understanding of team dynamics, situational awareness, and human factors and ergonomics are central to how they work. Safety protocols are followed without question. Staff are expected to raise any concerns about safety and do so as a matter of course. There is no hesitation in stopping operational processes if safety is thought to be in any way compromised.

Safety training is never regarded as optional. They stressed to us that errors were inevitable and that everything they do is planned with this in mind.

Health care, which in statistical terms is higher risk than any of the industries we consulted, in contrast took the view that safety was the norm and things only went wrong exceptionally. Staff are not expected to make errors. This leads to a search for quick fixes and technical solutions, when Never Events occur. Our analysis showed that only 4% of Never Events are amenable to this approach, the overwhelming majority require human factors based solutions.

There is a contradiction between how health care culturally thinks about patient safety and the experience of individual members of staff. Staff know that what they do carries risk, but the culture in which they work is one that considers itself as essentially safe. We have repeatedly highlighted in our inspection reports that staff are often unwilling or unable to raise safety concerns. Raising concerns challenges the cultural norms of the workplace and the dichotomy between the safety reality and the safety culture may be the reason why this has proved such an intractable problem. Just like the persistent number of Never Events, our observations of this problem in our inspections sends us a message about the underlying weaknesses in the safety culture of the NHS.

The contradiction between culture and reality also leads to defensive behaviour when things do inevitably go wrong. Defensiveness weakens our ability to understand why safety problems have occurred and too often leads to individuals being blamed for real or perceived errors. The

safety experts we spoke to from outside health care told us that this behaviour led to increased risk. They also highlighted how they had learnt that hierarchical cultures were inimical to safety and had to be eradicated. In the NHS this lesson has not been learned and rigid professional and managerial hierarchies remain widespread.

We have been constantly impressed by the commitment we have found in staff across the NHS to patient safety. Our challenge is to turn this commitment into real change for the better. Fundamentally, the safety culture of the NHS has to radically transform if we are to reduce the toll of Never Events and the much greater number of other safety events. Cultural change is not easy; the other industries we spoke to told us it had taken them years to achieve. Many will find challenge to their cultural norms to be uncomfortable. We have made recommendations that will start the process of building an NHS that delivers the safest possible health care. But mechanistic implementation of the recommendations alone will not be enough to achieve the change that is needed. A new era of leadership, focused on safety culture, engaging staff and involving patients is essential.

Professor Ted Baker
Chief Inspector of Hospitals

Summary

Never Events are serious incidents that are considered to be 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. However, Never Events continue to happen: there were 468 incidents provisionally classified as Never Events between 1 April 2017 and 31 March 2018.[1,a]

We have examined the underlying issues in NHS trusts that contribute to the occurrence of Never Events and the learning that we can apply to wider safety issues.

Within the scope of this review we wanted to understand what makes it easier, and what makes it harder, for the different people and organisations in the system to prevent Never Events and deliver safe care more widely. We sought to answer:

- How is the guidance to prevent Never Events, including patient safety alerts, regarded by trusts?
- How effectively do trusts implement the safety guidance?
- How do other system partners support trusts with the implementation of safety guidance?
- What can we learn from other industries?

Between April and June 2018, we visited 18 NHS acute and mental health trusts, carrying out one-to-one interviews, visiting different services and reviewing policies and procedures. Over the last year, we held forums and workshops with patient representatives, people from the NHS, other healthcare organisations and other industries, and safety and human factors experts. We held focus groups with frontline staff and asked for information from arm's length bodies about their role in patient safety. We spoke to many experts as part of this thematic review. A key focus of our review was to understand the approach to safety of other safety-critical industries, such as aviation, nuclear and fire and rescue.

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a. Note: data is combination of provisional data for 1 April 2017 to 31 January 2018 and for 1 February to 31 March 2018. In addition to the incidents removed from the total counts in the published provisional data, one more incident, so far, has been removed as it did not meet the definition of a never event, bringing the total count to 468.

What we found

The challenges faced by trusts

While patient safety alerts are generally viewed as an effective way to disseminate safety guidance to trusts, the context in which they are landing creates numerous challenges for trusts.

- With the competing pressures on staff due to high workloads, implementing patient safety alerts can be seen as just one more thing to do, and can lead to staff taking a mechanistic and siloed approach to implementation. This might mean passing responsibility for implementing alerts to multiple individuals, rather than having a system in place to coordinate implementation. This can lead to many adaptations of the same piece of guidance.

- Greater standardisation of processes, like the approach taken in other industries, might help to ease this pressure, and make it easier for staff to speak up with confidence if processes are not being followed. However, standardisation should not override clinicians' ability to use their professional judgement and act flexibly when circumstances require this.

- Different approaches to governance mean that processes are not in place to drive or monitor progress effectively, and too much reliance is placed on the individuals delegated the task of implementing alerts. In addition, boards are not consistently prioritising meaningful discussions about Never Events and associated safety alerts.

- Leadership styles and hierarchies can have a detrimental effect on trust safety cultures; we heard that rigid hierarchical structures prevent people from speaking up about potential safety critical incidents. A number of initiatives across the NHS are helping to tackle this problem.

The challenges across the healthcare system as a whole

Arm's-length bodies, including CQC, royal colleges and professional regulators, have a substantial role to play within patient safety, but the current system is confused and complex, with no clear understanding of how it is organised and who is responsible for what. This makes it difficult for trusts to prioritise what needs to be done and when.

- Trusts receive too many safety-related messages from too many different sources. The trusts we spoke to said there needed to be better communication and coordination between national bodies, and greater clarity around the roles of the various organisations that send these messages.

- Trusts were generally positive about the support available from clinical commissioning groups (CCGs) following the publication of an alert or after a Never Event. However, this is variable. Some CCGs were comprehensive and collaborative in their approach, visiting trusts to observe how they implemented guidance, talking with staff and patients, and having frequent meetings with trust leaders. Some saw assurance and monitoring as simply checking what trusts are doing administratively, without getting involved.

- There is no clear system for staff to learn from each other at a national level. Local reporting systems are often poor quality and do not support staff well. There are lessons that can be learned from other industries with simpler and more transparent reporting systems, backed up by a culture that drives good reporting. Patient safety collaboratives are uniquely placed to support organisations to improve patient safety outcomes.

- Patient safety systems are more likely to be effective if patients are actively involved, but patient involvement is not done consistently well.

The challenges in educating and training staff

Various bodies are responsible for different aspects of clinical and wider professional education in England, including universities, royal colleges, professional regulators, Health Education England and employers like NHS trusts. It is not easy to establish who is responsible for which elements of education or who has the authority to deem any element of training mandatory, for example around

patient safety, and place it consistently within training programmes. As patient safety training is incorporated implicitly within professional healthcare programmes, it can sometimes be difficult, for both the learner and the casual observer, to identify where it is explicit.

- Understanding human factors and ergonomics is a key element of building a better patient safety system. Training in human factors and ergonomics as part of safety system design, incident investigation and solution development has long been recognised as important but has not been effectively implemented. The role of human factors and ergonomics within safety is encouragingly being recognised more widely, and there is an opportunity to learn from other high-risk industries, for example nuclear, where this type of training is already being delivered as a core element of staff education.[2]

- People we spoke with and the existing literature we reviewed talked about the benefits of multidisciplinary training rather than training in individual clinical groups. Working and training as a multidisciplinary team is important for many reasons, not least because it can help to break down hierarchies. Again, there is an opportunity to learn from other industries that have implemented this.

- People we spoke with told us that while trusts recognised the importance of patient safety, safety education is not a priority for leaders in the same way that operational targets are. Other industries regard ongoing training as crucial to prevent habitual behaviour and errors.

- Training in human factors – that is human-system interactions and the effect this has on risk and safety, as part of safety system design – incident investigation and solution development has long been recognised as important but has not been effectively implemented.

Our conclusions

Never Events continue to happen despite the hard work and efforts of frontline staff. Staff are struggling to cope with large volumes of safety guidance, they have little time and space to implement guidance effectively, and the systems and processes around them are not always supportive. Where staff are trying to implement guidance, they are often doing this in addition to a demanding and busy role that makes it difficult to give the work the time it requires.

In terms of the wider system, we have found that the different parts at national, regional and local level do not always work together in the most supportive way. There is a lot of confusion about the roles of different bodies and where trusts can go to get the most appropriate support.

While we recognise that there is a lot of positive work taking place and that change cannot happen overnight, we found that education and training for patient safety could be further improved and the pace of change could be hastened. Patient safety training should be explicit and delivered at an undergraduate level. However, we found that not only is it failing to gain traction at this stage in health professionals' careers, but staff are also not being given the time to do appropriate levels of training on patient safety once they have entered their clinical careers.

Everyone who has a role in health care or who receives health care in England should recognise the importance of making patient safety a top priority and the extent of the cultural change needed to make this a reality.

The recommendations that we are making in this report do not underestimate the huge level of enthusiasm and work which is already happening. We want them to lead to a change in culture and behaviour at both a system level and within individual organisations; enabling the NHS to respond appropriately to safety alerts and thereby reduce the risk of harm to patients. They reflect the journey to embedding patient safety expertise throughout the workforce and putting safety at the heart of our health system.

Our recommendations

1. NHS Improvement should work in partnership with Health Education England and others to make sure that the entire NHS workforce has a common understanding of patient safety and the skills and behaviours and leadership culture necessary to make it a priority. NHS Improvement and Health Education England should also develop accessible, specialist training in patient safety that staff can study as part of their clinical education or as a separate discipline.

2. The National Patient Safety Strategy must support the NHS to have safety as a top priority. Driven by the National Director of Patient Safety at NHS Improvement, it should set out a clear vision on patient safety, clarifying the roles and responsibilities of key players, including patients, with clear milestones for deliverables. It should ensure that an effective safety culture is embedded at every level, from senior leadership to the frontline.

3. Leaders with a responsibility for patient safety must have the appropriate training, expertise and support to drive safety improvement in trusts. Their role is to make sure that the trust reviews its safety culture on an ongoing basis, so that it meets the highest possible standards and is centred on learning and improvement. They should have an active role in feeding this insight back to NHS Improvement so that other NHS organisations can learn from it, as is the case in other industries.

4. NHS Improvement should work with professional regulators, royal colleges, frontline staff and patient groups to develop a framework for identifying where clinical processes and other elements, such as equipment and governance processes, can and should be standardised.

5. The National Patient Safety Alert Committee (NaPSAC) should oversee a standardised patient safety alert system that aligns the processes and outputs of all bodies and teams that issue alerts, and make sure that they set out clear and effective actions that providers must take on safety-critical issues.

6. NHS Improvement should work with professional regulators and royal colleges to review the Never Events framework, focusing on leadership and safety culture, and exploring the barriers to preventing errors such as human behaviours.

7. CQC will use the findings of this report to improve the way we assess and regulate safety, to ensure that the entire NHS workforce has a common understanding of leadership and just culture, and the skills and behaviours necessary to make safety a priority.

Introduction

In Autumn 2017, the Secretary of State for Health and Social Care asked the Care Quality Commission (CQC), in collaboration with NHS Improvement, to examine the underlying issues in NHS trusts that contribute to the occurrence of Never Events and the learning we can apply to wider safety issues.

Never Events are serious incidents that are regarded as 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. What defines a Never Event is not the effect it has relative to other incidents, but rather the fact that had the relevant protective barriers been in place it would not have occurred. Each Never Event has the potential to cause serious patient harm or death.

A well-functioning clinical governance system should make sure that Never Events are prevented, but a single Never Event can act as a red flag that an organisation's systems may not be robust. When a Never Event happens, it should trigger a substantial response, with a focus on learning not blame.

A framework for identifying and monitoring Never Events in the NHS in England was launched by the National Patient Safety Agency in March 2009, following the publication of Lord Darzi's report *High quality care for all*.

There are currently 15 types of incident that NHS Improvement classifies as Never Events and include, for example, wrong-site surgery, retained foreign body post procedure and medication administration errors (see appendix A).[3]

Healthcare providers must report on the occurrence of Never Events and other serious incidents through the Strategic Executive Information System (StEIS), a system that assists the reporting and monitoring of investigations between NHS providers and commissioners. Provisional data between 1 April 2017 and 31 March 2018 shows 468 incidents were classified as Never Events. These numbers are subject to change when all incidents are reviewed, but included:

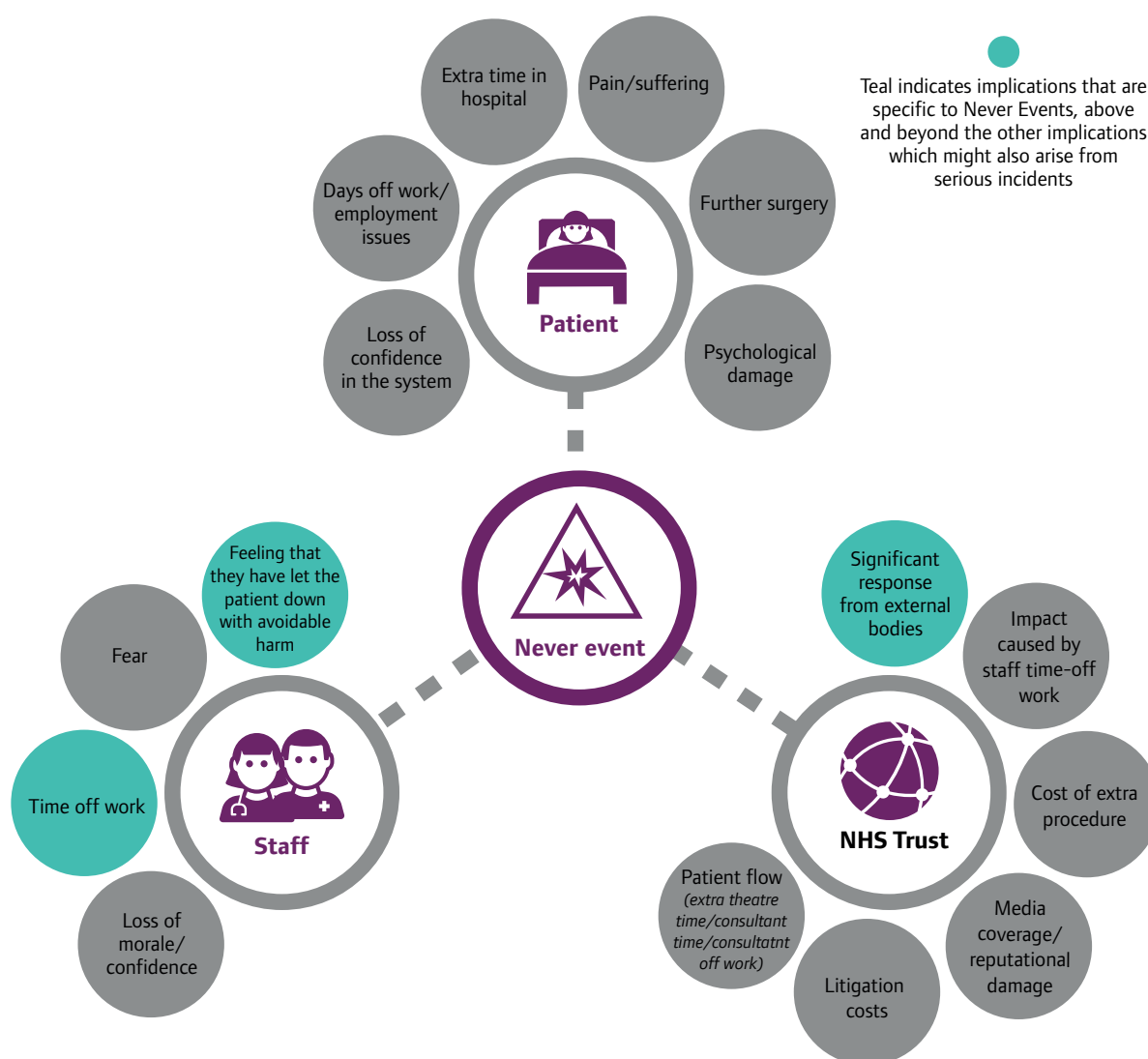- 203 wrong site surgery incidents (for example, ovaries removed in error during a hysterectomy, wrong eye injection, wrong level spinal surgery)
- 112 retained foreign body post procedures (for example, guide wires, surgical swab, needle)
- 64 wrong implant/prosthesis (for example, hip, knee, lens)
- 26 misplaced naso- or orogastric tubes
- 35 medication administration errors (including, administering medication by the wrong route,

overdoes of methotrexate or insulin, and mis-selection of strong potassium solution).[4,b]

However, it is important to put the occurrence of Never Events into context. Never Events are only a very small proportion of the approximately two million patient safety incidents reported to the National Reporting and Learning System (NRLS) annually (around 74% of these reported incidents caused no harm to the patient)[5] and approximately 21,500 serious incidents reported in 2017/18 in the NHS in England.

Not only can Never Events affect people's wellbeing, but they can also have financial consequences. In monetary terms, the NHS has paid almost £52 million on claims relating to possible or identified Never Events since 2009 (based on NHS Resolution data). Other costs of Never Events can include delayed care and additional treatment for the patient and their family, and carrying out investigations and follow up for staff and the NHS **(FIGURE 1)**.

FIGURE 1: POSSIBLE IMPLICATIONS OF A NEVER EVENT*

Teal indicates implications that are specific to Never Events, above and beyond the other implications which might also arise from serious incidents

Patient
- Extra time in hospital
- Pain/suffering
- Days off work/employment issues
- Further surgery
- Loss of confidence in the system
- Psychological damage

Never event

Staff
- Feeling that they have let the patient down with avoidable harm
- Fear
- Time off work
- Loss of morale/confidence

NHS Trust
- Significant response from external bodies
- Impact caused by staff time-off work
- Cost of extra procedure
- Patient flow (extra theatre time/consultant time/consultatnt off work)
- Media coverage/reputational damage
- Litigation costs

* Never Events will have different consquences for different people and groups.
  This graphic represents things people have told us can sometimes happen as a result of a Never Event.

b. Note: data is combination of provisional data for 1 April 2017 to 31 January 2018 and for 1 February to 31 March 2018. In addition to the incidents removed from the total counts in the published provisional data, one more incident, so far, has been removed as it did not meet the definition of a never event, bringing the total count to 468. The counts listed in our report include amendments to the published provisional data as one incident was wrongly categorised as a wrong implant/prothesis when it was a wrong-site surgery.

Within the scope of this review we wanted to understand what makes it easier, and what makes it harder, for the different people and organisations in the NHS to prevent Never Events and deliver safe care more widely. We also wanted to understand if there were any insights we could gain from other industries and countries which could support the English NHS.

The review therefore sought to answer four questions:

- How is the guidance to prevent Never Events regarded by trusts?
- How effectively do trusts implement the safety guidance?
- How do other system partners support trusts with the implementation of safety guidance?
- What can we learn from other industries?

To answer these questions, we worked with NHS Improvement to collect evidence. We visited 18 NHS trusts, held focus groups with frontline staff, and spoke to arms-length bodies about their role in patient safety. We also held a number of engagement workshops, which included patient representatives, experts from other safety critical industries, healthcare services rated as outstanding for safety, and experts in human factors. We have used the expert opinion gathered from these engagement workshops, expert advisory group meetings and one-to-one conversations with safety specialists to test and develop our key findings and recommendations. See appendix B for more details of our approach.

We found that simply focusing on Never Events as part of this review would not have been helpful. Many of the challenges trusts have implementing patient safety guidance to prevent Never Events are equally true for other important areas affecting patient safety. We have therefore looked more widely than Never Events, both in terms of our approach and when drafting our recommendations. This approach was necessary to make sure that within the review we were able to find solutions to system problems rather than focus on specific elements that would place an extra burden on staff, without the promise of useful and sustainable improvement.

We also recognise the importance of high-quality investigations following incidents. While we did not look specifically at investigations as part of this review, we have previously commented on the implications of not getting these right, for example in our report *Learning, candour and accountability: A review of the way NHS trusts review and investigate the deaths of patients in England*.[6] We should not forget that investigations form an important part of the process following an incident, but this was not a focus of this review so we have not addressed it in detail.

Patient safety and the challenges for NHS trusts

Key points

- Patient safety alerts are generally viewed as an effective way to disseminate guidance to trusts, but it is the context into which they land that creates challenges.

- With the competing pressures on staff due to high workloads, implementing patient safety alerts can be seen as just one more thing to do, and can lead to staff taking a mechanistic and siloed approach to implementation. This might mean passing responsibility for implementing alerts to multiple individuals, rather than having a system in place to coordinate implementation. This can lead to many adaptations of the same piece of guidance.

- Greater standardisation of processes, like the approach taken in other industries, might help to ease this pressure, and make it easier for staff to speak up with confidence if processes are not being followed. However, standardisation should not override clinician's ability to use their professional judgement and act flexibly when circumstances require this.

- Different approaches to governance mean that processes are not in place to drive or monitor progress effectively, and too much reliance is placed on the individuals delegated the task of implementing alerts. In addition, boards are not consistently prioritising meaningful discussions about Never Events and associated safety alerts.

- Leadership styles and hierarchies can have a detrimental effect on trust safety cultures; we heard that rigid hierarchical structures prevent people from speaking up about potential safety critical incidents. A number of initiatives across the NHS are helping to tackle this problem.

NEVER EVENT: RETAINED FOREIGN OBJECT POST PROCEDURE

Mohammed*, a 55-year-old man, was admitted to hospital for elective (non-emergency) liver surgery. At the beginning of the surgery, the team completed an initial count of all the swabs and instruments to be used in his operation, which was then written on the white board in the operating theatre, as per safety guidance.

During the surgery a total of five abdominal swabs were used. Two abdominal swabs were used in the first instance (one to clean the surgical site and another for blood) and placed in a bowl after use. A further three abdominal swabs were placed under the liver to lift the liver up so that the surgeon had better access to it, of which the team were informed.

At the end of the operation just before the team closed Mohammed's abdomen, the team completed another count. A number of smaller swabs (some clean and some used) were counted in to the bowl on top of the two abdominal swabs already in the bowl. The two abdominal swabs were not removed from the bowl and therefore not seen during the pre-closure count, as a result it was thought that there were actually five abdominal swabs in the bowl and so five were crossed off the white board. The surgical wound was closed and the final count performed (which counts only those swabs that had not previously been counted). The three abdominal swabs were not identified as unaccounted for and were left behind in his abdomen when it was closed. They were identified a few days later following an x-ray and Mohammed needed a further operation to remove the swabs. He made a full recovery but was in hospital for a week longer than necessary.

Mohammed had experienced a retained foreign object post procedure. This type of incident is considered very preventable because healthcare providers are expected to carry out specific counting and checking procedures as specified by safety guidance, such as the 2015 patient safety alert 'Supporting the Introduction of the National Safety Standards for Invasive Procedures (NatSSIPs)'. These standards support safe and consistent practice in accounting for all items used during invasive procedures and in minimising the risk of them being retained unintentionally.

The local investigation identified that there was a trust policy for counting items during the procedure, but that this was not completely followed. It also picked up that swab counting across the organisation varied and that there was no clear guidance about what should be included in the count. The NatSSIPs guidance does recommend a single, organisation-wide approach to swab counts. There was also a belief in this organisation that the abdominal swabs being used were too big to be left inside the abdomen unintentionally, so staff may not have been as diligent as they should have been about the larger swabs when doing the count. The team concerned were also relatively junior and the investigation identified several interruptions that occurred during the swab counting process.

*Case study based on real events

Never Events are patient safety incidents that should never happen if safety guidance, in particular NHS Improvement's patient safety alerts, is put into place. We wanted to understand how effective these alerts were in practice. We therefore looked at the alert implementation process in detail to gather new evidence on what works and what does not work. We found that while the patient safety alerts themselves are generally viewed as an effective way to disseminate guidance to trusts, it is often the context in which they are landing that creates challenges. The three key issues identified as barriers to implementation were:

1. difficulties with staff workload and competing priorities

2. a lack of clear standards and expectations

3. a lack of support from leaders in the trusts.

This chapter looks in more detail at these findings on the contextual barriers in organisations that prevent trusts and staff from implementing patient safety alerts.

1. Workload and prioritisation

Overall, people we spoke with were positive about patient safety alerts and said that they were clear and effective in communicating the actions needed when safety issues arise. However, they also told us that one of the biggest barriers to implementing these actions was a lack of time and resources.
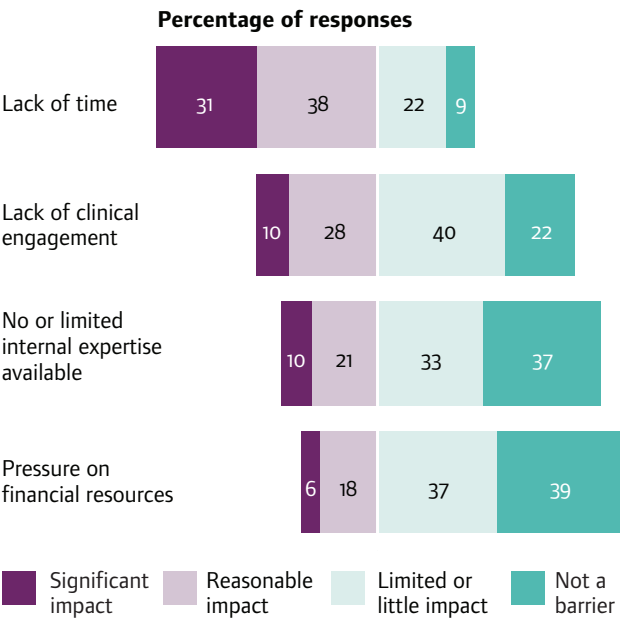
Time and resources

Staff at both leadership and frontline levels told us that they felt overwhelmed by the volume and nature of the demands currently placed on them. The number of alerts and amount of other information from multiple organisations, for example about different targets and initiatives, can be unmanageable. There are also substantial pressures on organisations to meet targets that focus on patient flow and throughput, which can conflict with processes designed to ensure safety.

These challenges are not only evident in trusts rated as inadequate or requires improvement. Trusts with services rated as outstanding for safety told us they faced similar issues when implementing alerts, including a lack of skilled and experienced staff, high turnover of staff, and reliance on less qualified staff taking on more senior roles. As a result, we were told, staff had limited time and space to engage in quality improvement initiatives that could support effective alert implementation, or to attend relevant training in in the trust.

These findings are supported by the 2018 National Safety Standards for Invasive Procedures (NatSSIPs) survey, which looked at how trusts had responded to the patient safety alert on implementing the NatSSIPs.[7] While this only relates to one alert, it highlights the concerns around implementation, and particularly the lack of time that staff have for this, with 69% reporting that this had a substantial or reasonable effect on being able to implement the alert **(FIGURE 2)**.

Percentage of responses

	Significant impact	Reasonable impact	Limited or little impact	Not a barrier
Lack of time	31	38	22	9
Lack of clinical engagement	10	28	40	22
No or limited internal expertise available	10	21	33	37
Pressure on financial resources	6	18	37	39

Source: The National Safety Standards for Invasive Procedures (NatSSIPs) implementation survey findings, NHS Improvement. Note: Due to rounding figures may not add up to 100%.

Where there are competing pressures, implementing patient safety alerts can become just one more thing to do, and can lead to staff taking a relatively uncoordinated, mechanistic and siloed approach to implementation. We heard examples of people who received the patient safety alerts passing responsibility for implementing alerts to multiple individuals, rather than having a system in place to coordinate implementation. People told us that working in large, complex organisations can lead to many adaptations of the same piece of guidance.

People also told us about the tension between ward teams being given the responsibility to design processes following receipt of an alert, but not being given the time or support to implement it well, and external organisations needing to be employed to implement it. For example, one trust brought in an external organisation to action an alert before giving

ward staff the necessary support to effectively implement it themselves. Ward teams were resistant to this, which highlights the importance of giving staff the time and support from leaders within the trust to implement alerts without looking to external organisations to provide solutions. We heard more than once that this type of centrally formulated or external guidance can lack the same effect as locally formed protocols.

Organisational and individual cultural issues

It is important to note that organisation and individual cultural issues can also hinder the implementation of safety guidance. For example, we heard how some clinicians and trusts did not always recognise the importance of the actions in the patient safety alerts. This may have been because there was a lack of recognition that this could happen to anyone at any level. We heard of examples where work to prevent Never Events only took place after the occurrence of the Never Event because trusts had believed it could not happen to them. One interviewee highlighted the importance of engaging people and convincing them of the importance of safety critical actions:

"We need to use the 'Think, Feel, Behave' approach. People can be made very aware of the existence of a risk like a Never Event (the 'think' bit), but they need to 'feel' its importance to drive the real change in behaviour. In our case the 'feel' was powerfully prompted by the event – not by an alert from the centre. The centre needs to get better at getting people to 'feel' the importance of their alerts. We need stories, appeal to the emotion. If people do not feel then they won't do.''

Interview with a trust's medical director

The NatSSIPs survey also identified resistance to change, with staff not seeing the alert as a priority, not considering it as applicable to their work, or feeling that their current processes were good enough. Trusts also reported that the alert could be too bureaucratic and take too much time to implement. Trusts being resistant to change does not necessarily imply that they see safety as unimportant. It could suggest that leaders are not motivating staff to embrace a safety culture, to continually look for opportunities to improve, or to allocate time for improvement work.

Support with implementation

As well as the importance of communicating and engaging people in the implementation of the alert, staff told us that they needed to be supported better to implement them effectively. Ideas for this included: better provision of supporting materials; a better understanding of 'what good looks like' and how trusts fit within this definition; and staff engagement at all levels to highlight the importance of having protected time for implementation and related activities.

There were also suggestions for how patient safety alerts themselves could be improved. This included providing a more multimedia approach to communicating patient safety alerts, for example increased use of videos, slides, animations, short podcasts; more advice on how to implement the actions in the alerts, such as sample implementation plans; and better access to case studies where alerts have been implemented successfully.

Clinical commissioning groups (CCGs) also had ideas for improving the auditing and monitoring of patient safety alerts. For example, interviewees suggested that alerts should be more explicit about how trusts should review actions, and that the alerts should provide greater clarity on what is expected of the CCG. However, they were unsure about how much involvement they should have in supporting a trust once a patient safety alert has been issued.

Some staff also told us that there were some situations where they simply wanted to be told what to do, how to do it and how to monitor it,

and there were frequent calls for standardisation of patient safety processes.

2. Lack of standard processes

Finding the time to work out how to implement change, share ideas and think about the challenges in different settings, is a clear barrier to implementation. Staff told us that this can make implementing the alert effectively feel too difficult and time consuming. As a result, there is a need to find ways to ease this pressure. One way to do this is by adopting greater standardisation where it is feasible and safe to do so. Work will be needed to ascertain which processes lend themselves to standardisation, which is why we are recommending NHS Improvement take this action forward. We also heard that greater standardisation would make it easier for locums, agency workers and more junior staff to speak up with confidence when these standard processes were not being followed.

However, standardisation does not come without its challenges. For example, we heard that:

- standardisation could be seen as something that reduces the ability of clinicians to act flexibly where necessary
- standard processes are not always followed, with a tolerance for workarounds in the NHS
- there is a lack of confidence that standardisation will improve practice.

Clinical professional judgement

While standardisation was seen as a good solution, people we spoke with felt strongly that clinicians should not lose the ability to use their professional judgement where the circumstances needed them to think more laterally. This is not a new finding and has been recognised as one of the main barriers to standardisation by the World Health Organization (WHO).[8] Accordingly, any standardisation would need to:

- relate only to those processes that clearly lend themselves to it

- make sure that the design involves extensive co-production with practising frontline staff, is evidence-based, and is clear about the benefits, for example lives being saved
- include a mechanism for discretion, for example where the standard approach is judged to carry a greater risk in exceptional circumstances.

Ultimately, where standardisation has been adopted this should become the process that is followed by everyone without exception. It is not appropriate for staff to ignore standard processes in favour of their own methods. Where there are safety issues that outweigh the use of the agreed standard, then suitably qualified and experienced staff should be able to make this judgement call and be supported in their actions by their trust.

Workarounds

Standardisation in the NHS is not a new concept, for example the WHO surgical safety checklist, National Safety Standards for Invasive Procedures (NatSSIPs) and Local Safety Standards for Invasive Procedures (LocSSIPs) are already in place.[c] However, we found that these are not always being implemented effectively to prevent surgical Never Events from occurring.

This is supported by the findings of a 2018 report that examined 38 Never Event root cause analyses and a 'South West Regional Review of Never Event Root Cause Analyses' completed by NHS England and NHS Improvement in 2016/17.[9,10] The latter report found that 49% of Never Events in that region were wrong-site surgery and most happened in general theatres. The key causes cited were not only "non-adherence to approved procedures", but also "human error", "complex pathways" and "time pressures". A lack of leadership, lack of staff and distractions were also cited as causes. Clearly, some of these factors are variables that are difficult to control, and others could lead to staff not adhering to the guidance and workarounds taking place.

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c   NatSSIPs are national safety standards that set out the key steps necessary to deliver safe care for patients undergoing invasive procedures. LocSSIPs are locally developed standards, based on NatSSIPs, that ensure a consistent approach to the care of patients undergoing invasive procedures in any location.

When invited to observe operations, we saw some excellent examples of the WHO surgical safety checklist in action, and we saw times when awareness of human factors overrode these distractions. For example, we observed a procedure led by a consultant involved in developing human factors training at their trust. During the procedure, someone was trying to ask the consultant a question and they politely said that this stage of the procedure required high levels of concentration so there could be no distractions during that time (see the example "Thinking innovatively about distractions" about how another trust has tried to reduce the risks of distractions).

However, we also saw how people's availability at key points, such as at time in and time out, changeovers of staff during procedure and distractions meant that processes were not always followed. At another trust we were invited to visit, there were safety procedures in place for surgery. However, as the WHO surgical checklist makes no requirement for a specified lead, compliance with and the effectiveness of the process relied on the resolve of certain individuals or champions to take responsibility for implementing it. This was made more challenging by frequent changes of personnel during theatre lists and individual procedures.

Feedback from our forums and focus groups with frontline staff also highlighted that not adhering to protocols is being tolerated in the NHS. This includes arriving late for theatre, and disregarding checklists and protocols. Frontline staff in our focus groups noted distraction as an issue and we saw many examples of distractions during procedures at trusts that invited us to observe surgeries. One patient representative, when reflecting on their experience of a Never Event, told us, "I had one checklist with a nurse who was interrupted by an anaesthetist, who was then interrupted by a surgeon".

THINKING INNOVATIVELY ABOUT DISTRACTIONS – TEN THOUSAND FEET

In January 2018, East Lancashire Hospitals NHS introduced the "10,000 Feet" concept for surgical staff. Based on the 'Below Ten Thousand' concept developed at the University Hospital Geelong, Australia, when any member of the surgical team find that noises and distractions are affecting their performance, they can use the trigger phrase "10,000 Feet" to allow the clinician the time and space to do their job safely. This could be, for example, when patients are to be extubated and the anaesthetist needs to focus.

Following its implementation, East Lancashire has reported that:

- junior members of the surgical team (including students) feel more empowered to speak up.

- staff have more awareness and are better educated about how noise and distraction is detrimental to patient safety.

- staff are more aware of the need for "below ten thousand moments". In particular, through the use of the phrase at time out and sign out, staff now recognise that these are the 'slowing down' moments that require teamwork for effective implementation

- everyone has control of the environment and are confident in calling "10,000 Feet" if at any point they feel that noise and distractions are impeding on the care of the patient.

Lack of confidence in standardisation

A lack of confidence in standard protocols was another challenge to introducing standardisation. For example, while clinicians in one trust we visited understood the reason for introducing additional checklists as the trust's preferred approach to implementing NatSSIPs, they were "cynical" of the benefits. As a result, we heard of examples where senior doctors and consultants would delegate to junior members of the team and not engage with the process themselves. We heard that any standardisation of practice and procedures needs to be constantly reviewed and improved, with clear feedback to the body setting the standard enabling regular iterations that are based on frontline experience.

Standardisation in other industries

There are lessons here that the NHS can learn from other industries. In other industries, such as aviation, frontline staff get involved in adapting guidance, in discussions around improving safety processes, including discussions after near misses and incidents, and in providing feedback on areas for improvement. This enables them to embrace a culture where everyone can be involved in creating standard operating procedures, challenge where these are not being followed, and understand the consequences for others if procedures are not followed.

Trusts need to embrace a culture where safety is seen as a key part of everyone's job and where all can be involved in designing standard processes, where these are appropriate and make the job of staff easier and clearer. However, embracing such a culture is entirely dependent on the leadership and governance in the trust and the way it prioritises safety.

LEARNING FROM OTHER INDUSTRIES: BRITISH AIRWAYS' APPROACH TO STANDARDISATION

British Airways (BA) told us about their approach to standardisation and in particular their use of checklists. BA recognises that there is a danger of checklists becoming a tick box exercise, which could lead to complacency. As a result, it does not view them as a one-size fits all solution, but as tools that need to work for their staff and make their jobs easier to do.

BA prioritises the intuitive design of checklists so that, for example, they can be modified locally where necessary, and are produced on A4 size sheets with just the key items highlighted rather than long protocols. They also make co-production with people who use the checklists part of the design process to ensure buy-in and adherence. BA emphasises that checklists should not be used to run a procedure. Procedures are done from memory and checklists are used to make sure that safety critical items have not been forgotten or missed after the procedure has been completed.

3. Leadership and governance

We heard, and have seen through our visits, how the governance and leadership in a trust can have a direct effect on being able to successfully implement safety guidance and prevent Never Events, as well as the overarching safety culture that exists in a hospital.

Inconsistent governance arrangements

Effective patient safety governance systems are essential to enable the safety guidance to be implemented, particularly where workloads feel overwhelming and priorities are difficult to balance. However, findings from our review suggest that each trust took a different approach to governance for patient safety alerts and safety more widely. While we recognise that each trust operates differently across England, not having a consistent approach to safety governance

may make it harder for staff to navigate trust governance systems when moving between trusts, and also make it more difficult for trusts and regulators to benchmark the effectiveness of their governance processes. Given the calls we heard for greater standardisation, this could be one area that may benefit from a standardised approach.

We found two key implications of poor governance structures:

1. limited ability to drive or monitor progress

2. lack of clear direction on effective implementation.

Ability to drive and monitor progress

In some trusts, we heard that staff were identified to lead on the actions of the patient safety alert (often in addition to their substantive role), but that the trust did not have the clinical governance structures in place to drive or monitor progress effectively. For example, an alert issued in 2017 required NHS organisations to carry out systematic identification of girls and women taking a drug called valproate. One interview with a chief pharmacist highlighted how their trust did not have the governance in place to monitor which patients were on valproate, even though this was the subject of a patient safety alert from NHS Improvement and the Medicines and Healthcare products Regulatory Agency (MHRA).

'[The trust] doesn't have a central list of patients on valproate. [There is] no system to create that list. No electronic medicines management system. [The trust] currently doesn't know centrally how many patients are on valproate.'

Reviewer's reflections on interview with a chief pharmacist

Lack of clear direction

We found that some trusts were taking action to address issues with governance. However, evidence from the majority of the trusts we visited, and the staff we spoke with, suggests that even where trusts have processes in place for receiving alerts (including identifying leads, communicating alerts to them and receiving assurance that actions had been taken), these are not always effective and there is too much reliance on the individuals delegated the task of implementing the actions. As noted earlier, this can lead to large, complex organisations taking a number of different approaches to implementing a single alert.

We found, for example, where staff try to embed important safety guidance, such as Local Safety Standards for Invasive Procedures (LocSSIPs), they are often not given protected time to do this. Implementing LocSSIPs involves modifying the National Safety Standards for Invasive Procedures (NatSSIPs) 2015 for local use. In some organisations, we found that individual clinicians had been delegated the task of implementing LocSSIPs, and were then required to spend a substantial amount of time doing extra work on top of their substantive role to do this. This put pressure on them as to what they should prioritise, and in some cases meant that the LocSSIPs had not been implemented effectively.

People also told us that it is important to have time to learn from a Never Event as part of evaluating the effectiveness of the original implementation alert process. Some trusts told us that they shared the learning from a Never Event through learning and improvement groups, newsletters, intranet or presentations. However, the success of these approaches to sharing learning was not clear.

Inconsistent prioritisation at board level

How patient safety alerts are viewed at board level was another key area we looked at as part of our review. We wanted to understand whether the implementation of these alerts was a priority for boards and/or whether it was being discussed at board level. We looked at 100 hospital quality reports for 2016/17, of which over 82% referred

generally to the occurrence of Never Events. However, only 59% of these referred to planned or implemented actions, and less than a fifth (18%) referred to the factors that had contributed to the occurrence of the Never Events.

To better understand if the implementation of patient safety alerts and their actions are discussed at board level we looked more closely at a sample of board papers for trusts that had reported a particular type of Never Event.

Most trusts in the sample we reviewed had neither recorded any board discussion on these Never Events nor asked for information about the actions needed, and no follow-up discussion was suggested. While it is not a specific requirement to do so, it is reasonable to assume that trust boards should be assuring themselves that serious incidents, including Never Events, are reported in a timely manner, and effectively and appropriately investigated, that robust action plans are developed and implemented, and that learning is shared as appropriate. It is possible that discussions about Never Events, either generally or specifically, may have taken place in other governance committees or have happened but not been noted. However, it appears that boards do not consistently prioritise meaningful discussions about Never Events and associated patient safety alerts.

Trusts need to review their safety culture, put more effective governance systems in place, and have leaders with a responsibility for safety that have the appropriate expertise for the role. Often these roles are filled by doctors or nurses who may not have the right skills or knowledge and are doing this work in addition to their substantive role.

Representatives from the Royal Air Force told us how they employ identifiable people with specific roles in safety to identify and reduce risks **(SEE BOX 'ROYAL AIR FORCE APPROACH TO SAFETY')**. While participants in our focus groups with frontline staff, and in our forum with other industries, expressed the view that having an identified lead patient safety specialist would help to drive the safety agenda in trusts, they also flagged the importance that in the NHS these roles should work closely with frontline staff rather than being a standalone role.

LEARNING FROM OTHER INDUSTRIES: ROYAL AIR FORCE APPROACH TO SAFETY

The Royal Air Force (RAF) told us about how they completely changed their approach to safety following a government report on a Nimrod crash over Afghanistan, which recommended that there needed to be clear ownership of risks and solutions.[11]

Following a review of their approach to safety, the RAF updated their safety system so that there are now appointed people (called aviation duty holders) with personal legal responsibility and accountability for the safe operation, continuing airworthiness and maintenance of systems in their area of responsibility, and for ensuring that risk to life is reduced to at least tolerable and as low as reasonably practicable (ALARP). These duty holders have a clear process to follow, which is also in use across a number of industries. This includes:

- Proactively identifying risks. Action is then taken to mitigate or reduce these risks to a level that is agreed to be 'as low as reasonably practicable' and tolerable. (Pilots will still fly when risks exist, but personnel are assured that everything has been done to reduce risks to an acceptable level.)

- Accepting that risk still exists and error could still occur, but all proportionate steps have been taken to negate it.

- Being clear about who is accountable for deciding what level of risk is acceptable. These people are also accountable for investing in safety measures.

- Reviewing errors using a just culture approach. If personnel have followed guidance and have not deliberately intended to cause harm, any mistake or error will be handled using just culture guidance to make sure that individuals are not blamed.[12]

As well as driving trusts' approach to safety and having clear governance systems in place, trust leaders have a key role in setting the culture of the organisation where patient safety is a top priority and people feel able to speak up.

Leadership and the influence on safety cultures

People told us that leadership styles and hierarchies can have a detrimental effect on safety cultures in NHS organisations.

We heard that rigid hierarchical structures still prevent people from speaking up about potential safety critical issues or incidents. For example, frontline staff told us that some staff, such as junior staff, nurses, or bank staff, are often very reluctant to question surgeons, and some surgeons were known for speaking down to junior staff. We were told about one case where:

"Forceps [were] left in the patient, but the nurse flagging the issue was completely dismissed. The patient was only x-rayed due to continued insistence by the nurse and the forceps were in the patient. Nothing happened to look at the surgeon's practice, and no one ever apologised to the nurse."

Attendee at a focus group with frontline staff

This is supported by the findings of the report, 'Surgical Never Events: Learning from 38 cases occurring in English hospitals between April 2016 and March 2017'. This concluded that while speaking up is key to developing a good safety culture, it often does not happen, potentially because of hierarchies and previous experiences of disruptive and rude behaviour.[13]

People in services rated as outstanding for safety told us how staff were empowered to speak up and identify if something is not right, and that there was transparency for staff, patients and leaders. For example, consultants and junior doctors are encouraged to call each other by their first name, and consultants are explicit that juniors can ring them at any time.

They also told us that it was important for leaders to both prioritise safety and instil a sense of trust in staff that people will be able to speak up without retribution. To achieve this 'just' culture in the organisation, they felt:

- leaders need to be less defensive when an incident occurs, and focus more on the identified learning
- there must be transparency for staff, patients and leaders
- when something goes wrong, patients and families should be involved in the investigation process from an early stage.

As well as speaking to outstanding trusts, we found other initiatives in the NHS designed to tackle the challenge of hierarchies.

HALT TOOL

St Helens and Knowsley Teaching Hospitals NHS Trust is using the HALT tool to support staff in speaking up freely. Based on human factors principles, the tool allows anyone in the surgical team to stop an operation due to a patient safety issue. The acronym acts as a prompt to support staff to speak up and stands for:

- **H**ave you noticed/considered?
- **A**sk did they hear/consider your suggestion?
- **L**et them know that this is a patient safety issue
- **T**ell the team to STOP until consensus agreement supports that it is safe to continue

Any team member is enabled to ask for clarification that the leader heard and considered their patient safety issue. The tool was used as part of the trust's safer surgery redesign. Along with the use of other human factors based approaches, it has helped the trust to significantly increase incident reporting over a six-month period following the redesign, and is now fully embedded in day-to-day clinical practice. The reporting of incidents that have resulted in harm has also decreased significantly.

The Sign up to Safety campaign, funded by the Department of Health and Social Care, acknowledges the challenges of hierarchies and aims to reduce the effect of these.[14] However, it is clear from the feedback we received during our review that universal change on hierarchies is yet to happen and many the distribution and balance of power in teams more of these initiatives will be needed.

As in previous sections, there are lessons that the NHS can learn from other industries. For example, British Airways have tools to manage hierarchies in their organisation, some which are aimed at leaders and others at operational staff. For example, they teach their staff that leaders should respond completely to questions and acknowledge contributions, while staff in non-leadership positions should be aware of and take action to manage it. Leaders should use eye contact and followers should use red flag acronyms that everyone is aware of, for example CUSS - 1) I am Concerned, 2) I am Uncomfortable, 3) This is not Safe, 4) Stop.

Summary

Patient safety alerts are seen as a valuable tool, but we have heard that in reality staff and trusts face a number of challenges and barriers to implementing the alerts. Staff do not consistently have the time or resources to be able to effectively put processes in place to protect patients, and implementing the alerts is not prioritised, but becomes another thing to do in an already pressurised environment.

Patient safety should be part of everyone's role, but this will require a cultural shift that will take time. Leaders with a responsibility for safety need to have the appropriate expertise to drive the safety agenda in trusts, and they should take an active role in feeding back this insight to NHS Improvement.

People also told us that there need to be changes that make their jobs easier to do. Standardised approaches to certain processes, which we have seen in place in other industries, could provide this support for staff and improve patient safety, as well as give staff the confidence to speak up if processes are not being followed. However, such standardisation should not override clinician's ability to use their professional judgement and act flexibly when circumstances require this.

Staff need to be clear about the actions required by safety alerts and supported effectively by trust leaders and governance processes, so that measures to prevent safety incidents are put in place effectively. A key factor to achieving this is having an alerts system that aligns the processes and outputs of all bodies that issue guidance on safety, which we discuss in the next chapter.

Patient safety in the wider healthcare system

Key points

- The current patient safety landscape is confused and complex, with no clear understanding of how it is organised and who is responsible for what tasks. This makes it difficult for trusts to prioritise what needs to be done and when.

- Trusts receive too many safety-related messages from too many different sources. The trusts we spoke to said there needed to be better communication and coordination between national bodies, and greater clarity around the roles of the various organisations that send these messages.

- Trusts were generally positive about the support available from clinical commissioning groups (CCGs) following the publication of an alert or after a Never Event. However, this is variable. Some CCGs were comprehensive and collaborative in their approach, visiting trusts to observe how they implemented

guidance, talking with staff and patients, and having frequent meetings with trust leaders. Some saw assurance and monitoring as simply checking what trusts are doing administratively, without getting involved.

- There is no clear system for staff to learn from each other at a national level. Local reporting systems are often poor quality and do not support staff well. There are lessons that can be learned from other industries with simpler and more transparent reporting systems, backed up by a culture that drives good reporting. Patient safety collaboratives are uniquely placed to support organisations to improve patient safety outcomes.

- Patient safety systems are more likely to be effective if patients are actively involved, but patient involvement is not done consistently well.

NEVER EVENT: WRONG-SITE SURGERY

Clara*, a 69-year-old suffering from chronic knee pain, was admitted to hospital for surgery on her knee to diagnose what was causing her chronic pain. Shortly after the start of the surgery, the anaesthetist realised that the surgeon was operating on the wrong knee. The surgery stopped immediately and the correct knee was then operated on during the same session. Clara was left with scars on both knees.

Clara experienced wrong-site surgery, when surgery is carried out on the wrong part of a patient's body. It is classed as a Never Event as this type of incident is considered preventable, with clear guidance and specific processes for verifying and marking the part of the patient's body that is to be operated on.[15,16]

The trust carried out an investigation into the incident and found that safety protocols were not embedded well enough in routine practice, and protocols were either not conducted or not done well. For example, the pen mark used to identify the correct knee was not put close enough to the operation site itself and, as a result, could not easily be seen after the patient was covered with the surgical sheets. The wrong knee was also partially exposed when Clara was moved while on the operating table, resulting in one of the sterile sheets slipping.

Other errors contributing to the Never Event included not all the surgical team members being present for the 'sign in' process. This takes place before the start of surgery and should involve the whole team. The purpose is to verbally confirm important facts including who the patient is, what the planned operation is, who are the members of the surgical team and what their roles during the procedure will be.

In addition, the whole team were not engaged in the pre-procedure 'time out'. This takes place immediately before the first cut is made by the surgeon. It should act as a final check of everyone's understanding of what the team are about to do. In this incident the first circulating nurse read out 'left leg' from the patient's notes but the second circulating nurse was holding the right leg. The first nurse asked if this was the correct leg but because the team were distracted and not paying attention to the 'time out' process, this did not alert anyone to the error. The surgical team went on to prepare the wrong leg for surgery.

*Case study based on real events

Arm's-length bodies, including CQC, royal colleges and professional regulators, have a substantial role to play in patient safety. As a result, we wanted to understand more about the current patient safety landscape and the roles and responsibilities of these organisations. Through our review, we found that the current system is confused and complex, with no clear understanding of how it is organised and who is responsible for what tasks.

In this chapter, we look at the following factors that affect safety in the wider healthcare system. This includes from the start when an alert is issued, through the support that is offered, where there are opportunities to learn, what happens at local level in the trust and finally how we involve the end user of services – the patient:

1. communication and coordination of patient safety messages

2. support for trusts from national bodies

3. support for trusts from regional bodies

4. sharing learning nationally

5. trust patient safety systems and cultures

6. importance of patients in the safety system.

1. Communication and coordination of messaging

People told us that trusts receive too many safety-related messages from too many different sources. Many of these messages are sent via the Central Alerting System (CAS). Hosted by the Medicines and Healthcare products Regulatory Agency (MHRA), this is a two-way communication route where NHS trusts, NHS England regional teams and clinical commissioning groups (CCGs) receive alerts by email and feed back to CAS when they have completed any actions required. From the beginning of November 2017 to the end of October 2018, 118 messages were sent via CAS from multiple organisations **(FIGURE 3)**.

Trusts also receive guidance, such as safety-related letters and notices, directly from national bodies (for example NHS England, NHS Improvement and CQC), and local commissioners. In addition, they receive a range of guidance and reports from other organisations, such as professional regulators and royal colleges. Not only does this make it difficult for trusts to prioritise what is a 'must do' and what would be 'helpful to do', it is also difficult to understand what applies to them and where to go for support.
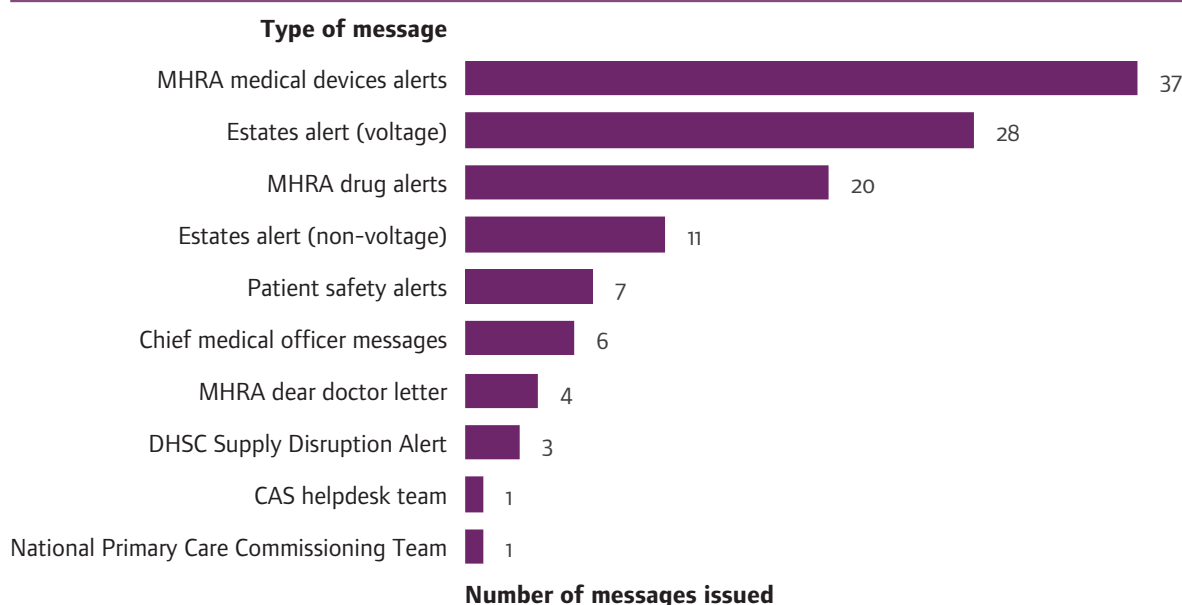
In addition, trusts we spoke with said there needed to be better communication between national bodies. Steps to address this are being taken. In June 2018, NHS Improvement set up the National Patient Safety Alerts Committee. This brings together the various bodies that issue alerts through CAS with the aim of improving alert consistency, reducing complexity and providing more clarity for regional and local organisations.

Improving the coordination of messaging is positive progress. However, we also heard that there needs to be greater clarity around the roles of the various organisations that send these messages, with trusts telling us that accessing national support on patient safety issues can be difficult.

2. Support from national bodies

On our visits to trusts, staff with a role in patient safety said that they often did not know where to go for support, as links to national bodies were poor and they were unsure where responsibilities lie. They felt that proactive support was lacking and it was only when something went wrong that support would arrive from national bodies. People working in services rated as outstanding for safety specifically told us that external organisations were still behaving in a punitive manner and continued to provide little support.

FIGURE 3: NUMBER OF MESSAGES ISSUED VIA CAS BETWEEN 1 NOVEMBER 2017 AND 31 OCTOBER 2018

Type of message

Type of message	Number of messages issued
MHRA medical devices alerts	37
Estates alert (voltage)	28
MHRA drug alerts	20
Estates alert (non-voltage)	11
Patient safety alerts	7
Chief medical officer messages	6
MHRA dear doctor letter	4
DHSC Supply Disruption Alert	3
CAS helpdesk team	1
National Primary Care Commissioning Team	1

Number of messages issued

Source: Central Alerting System, November 2017 to October 2018

This was corroborated by staff we spoke with in trusts who had mixed views about the role of regulators and royal colleges in supporting trusts following the publication of an alert or the occurrence of a Never Event. One board representative for safety went as far as saying that the trust received no support from NHS England or NHS Improvement. Others stated that not only was there a perceived lack of support but, collectively, the involvement of NHS England, NHS Improvement, royal colleges and/ or CQC in relation to Never Events was commonly considered to cause "pressure" and "increased anxiety".

Across the review, we heard that communication between different national and regional bodies could be improved when responding to a Never Event. For example, members of our expert advisory group told us that after reporting a Never Event, a trust will sometimes receive multiple uncoordinated requests for the same information from a number of organisations, including CCGs, NHS Improvement, CQC and Health Education England (if the incident involves a trainee).

People told us that better communication between regulators, and between departments of NHS Improvement, would support trusts with implementing alerts and decision-making around Never Events:

'The governance team will always err on the side of caution to report [even] if [it] may not be a Never Event. But it would be easier if … [trusts] just had one organisation that [they] needed to talk to, to understand whether it was a Never Event or not.'

Interview with a trust's head of governance

We heard some good examples of trusts working with regulators, for example, NHS Improvement supporting a trust with training about Never Events.

3. Support from clinical commissioning groups

Trusts were generally positive about the support available at CCG level following the publication of an alert or after a Never Event. For example, one trust told us:

"[We] have good working relationships with individual staff in the CCG. [The] safety team in [the] CCG meet with [our] governance team monthly to review serious incidents. In the past, the governance team have been able to [talk to] the CCG… to get their thoughts on an incident and whether it is a serious incident or [a] Never Event.'

Interview with a trust's head of governance

Trusts told us that they kept CCGs informed about Never Events and other serious incidents through a variety of channels, for example by email, over the phone, or with site visits. Some trusts met regularly with their CCGs through safety-related meetings, but the frequency of these varied depending on the trust.

At one trust that invited us to observe surgical operations, senior staff told us that they felt that the support from CCGs can be good but, in their experience, had only come after multiple Never Events. The medical director at the trust told us how following a run of three Never Events, NHS Improvement came to advise them about how to improve. Following the improvement work, the three CCGs that cover the trust came to see the improvement work and now come every year for assurance.

Despite trusts generally being positive about support received from CCGs, not all trusts felt supported. When we looked at the reasons behind this difference of opinion on CCGs, we found that the level of support offered may

vary because CCGs are not always completely clear themselves on what their role in patient safety should be. They know, for instance, that it includes assurance and monitoring, but what this means in practice is not consistent. For example, some CCGs saw assurance and monitoring as simply checking what trusts are doing administratively without getting involved. One way they did this was by providing oversight of formal reports produced by trusts and cross checking the content.

Others felt that they could offer some support but would not generally concern themselves with the practicalities of responding to alerts or if a Never Event occurred. Some CCGs were much more comprehensive and collaborative in their approach, visiting trusts to observe how they implemented guidance, talking with staff and patients, checking policies and frameworks, attending forums and having frequent meetings with trust leaders to discuss any identified issues.

There were also examples of some CCGs playing a more analytical role and using other sources of data to provide support to trusts. For example, one CCG described triangulating patient safety intelligence with CCG data, trust data, board reports and data from the National Reporting and Learning System (NRLS).

A few CCGs suggested that their role was to challenge trusts' decisions and the processes that they use:

"It's about monitoring the safety in the hospital and challenging them where we think their processes need to be tightened up [for example] the trust [had] quite a backlog of serious incident reports not being completed in the deadline and complaints responses, so we [asked] questions on that basis."

Interview with a CCG representative

And some CCGs prioritised certain alerts over others, although it is not clear how they identified the 'higher level' patient safety alerts:

"[The CCG] will monitor the higher level [patient safety alerts]. For example, the LocSSIPs, was monitored quite thoroughly through, and even after, the event."

Interview with a CCG representative

While it is clear that there needs to be greater clarity of roles of national and regional bodies, as well as a reduction in the volume of messaging, we also found that there needs to be more support in helping trusts to share learning from patient safety incidents or improvement work.

4. Sharing learning nationally

Findings from our review suggest that there are currently no widely accessed national systems – technical or otherwise – that enable and promote the sharing of softer 'learning' between trusts and other insights from patient safety improvement work or Never Events in particular.

People in trusts told us that, currently, sharing of information and insight externally about Never Events often happens face-to-face through forums, groups and projects, and often at a senior level, for example medical directors or directors of nursing. While efforts to support peer-to-peer networking and sharing do exist, such as the Q Initiative by the Health Foundation, these are not purely focused on safety and are not accessed by large numbers of frontline staff.

NHS Improvement is currently developing a replacement for the NRLS, which will include new mechanisms for sharing insight and information about preventing Never Events and other patient safety improvement issues. The Patient Safety Incident Management System is due to go live in 2019.

While this progress is positive, we heard that changes in culture and behaviour are also needed to tackle patient safety challenges when it comes to sharing learning in the NHS. Trusts told us that sharing their experiences with other trusts or agencies has mixed results. For example, one lead for safety at a trust told us that while they had received support from one acute trust, they had approached another trust that was not willing to share details of their actions or support.

We also heard from our forums with people working in other industries and services rated as outstanding for safety, focus groups with frontline staff and conversations with our expert advisory group, that people were particularly reluctant to share their experiences of Never Events. It was suggested that this may be due to the stigma attached, and potential issues around confidentiality and liability where there is an ongoing investigation. This means that the ability to share ideas, initiatives and improvement strategies can be affected by substantial delays, of sometimes years, while trusts wait for legal proceedings to conclude.

Established in 2014, patient safety collaboratives are designed to overcome some of these barriers and to bring together patient safety ideas and experiences.[17] The initiative is funded and nationally coordinated by NHS Improvement and delivered locally by the Academic Health Science Networks. Fifteen patient safety collaboratives are currently in operation with the aim of:

- creating safer systems of care that reflect continuous learning and improvement
- creating the conditions for a culture of safety to flourish
- drawing out the learning from errors and excellence
- reducing avoidable harm and variations in safe care delivery
- sharing improvement learning with a view to national scale-up and adoption.

These 15 patient safety collaboratives are well placed to support organisations and teams with patient safety improvement work and to systematically and sustainably achieve improved patient safety outcomes.

While problems with sharing information and learning from patient safety incidents between trusts is being addressed, there are also issues in trusts themselves that need to be resolved.

5. Trust patient safety systems and cultures

Effective incident reporting systems in trusts, which collect data on patient safety incidents near misses and staff concerns, are a crucial part of a well-functioning patient safety system. However, the safety culture and reporting systems do not always support staff to do the right thing. We heard from people working in trusts that to improve reporting there needs to be:

- greater clarity in what should be reported
- more feedback on reported incidents, including open and honest conversations about what happened
- more effective systems for reporting Never Events.

If staff are not given the right tools and information to report incidents, near misses and concerns, they will not be able to provide the data needed to improve patient safety within NHS trusts. Reporting in the NHS is high and does include a large number of no harm incident reports (74%), but from what we heard this could be improved further with clearer expectations and better reporting systems.[18]

Other industries use certain approaches to improve reporting, some of which could be transferable to health care and others that would be more of a challenge (FIGURE 4).

FIGURE 4: BARRIERS AND ENABLERS TO INCIDENT REPORTING IDENTIFIED IN OTHER INDUSTRIES

Barriers to incident reporting	Enablers of incident reporting
• Fear of disciplinary action • Pressure to not report	• Indemnity against disciplinary proceedings • Confidentiality or de-identification • Separation between the agency that collects data and analysis of data
• Perception that reporting does not lead to change • Lack of feedback when reporting	• Rapid, useful and intelligible feedback to wide reporting community
• Practical reasons: too time consuming, too difficult • Confusion of what types of incidents to report and to whom	• Ease of making the report
• Risk acceptance: incidents are part of the job	

Source: based on review of literature and discussions during forum with representatives from the NHS, other industries and safety experts.

During our forum with other industries, we heard about different approaches to tackle issues with reporting. The Fire and Rescue service told us that they have simplified their reporting system, but noted that it is culture that drives good reporting. Others told us how they embrace the importance of reporting and recognise the significance of near misses. For example, in aviation and the Royal Air Force (RAF) there are transparent reporting systems, which also focus on near misses, as well as actual incidents or accidents. This approach relies on a good reporting culture and an assertive risk management culture that aim to predict safety events rather than waiting for them to happen before looking for the root cause.

However, patient safety is not just about having the right systems in place for reporting and sharing information, but about the wider conditions that staff work in. This includes factors such as:

- **environment** – for example layout of the environment overall and where areas, such as recovery, are situated in relation to the operating theatre; how treatment rooms are set out; and where equipment is stored and whether it can be accessed easily and quickly. In the oil and gas industries, the layout of

sites and storage of equipment is key to ensuring a safe environment and is taken seriously by people responsible for safety.

- **processes and protocols** – including allocating responsibilities in terms of who does what, when and how to make sure that actions are carried out safely. We saw this clear allocation of tasks and actions in the RAF system.

- **investigations** – moving away from a culture of blame, to one that accepts that errors do occur and is supportive of staff, where investigations focus on the context in which clinicians are working and not just the individual. We found a clear investigation process when we looked at the aviation industry.

We found that in the NHS, system factors are not always designed in a way that help staff to work safely, and there was room for improvement. Looking at these issues as a whole is called 'systems thinking'.

Systems models such as the Safety I and Safety II frameworks, the Yorkshire Contributory Factors Framework, and the Carayon model are designed to help staff identify options for change in these types of areas.[19,20,21] However, we found that

they are not being widely used and that the concept of 'systems thinking' in healthcare safety is not widely understood and implemented.

A key part of systems thinking involves how we approach innovation. People told us that innovation is closely linked to improving safety in the NHS, and we heard examples of trusts developing innovative solutions to system-wide problems. For example, at a patient safety conference we heard about one trust that had developed an information and learning app for their staff, which cost very little to set up and run, but provided a wealth of easily accessible information in one place, including information on Never Events and patient safety more broadly. However, progress was difficult because of the level of proof needed to show effectiveness, and a lack of financial incentive or ability for trusts to invest in products.

The use of bar coding to prevent error was highlighted as another potential solution to improving safety. The Healthcare Safety Investigation Branch (HSIB) has recently reported on the value of bar coding and has recommended that the Department for Health and Social Care should, for example, introduce a barcode scanning system in theatres to identify incompatible prostheses before they are implanted in patients.[22]

During our review, we also found that there are additional opportunities for the NHS to learn from healthcare organisations in other countries. In April 2018, we ran a workshop with 15 different countries using the European Partnership of Supervisory Organisations (EPSO) network. At this event, delegates from Denmark described how a collaboration between the Danish Medicines Agency, the Danish Patient Safety Authority and pharmaceutical companies has been successful in reducing prescribing errors with the low-molecular-weight heparins **(SEE BOX 'DESIGNING OUT ERROR')**.

6. Involving patients

Involving patients in improving the safety of their care is vital, but we know from our previous thematic reviews, such as *Better care in my hands*,

that patient involvement is not done consistently well.[23] In general, we found that national bodies, for example CQC, the National Institute for Clinical Excellence (NICE) and NHS Improvement, were good at involving patients in developing guidance to make sure that it is robust and takes account of all relevant views.[24,25,26] However, at a local level we did not see similar examples where patients were involved in improving patient safety processes in hospitals. Some trusts told us that they have patient participation groups or patient representatives on their boards, but that they were not involved with specific work in implementing safety guidance, for example patient safety alerts.

Patients we spoke with believed that partnership working could help to improve care, reduce error and promote transparency in hospitals. Even with the most technical processes, the voice of the patient adds value and a different perspective. Trusts may need to be given support on how to involve patients in a meaningful way so that their voice is heard, and make sure that it is not overlooked or that they are not involved in a tokenistic way.

Listening to patients is particularly important at the point of delivery of care. Patients we spoke with accepted that not everyone would want to be involved in their care to the same level. However, they felt strongly that where relevant, patients should be involved to help improve care, reduce error and promote transparency. There was a feeling that patients and/or their families and carers know a lot about their condition so have a potentially valuable role in supporting doctors to deliver care.

They felt that health care was too paternalistic, and that it was important to give patients a better understanding about how mistakes can occur. They also felt that there also needs to be better awareness and acceptance in the first place that clinicians will make mistakes.

One way to improve dialogue, help to involve patients in decisions, reduce perceived hierarchy between doctors and patients and help change the culture is to change the language of Never Events and safety alerts, which is discussed in greater detail in the next chapter.
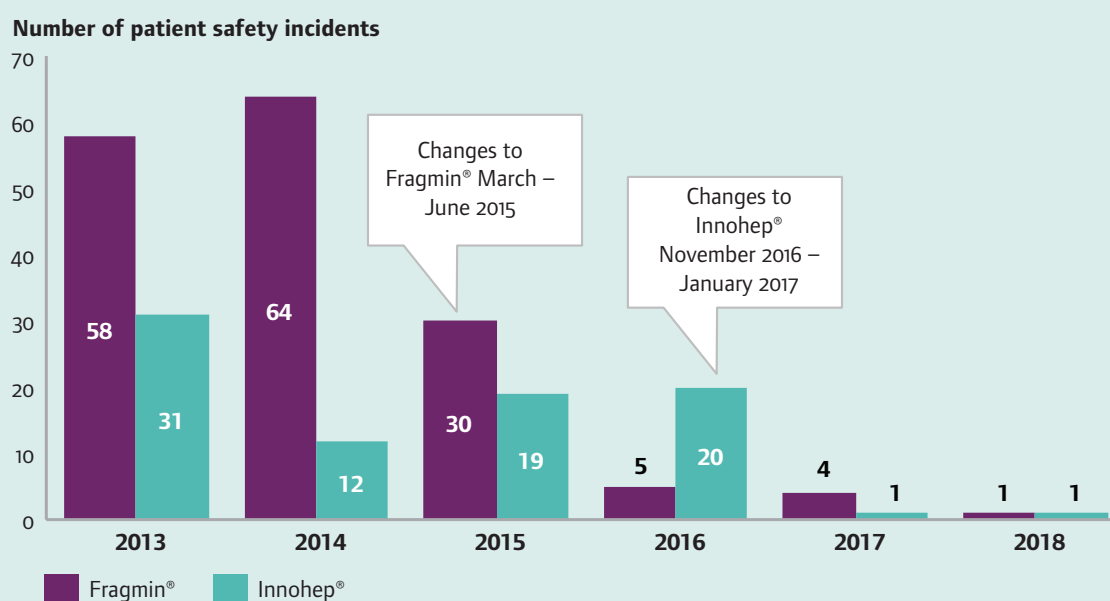
DESIGNING OUT ERROR: THE DANISH MEDICINES AGENCY AND THE DANISH PATIENT SAFETY AUTHORITY

The Danish Medicines Agency and the Danish Patient Safety Authority collaborated with the two pharmaceutical companies responsible for the low-molecular-weight heparins in the Danish market, Innohep® and Fragmin®, to find a solution to prescribing errors.

A decision was made to split the existing marketing authorisations into several different products and make the dose of each product clearly distinguishable in the systems used by physicians to prescribe medicines. The changes took effect from March to June 2015 for Fragmin® and from November 2016 to January 2017 for Innohep®.

A follow-up analysis of patient safety incidents reported to the Danish Patient Safety Authority involving prescription errors of the two products revealed a substantial drop in patient safety incidents. This coincided with the implementation of the new marketing authorisations and the subsequent changes in the information available to prescribing physicians **(FIGURE 5)**. This is a strong indication that the collaborative efforts of the pharmaceutical companies, pharmacies and the two authorities had a positive effect on patient safety where low-molecular-weight heparins are involved.

FIGURE 5: NUMBER OF PATIENT SAFETY INCIDENTS WHERE THE STRENGTH AND DOSE DID NOT MATCH THE PRESCRIPTION FOR LOW-MOLECULAR-WEIGHT HEPARINS

Number of patient safety incidents

Source: Patient Safety Board, Denmark

Summary

The current patient safety landscape is confused and complex, with no clear understanding of how it is organised or who is responsible for what tasks. Throughout our review we heard how trusts receive multiple messages from various national bodies. This adds pressure on trusts who often feel overwhelmed with the volume of guidance, and makes it difficult for them to prioritise what needs to be done. While trusts were generally positive about the support available from CCGs, national support with implementing patient safety alerts and other guidance is lacking and trusts are unclear about where to go for support. The recently formed National Patient Safety Alerts Committee is in a strong position to oversee a new alerts system that aligns processes and outputs of these bodies, and make sure that there are clear and effective actions for providers.

The ability of NHS trusts to learn from incidents locally and at a wider level is also hampered, with slow and unresponsive reporting processes that can discourage staff from reporting incidents in the first place. Where good reporting does not take place, this can have important implications on the investigation stage and any subsequent learning. Trust cultures can also create barriers to sharing information. With no national systems in place to support this, trusts are not incentivised to collaborate with each other and act together to learn from incidents that have happened. Better technology and improved organisational safety cultures are needed to encourage staff to report all incidents whether they happened or could have happened. Patient safety collaboratives are also well placed to support trusts to improve patient safety outcomes.

Patient safety systems are also more likely to be effective if patients are actively involved. Patients need to be encouraged to play a greater part in their care to make sure that they remain safe when treated by the NHS.

Education and training for staff on safety systems and processes

Key points

- The health education system is complex, with multiple bodies working at different levels with different staff types. This means it is not easy to establish who is responsible for which elements of education or who has the authority to deem any element of training mandatory. As patient safety training is incorporated implicitly within professional healthcare programmes, it can sometimes be difficult, for both the learner and the casual observer, to identify where it is explicit.

- Understanding human factors and ergonomics is a key element of building a better patient safety system. Training in human factors and ergonomics as part of safety system design, incident investigation and solution development has long been recognised as important but has not been effectively implemented. Attitudes to the role of human factors and ergonomics in safety is being recognised more widely, and there is an opportunity to learn from other high-risk industries, for example nuclear, where this type of training is already being delivered as a core element of staff education.[27]

- People we spoke with and the existing literature talked about the benefits of multidisciplinary training rather than training in individual clinical groups. Working and training as a multidisciplinary team is important for many reasons, not least because it can help to break down hierarchies. Again, there is an opportunity to learn from other industries, such as aviation, that have implemented this.

- People we spoke with told us that while trusts recognised the importance of patient safety, safety education is not a priority for leaders in the same way that operational targets are. Other industries regard ongoing training as crucial to prevent habitual behaviour and errors.

NEVER EVENT – MISPLACED NASO- OR OROGASTRIC TUBES

Connie*, an 86-year-old woman, had a fall at home resulting in a subdural haemorrhage (a traumatic injury to the head that can put pressure on the brain). Connie was unable to safely swallow so had a nasogastric tube inserted at her bedside. Nursing staff were unable to obtain any aspirate (liquid from her stomach) through the tube to confirm placement so requested x-ray confirmation of the tube's position. The on-call doctor reviewed the chest x-ray, confirmed that the tube was in the correct position and advised that feeding could start.

Connie's condition got worse, and she became chesty and short of breath. When she was reviewed, the medical team looked at the x-ray again and found that the tube was in the right lung and she had received approximately 500mls of feed into her lung. Connie had experienced the Never Event of a misplaced nasogastric tube. She later died and the death was reported to the coroner.

It is widely understood that nasogastric tubes can be accidentally inserted into the lungs rather than the stomach. In itself this is not a Never Event. It becomes a Never Event when the position of the tube is not checked properly and food or medicine is put down the tube into the lungs. This type of incident is considered very preventable because healthcare providers are expected to carry out specific checks that verify where the tube has been placed.[28,29] To check where the tube is placed, the acidity of liquid that is sucked up through the tube is checked to see if it is stomach acid. If this check is not possible, x-rays should be reviewed to check placement at four anatomical points.

The initial response from the trust was to refer the doctor to their responsible officer because of concerns about their competency. However, the local investigation found that the doctor had not been trained in the correct 'four criteria' x-ray interpretation technique. While the trust acknowledged that training for doctors in reading x-rays for correct nasogastric tube placement was essential, the doctor in question had not been made aware of this and no local training had been provided by the trust. Following the investigation, the trust made a range of improvements to policy and to training provision, including providing two interactive teaching sessions for their foundation year doctors, providing an eLearning module in nasogastric x-ray interpretation, and making completion of the eLearning mandatory initially for their consultant staff, and then for all junior doctors from April 2018.

However, neither the trust or their commissioners appeared to have recognised this Never Event as a 'red flag' for wider issues with the trust's implementation of safety advice and guidance. There was no reference in the summary of local investigation as to how the NHS Improvement alert of 2016 appeared to have been signed off during 2017 as 'action complete' without having actually completed the actions it required (including review of training provided for medical staff).

*Case study based on real events

We wanted to understand what patient safety training and education healthcare staff currently received and the influence that this may have on the occurrence of Never Events. In this chapter, we explore the:

1. landscape of national patient safety education

2. availability of local and post qualification patient safety education

3. importance of leadership in patient safety education.

1. National patient safety education

The provision of health education in England is complex, with various bodies responsible for different aspects of clinical and wider professional education, including universities, royal colleges, professional regulators, Health Education England and employers like NHS trusts. As a result, it is not easy to establish who is responsible for which elements of education or who has the authority to deem any element of training mandatory, for example around patient safety, and place it consistently in training programmes either at undergraduate level or once healthcare professionals are practising.

This is leading to confusion as to what can be accessed. As patient safety training is incorporated implicitly within professional healthcare programmes, it can sometimes be difficult, for both the learner and the casual observer, to identify where it is explicit.

The confusion also means that people in the NHS do not share a common understanding about what is meant by patient safety and related terms, such as Never Events, human factors and risk, which needs to be urgently addressed.

Early healthcare education

Our expert advisory group were clear that safety needs to be a thread that runs through the lifetime of a healthcare professional's career and be part of everything they do, not an additional or optional part of their role. We were told by some that undergraduate training in patient safety was variable across universities and was not a mandatory part of courses, nor did it form a specific discipline or module. Education around human factors and ergonomics (see page x), and safety systems is even more specialised and appeared less on curriculums, although the concept may feature as a part of other substantive modules.

Recent studies also confirm that patient safety is not, in general, well covered during clinicians' training. For example, a higher proportion of attendees at a General Medical Council and the Medical Schools Council conference workshop on education felt that patient safety was not well

covered in existing curricula (42%) compared to those who felt it was (24%, with 34% "neutral").[30]

At postgraduate level there are specific degrees available to clinicians and non-clinicians alike, such as the MSc in Patient Safety at Imperial College London, but these are not widespread.

As a result, patient safety is struggling to feature as a mandatory part of healthcare education, and the concept of a specific patient safety specialism, for example a chartered or accredited profession of patient safety specialist as there is in other industries, seems a long way off. However, it is encouraging to note that Health Education England has commissioned the Academy of Medical Royal Colleges to develop a 'Safer Clinical Systems' multi-professional patient safety curriculum, to provide a more consistent and explicit inclusion in training and will be working with NHS Improvement to take this work forward. This will go some way to creating a much needed alignment of approach.

Having an aligned understanding of the core principles of patient safety may be an important tool for embedding safety as a specialism into the culture of the NHS, and the bodies responsible for education need to be the ones to drive this. However, people told us that the language of Never Events also needs to be addressed if the NHS is to improve its safety culture.

Common knowledge and understanding of Never Events

People we spoke with described the language of Never Events as not helpful and confusing. We heard that it was perceived as naive and not fit for purpose, with people feeling that it created a culture of fear and blame, where learning and a focus on the system were not prioritised. However, opinion varied about what should change.

Some people felt that patients, experts and communications professionals needed to work together to develop a more appropriate language and messaging around Never Events. However, others felt that it is not the term that should change, but that there needed to be more focus on improving how trusts create a just culture where learning, and not blame, is the priority. We were also told that 'Never Events' have a brand

and changing the language at this stage could cause confusion and suspicion. Any approach needs to allow definitions that are more reflective of how Never Events take place by, for example, adopting more of a 'storytelling approach' and using compelling examples to help overcome the fear around the language.

Opinion about the definition and list of Never Events also varied. We heard that the barriers to prevent Never Events are not equal across the list. While some processes could be designed to make sure that errors related to Never Events could not occur, for example technology solutions that make the error impossible, others relied on human interactions. As a result, participants felt that it was flawed to think a system could be designed for all errors to be eliminated.

People felt instead that educating staff around human factors and ergonomics was a key element of building a better patient safety system, which we discuss in more detail below.

We spoke with other countries about how they define never events. New Zealand and Iceland told us that their categories are based on the seriousness of the incident, rather than preventability. Denmark have "preventable events" that are categorised as mild, moderate or serious harm, or death. These incidents are described as preventable rather than "never" due to the belief that error cannot be entirely prevented and that regardless of its quality, guidance cannot eradicate mistakes.

Following this feedback, we carried out an exercise to categorise the 15 Never Events by the frequency of actions needed to prevent them. This included: actions that needed to be completed once, actions that needed to be completed once but with infrequent checks, and those that required regular actions by humans **(FIGURE 6)**.
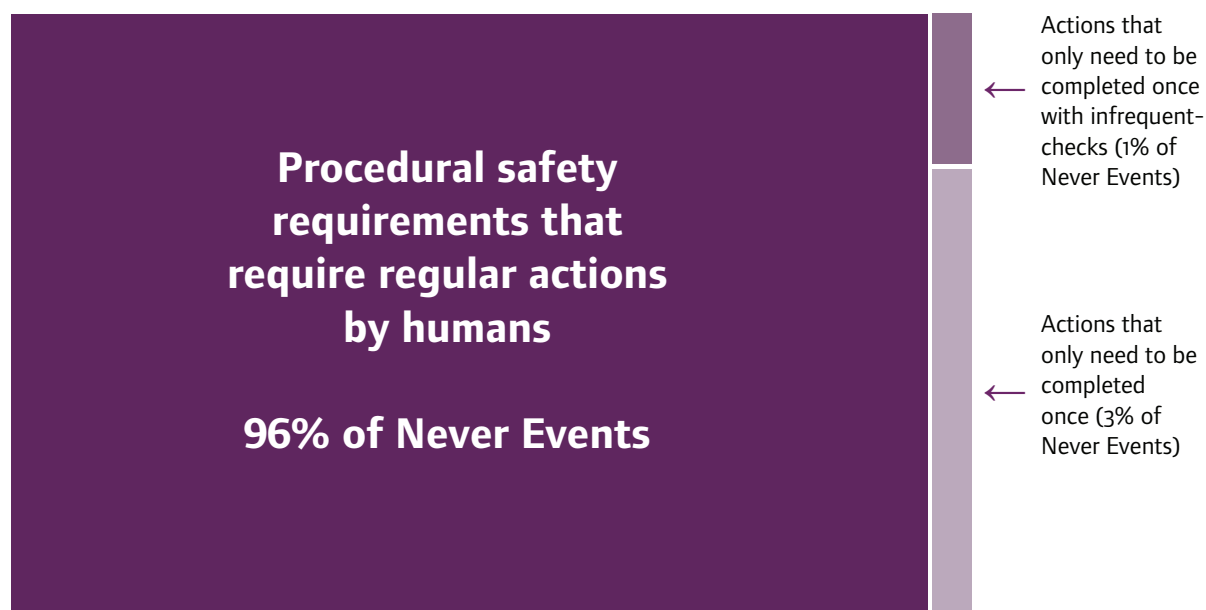
We then applied these categories to the 468 Never Events reported in 2017/18 (based on preliminary data released by NHS Improvement that is subject to change).[31,d] We found that the majority of incidents should have been prevented with regular actions by humans (96%), and very few could have been prevented when an action was only required once with or without infrequent checks (4%) **(FIGURE 7)**. Given these figures, the term Never Event may need to be redefined to take into account the influence of human factors in the majority of cases covered by the current definition.

FIGURE 6: LIST OF NEVER EVENTS BY FREQUENCY OF ACTIONS NEEDED TO PREVENT THEM

Procedural safety requirements that require consistent action by humans	**One-off actions required with infrequent checks**
• Wrong-site surgery • Wrong implant/prosthesis surgery • Retained foreign objects • Administration of medication by the wrong route • Overdose of insulin due to abbreviations or incorrect device • Overdose of methotrexate for non-cancer treatment • Transfusion or transplantation of ABO-incompatible blood components or organs • Misplaced naso- or orogastric tubes • Scalding of patients	• Mis-selection of a strong potassium solution (solution should not be readily available) • Failure to install functional collapsible shower or curtain rails • Falls from poorly restricted windows
	One-off actions required
	• Chest or neck entrapment in bed rails • Unintentional connection of a patient requiring oxygen to an air flowmeter

d. Note: data is combination of provisional data for 1 April 2017 to 31 January 2018 and for 1 February to 31 March 2018. In addition to the incidents removed from the total counts in the published provisional data, one more incident, so far, has been removed as it did not meet the definition of a never event, bringing the total count to 468.

FIGURE 7: NUMBER OF NEVER EVENTS IN 2017/18 BY FREQUENCY OF ACTIONS REQUIRED IN BARRIERS TO PREVENT THEM

Note. There were a total of 468 Never Events in 2017/18. Unintentional connection of a patient requiring oxygen to an air flowmeter were only recorded as Never Events from 1 February 2018 but were added in to this analysis (in "actions that only need to be completed once").

Source: Provisional Never Events data, NHS Improvement, 2017/18

However, simply reviewing this framework will not be enough on its own. Staff need to have training throughout their careers to make sure that they are up to date with the latest thinking and knowledge around patient safety.

2. Local and post-qualification education

Healthcare professionals told us that access to continuing professional development (CPD) throughout their careers is inconsistent. We heard that doctors tend to rely on medical or peer-to-peer training, rather than training from trusts, and that trusts view the training of doctors differently to other staff. For example, we heard of nurses receiving specific trust training on the placement of nasogastric tubes, but the same was not always expected for doctors. It is difficult to see how staff can reliably access CPD where there is such inconsistency in delivery.

People we spoke with talked extensively about the benefits of multidisciplinary training rather than training in individual clinical groups, but this is still not commonplace. The NatSSIPs

survey showed that while 57% of trusts had multidisciplinary training before NatSSIPs and LocSSIPS were introduced, no multidisciplinary training at all had been provided in more than one-quarter of organisations (29%) and only 15% of trusts have provided multidisciplinary training as a direct result of NatSSIPs and LocSSIPs. No change had been made to training provisions for multidisciplinary teams in 69% organisations as a result of implementing NatSSIPs and LocSSIPs.

Working and training staff as a multidisciplinary team is important for many reasons, not least because it can help to break down hierarchies. Other industries have recognised this. For example, British Airways told us that they train their teams both together and separately using simulation. Not only does this help individuals to appreciate the work of others in the team, but it also helps to reduce hierarchies in the team that act as barriers to safety.

Other high-risk organisations and industries also prioritise the use of multidisciplinary team approaches. For example, NASA describes its

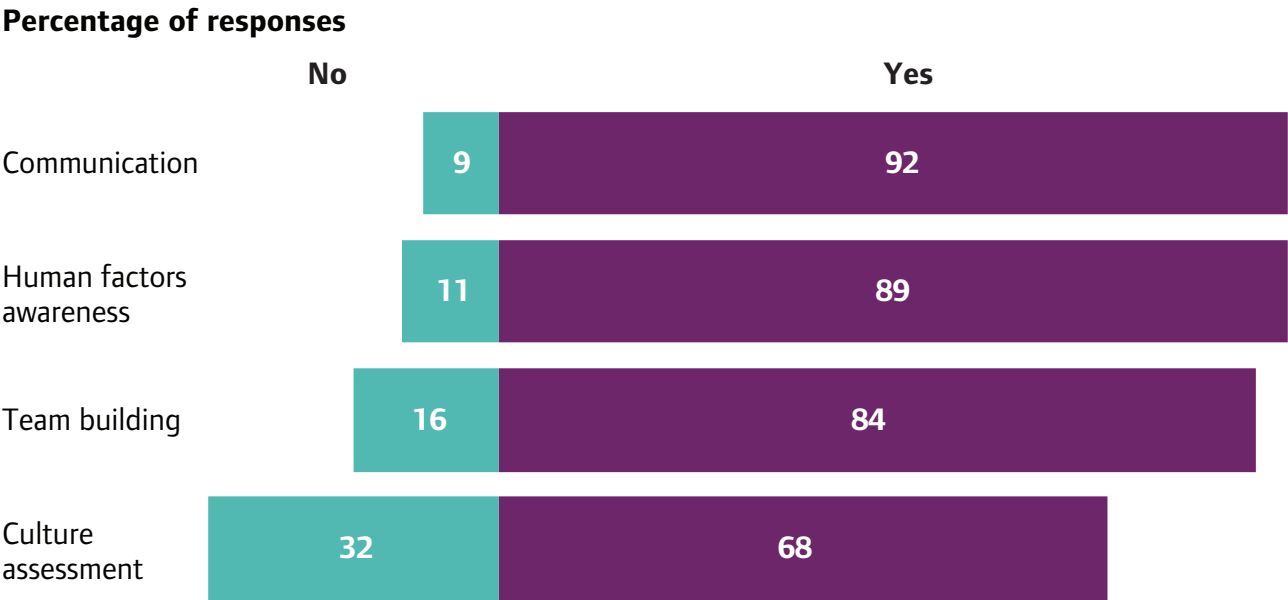crew resource management training as training that:

"..directly addresses the human factors issues that most often cause problems in team and crew interaction. No one who works in a team or on a crew, especially in high stress activities, is immune to these effects…The two versions of this course are applicable both to those in aircrew-type operations and also to personnel operating consoles for hazardous testing or on-orbit mission operations. It is preferable that a 'team' experiences the course as a group if possible."

NASA Safety Training Center Featured Courses[32]

Leaders from trusts with services rated as outstanding for safety told us that they are continually developing a stable, skilled and supportive workforce. There are shared staff values and an understanding that little improvements make a big difference; staff have permission at appropriate times to 'stop and decompress' under pressure.

Training in skills beyond specific clinical processes was also highlighted by staff as important during our review. **FIGURE 8** shows the percentage of trusts providing different types of non-technical skills training. Many trusts (89%) reported providing human factors training in the NatSSIPs survey. This is supported by the findings of a review of investigations of 38 surgical Never Events, which highlighted that the 2016/17 Never Events investigations reviewed had started to note issues relating to human factors and situational awareness, such as staff working on autopilot. In these cases there was less blame attached to individuals for not recognising issues and more awareness of human factors than there was in a previous examination of investigations in 2014.[33]

FIGURE 8: PERCENTAGE OF TRUSTS PROVIDING DIFFERENT TYPES OF NON-TECHNICAL SKILLS TRAINING

Percentage of responses

	No	Yes
Communication	9	92
Human factors awareness	11	89
Team building	16	84
Culture assessment	32	68

Source: The National Safety Standards for Invasive Procedures (NatSSIPs) implementation survey findings, NHS Improvement, 2018

Focus on human factors and patient safety education

WHAT IS HUMAN FACTORS SCIENCE?

Human factors, often referred to as ergonomics, is an established scientific discipline used in many other safety critical industries. It is important to understand the human-system interactions and the effect this has on risk and safety. This includes an understanding of the influence of equipment and workplace design on human performance; the effect of the organisational and team characteristics on safety related behaviour; and the effect of non-technical skills on a person's work. Non-technical skills are "the cognitive, social and personal resource skills that complement technical skills and contribute to safe and efficient task performance."[34] These include:

- **Situation awareness:** not gathering enough information; overlooking anomalies; not checking 'mental pictures' with others; not recognizing increased risks.

- **Decision-making:** proceeding with the task rather than checking when uncertain; an over-reliance on assumptions as to correct location, such as prepositioned patients.

- **Teamwork:** failures in the team to speak up; inadequate exchange of information to ensure a shared understanding of what was to be done.[35]

Clinical human factors is defined as enhancing clinical performance through an understanding of the effects on human behaviour of teamwork, tasks, equipment, workspace, culture and organisation, and applying that knowledge in clinical settings.[36]

The role of human factors and ergonomics and the importance of patient safety education, from the point at which an incident happens through to the investigation, has been highlighted in previous national reports including the Report of the Inquiry into Mid Staffordshire NHS Foundation Trust.[37]

In its response to the Inquiry, the National Quality Board published a 'Human factors in Healthcare Concordat', which was signed by all of the national bodies with a role in patient safety. This concordat recognised the importance of human factors principles and practices in improving the safety of care for patients and committed to supporting the NHS to drive improvement in quality, of which education and training was a key factor. It specifically stated:

"Human factors principles can be applied in the identification, assessment and management of patient safety risks, and in the analysis of incidents to identify learning and corrective actions."

Health Education England (HEE) published its report 'Improving safety through education and training' in 2016. This recommended that:

- a common language for human factors and quality improvement should be developed

- principles of human factors and ergonomics should be embedded across all education and training

- there should be increased opportunities for inter-professional learning

- staff should have the skills to identify and manage potential risks.[38]

HEE has also developed a number of workstreams across the country, which have shown some promising results.[39,40] However, we are concerned that momentum has slowed. While there is some positive work that is concentrated in pockets of the country, national spread of locally formed initiatives is less evident.

Attitudes to the role of human factors and ergonomics in safety is being recognised more widely. The General Medical Council recently announced that it will take account of human factors as part of investigations, and make sure that the relevant staff are trained in

this discipline.[41] The Chartered Institute of Ergonomics and Human Factors also recently published a white paper which cited the importance of a human factors specialist (suitably, qualified, experienced personnel) in every health and social care organisation.[42]

However, while it is clear that there have been pockets of improvements and the conversation about human factors is starting to gain momentum, without a transparent national learning system to take ownership of this type of training, wide-scale improvements in safety might be difficult.

There is an opportunity to learn from other high-risk industries where this type of training is already being delivered as a core and crucial element of staff education. In the nuclear industry, training in safety is a fundamental requirement and staff must meet certain standards. Defined training is instrumental in developing and sustaining competence. Nuclear sites need to meet certain conditions relating to training and competence of staff by the industry regulator, the Office of Nuclear Regulation, which has the power to grant and refuse licences depending on a site's ability to meet defined conditions.[43] In contrast in healthcare, the lack of defined standards of safety training limit the impact of regulation in this area.

The development of this training and positive safety culture in the nuclear industry has taken time. The importance of human factors and ergonomics, and recognition of this as a vital element of safety, first took place in the 1980s.[44] It is now part of international standards of mandatory training defined in the International Atomic Energy Agency safety standards series.[45] The same type of change needs to take place in the NHS, driven by clear leadership in education and a coherent patient safety curriculum.

3. Leadership in patient safety education

Our findings above suggest that nationally more could be done to align the education systems for healthcare professional staff. There is also an urgent need to prioritise the importance of patient safety in curriculums and training courses. In achieving this it would be helpful if there was clear leadership of what is expected and greater consistency of what is on offer rather than a multitude of bodies with different roles and influences over what staff learn before they start their careers in the NHS.

However, this is not just a national problem, as patient safety education needs to be prioritised locally too. People we spoke with told us that while trusts recognised the importance of patient safety, safety education is not a priority for leaders in the same way that operational targets are. They explained that there was not always enough time set aside for staff to do relevant training and that pressures in the system make it difficult to take time out for training.

At one trust that invited us to visit them, we heard of an initiative in place that brought more human factors thinking into practice from the moment a patient accessed the health services, through to the investigation stage if something were to go wrong. This initiative has received positive evaluations and has had the support of some key national patient safety leaders, because of the effect that the time spent of the course was having on staff in the trust. However, the training providers were asked to reduce it from a two-day to a one-day course.

LEARNING FROM OTHER INDUSTRIES: BRITISH AIRWAYS AND HUMAN FACTORS TRAINING

North Middlesex University Hospital NHS Trust developed a safety training initiative with British Airways, which is now delivered by pilots and clinicians in collaboration with the Royal College of Anaesthetists at Heathrow Airport.

The course covers the reasons behind errors (including human factors and situational awareness), how people make decisions and the importance of a just culture. The course also provides information about authority gradients and how aviation reduces the risks associated with human factors, situational awareness and ensuring a just culture. After the information is presented, the course attendees participate in two simulation activities on a plane, which aims to test situational awareness by adding distractions such as a child crying, a person complaining and another person being sick. Following the simulation activities, attendees reviewed what had happened during the exercise to allow time for reflection on what they had learnt from the experience.

Attendees of the course were positive about the course and were hopeful that they could take the leaning from the course to develop more solutions to some of the more common human factors challenges in their trusts.

However, feedback from clinicians who had previously taken the course highlighted that they have found it difficult to put the safety lessons they learned into place at their own trust because they had limited support from leaders.

Other high-risk industries are in a very different place to the NHS, despite sometimes being large global entities. We found that ongoing training here is seen as crucial for everyone to prevent habitual behavioural and errors. The National Examination Board in Occupational Safety and Health, for example, offers a comprehensive range of globally-recognised safety qualifications designed to meet the health, safety and environmental management needs of all places of work including oil and gas, chemicals, plastics and pharmaceuticals. Individual industry regulators, such as the Office of Nuclear Regulation, are then expected to make sure that all staff whether directly involved in safety or not and whether agency, part-time or substantive in role will have defined safety competencies.

In the NHS, CQC monitors and reports on the attendance of staff at mandatory safety training. Regulators in other industries go much further. They stipulate that training in safety should not only be up to date, but should meet essential minimum standard, such as including work on human factors and ergonomics and promoting a just safety culture.[46] These industries are joined-up in terms of what is expected and how that expectation is regulated, which gives clarity to those organisations on the ground on how to train their staff to the required standards.

The message is that elsewhere training in safety is a key priority for leaders, clearly set out and deemed to part of the development of a healthy safety culture. The NHS is not yet at this stage and more needs to be done by leadership at trust, regional and national level to progress this agenda.

However, changing attitudes to patient safety in the NHS is not just about prioritising education in patient safety, it is about prioritising the right things. Education specialists told us that providing more training or safety solutions, such as checklists and swab counts, is important but cannot work alone. There needs to be much more thinking too about the bigger picture to identify where other issues in trust safety systems need to be addressed, for example the environment and equipment, and in what order. If this is done in a pragmatic and inclusive way using systems thinking models such as those highlighted in this report, this will help staff to understand the changes to practice when they are implemented.

Summary

Patient safety needs to be an essential thread that runs through the lifetime of a healthcare professional's career, starting from an undergraduate level or the point at which the professional starts working for an NHS trust. The importance of patient safety education, and in particular training around human factors and ergonomics, has been recognised, but experts in human factors told us implementation is still inconsistent.

The health education system is complex, with multiple bodies working at different levels with different staff types. This means that it is difficult to establish who is responsible for which elements of education or who has the authority to deem any element of training mandatory. While training in human factors and ergonomics is being recognised as important more widely, it is not being implemented effectively. There is an opportunity to learn from other industries where human factors training is delivered as a core element of staff education.

As well as greater clarity in the education system and consistency of training, there also needs to be a clearer framework for Never Events. Our review has highlighted the potential difficulties with the different barriers for different types of Never Events. This is particularly important given that we found 96% of Never Events reported in 2017/18 should have been preventable with regular actions by humans. This suggests that there needs to be a review of the Never Events framework itself, to take into account human factors when designing solutions to prevent recurrence, and make sure that there is clarity of approach that does not contradict the common knowledge and understanding that is needed in patient safety. There is also an opportunity for CQC to work with NHS Improvement to assess compliance with the Never Events framework to drive the right behaviours, both at a local and national level.

There also needs to be clear leadership in education and a coherent patient safety curriculum. Unlike other industries, and healthcare organisations in other countries, competing demands and pressures on trusts means that they do not always prioritise safety and are sometimes reluctant or unable to release staff to give them the time and space to do training.

This report has highlighted the work underway by Health Education England, and the Human Factors in Healthcare Concordat, to make sure that staff receive the appropriate education and training around patient safety. However, there is much more work to do to improve patient safety education and training, both at the start of healthcare careers and as part of continuing professional development. This is essential if we are to make sure that the NHS workforce has a common understanding of patient safety, the principles and processes to support a good patient safety culture, and the skills and expertise to respond appropriately and effectively to identified risk where avoidable harm occurs.

Conclusion

Never Events continue to happen despite the hard work and efforts of frontline staff. Our findings across the review have led us to conclude that this continual recurrence means that if we are to give patient safety the priority it needs, the safety culture of the NHS need to change.

Staff are struggling to cope with large volumes of safety guidance, they have little time and space to implement guidance effectively, and the systems and processes around them are not always supportive. Where staff are trying to implement guidance they are often doing this in addition to a demanding and busy role. This makes it difficult to give this work the time it requires.

While safety needs to be part of what everyone does, and part of the culture of trusts, it is clear that the NHS does not yet have the right approach. Leaders with a responsibility in safety need to have the appropriate expertise and be properly resourced to help embed an effective safety culture. These roles will be able to be part of, and navigate, trust governance systems, support staff to drive the safety agenda, ensure high-quality investigations, implement quality improvement initiatives, and act as a central reference point for all who have safety concerns or suggestions.

It also needs to be easier for trust staff to do the right thing. Greater standardisation, not just in terms of clinical protocols, but also for things like equipment and processes in hospitals, should be

considered. While standardisation will not work for everything, there is scope to look again at where there can be a more consistent approach that makes it easier for staff to embed a clear plan, rather than ask them to think through how something should be done when they have limited time to do this.

The National Patient Safety Alert Committee is well placed to help trusts manage the pressures they face by testing the quality of alerts that are sent out, ensuring they are clear and helpful, and that they do not contradict what has gone before or alerts from different organisations.

In terms of the wider system, we have found that the different parts at national, regional and local level do not always work together in the most supportive way. There is a lot of confusion about the roles of different bodies and where trusts can go to get the most appropriate support. Regional bodies are providing support to trusts but this varies from place to place, and support for trusts from national bodies is lacking.

The introduction of the National Patient Safety Strategy provides an opportunity to clarify what the roles of different bodies are and where

different responsibilities lie, so that trusts know who to contact when they need advice. This will also help trusts' patient safety leads and teams to build relationships with the right people and develop a national and regional network that they can quickly access.

This strategy should also outline clearly what the role of patients is within this landscape. It is not appropriate to think that patient safety can be considered without thinking about the person who is receiving care or treatment. They should be active partners in their care and the strategy should set out how this can happen.

National bodies also have an opportunity to offer more clarity around Never Events themselves. One way to do this is by reviewing the Never Events framework. The current framework assumes that human interactions can prevent certain incidents from occurring. However, the growing knowledge and understanding of patient safety, including through the study of human factors and ergonomics and systems thinking, leads us to question whether it is appropriate to designate some events as entirely preventable, especially when that prevention relies on human interactions. As a result, we think that the framework need to be reviewed so that the most appropriate response to different types of incident can be found at all levels in the system.

Finally, we found that, despite all the work taking place, patient safety could be further improved. Staff are either not getting the training they need at the start of their careers or they are not given the time to do appropriate levels of training on patient safety once they have entered their clinical careers. This is not helped by a disjointed education system with no overall ownership.

However, this is not just about the education and training of clinicians. To truly have a safe NHS, all who work in it need to share a basic knowledge and understanding of what we mean by patient safety and be educated in some basic, common principles. Other industries share a common understanding of safety regardless of the role they are in. This is something the NHS needs to achieve. Taking this approach will help to move to a culture where it is accepted that error can happen and that systems need to be planned with

this understanding. Recognising the fallibility of individuals and the inherent risk in providing health care is essential to create a just culture. It will help to encourage people to speak up when there are safety concerns, and also provide teams with greater motivation to actively create solutions where problems are identified.

As part of the improvement of patient safety education and training it is time to introduce a specialism in patient safety. This could be part of staff's clinical education, or as a standalone course for non-clinical staff. This training could be the foundation for patient safety leads and teams. Alternatively, it could provide a movement of staff in hospitals who will support specialist teams to change culture from the bottom up.

CQC has an important role in supporting some the changes identified by our review. We will need to improve our own knowledge and understanding of patient safety so that we can be confident that our regulatory frameworks and methodologies are focusing on the right things, particularly as the health and social care system changes around us. We will need to think carefully about how we react when a Never Event occurs, and what action we should take that is both supportive and proportionate but can also flex to be stronger where the circumstances demand a different approach in the interests of patient safety.

We will not be able to do this if we do not improve the knowledge of our staff in patient safety, investigative techniques, human factors and ergonomics, and systems thinking, which we commit to do. We will look at how specific patient safety alerts are implemented, as outlined by the National Patient Safety Alert Committee, to make sure that required action is being taken and think about the support and signposting we can provide for trusts. And we will need to make sure that where we use patient experts in our work, they are focusing on safety, and have the required knowledge and understanding to observe implementation processes in trusts to make sure that there is transparency and clarity of expectations for those receiving care.

While much progress has been made to improve the safety of patients, it is clear that there is much more to do to embed a safety culture.

Effective leadership at all levels in the system is essential to bring about the change in culture that is needed. Boards and trust leaders need to recognise the need to change and they should ensure they listen to staff concerns and actively promote an organisational safety culture. Staff across the landscape, in clinical and non-clinical roles, should be curious and creative in finding solutions to safety problems and work together in multidisciplinary teams to develop ideas that can spread across all hospitals. There is something we can all do to change the safety of our patients but we should not work alone. Finding workarounds or disregarding standardised protocols should be a thing of the past with a more open and honest dialogue taking its place where we are talking a common language and improving safety together.

Recommendations

Everyone who has a role in health care or who receives health care in England should recognise the importance of making patient safety a top priority and the extent of the cultural change needed to make this a reality. We can all do something to change the conversation, whether it is insisting on extra training, recruiting more patient safety specialists or questioning the safety of our care. There are many ways to change the safety culture in the NHS but no one person, team, hospital or national body can do this alone. While the following recommendations are directed at a system level, they will only have the effect needed if trusts embrace and respond to the outputs of these.

Our recommendations do not underestimate the huge level of enthusiasm and work that is already happening. The aim is that the recommendations promote the change in safety culture that is needed and bring everyone together to assist behavioural change, both at a system level and in individual organisations, to implement safety alerts and in turn reduce the risk of harm to patients. These recommendations reflect the journey we need to take to embed patient safety expertise throughout the workforce and put safety at the heart of our health system.

1. NHS Improvement and Health Education England working together to develop a common curriculum and basis for patient safety education, training and ongoing development

NHS Improvement should work in partnership with Health Education England and others to make sure that the entire clinical and non-clinical NHS workforce has a common understanding of patient safety and the skills and behaviours and leadership culture necessary to make it a priority. The role of systems, design, effective communication, risk, just culture, human factors and ergonomics must be understood by all, and taken as seriously as other related areas such as health and safety at work.

High-quality safety training should start as soon as staff begin their education and training, whether that is at a higher education institution or in the trust itself.

This national drive to improve patient safety education must be replicated in NHS trusts and indeed all healthcare organisations. Here, patient safety should form part of ongoing mandatory training, and be included as part of continuing professional development (CPD) requirements and ongoing development. Leaders should release their staff from their substantive duties to carry out this development, not as an optional extra, but as a vital part of every employee's role.

A new education, training and CPD plan should set out key milestones to be delivered. The end goal should be a specialism in patient safety that staff can study as part of their clinical training or as a separate discipline.eir clinical training or as a separate discipline.

This recommendation should build on work already taking place across England. There should be a clear plan outlined on how it will be achieved with key milestones articulated to all system partners.

2. Patient safety strategy

The recently announced National Patient Safety Strategy must support the NHS to have safety as a top priority. It should be developed

in partnership with professional regulators, royal colleges, frontline staff and patient representatives. We recommend this includes:

- a clear vision of patient safety with a roadmap setting out how we can achieve these priorities

- a description of the roles and responsibilities of each of the main players in achieving these priorities – including commissioners, regulators and professional bodies

- a description of how this system would support the NHS to balance safety with efficiency and productivity to deliver high-quality care at times of greatest demand

- embedding an effective safety culture at every level from senior leadership to the frontline

- explicit explanation of the patient role in the system.

The National Director of Patient Safety at NHS Improvement should oversee progress and be clear who is accountable for delivering the strategy and the recommendations in this report.

3. Leaders in patient safety in NHS trusts

Leaders with a responsibility for patient safety must have the appropriate training, expertise and support to drive safety improvement in trusts. Their role is to make sure that the trust reviews its safety culture on an ongoing basis, to make sure that it meets the highest possible standards and is centred on learning and improvement. They should have an active role in feeding this insight back to NHS Improvement so that other NHS organisations can learn from it, as is the case in other industries.

NHS Improvement should specify the responsibilities, skills and experience required for these leaders, as part of its work to devise a curriculum for patient safety (recommendation 1). They should also put in place the mechanisms for trusts to be able to provide early feedback on alerts and guidance.

Professional regulators also have a role in gathering insight and feedback on patient safety from staff and using this to feedback to NHS Improvement.

NHS Improvement should also create and maintain a network of patient safety leaders to support every NHS organisation, with all working towards a just safety culture that supports the implementation of patient safety alerts and continuous safety improvement.

4. Standardisation

NHS Improvement should work with professional regulators, royal colleges, frontline staff and patient groups to develop a framework for identifying clinical processes and other elements, such as equipment and governance processes, that could benefit from standardisation, how this will happen and where the standardisation should apply. This will include clarity on how the framework will lead to tangible action and delivery of standardisation throughout the health sector.

5. NaPSAC support with patient safety alert development for all bodies issuing alerts

The National Patient Safety Alert Committee (NaPSAC) should oversee a new patient safety alerts system that aligns the processes and outputs of all bodies and teams that issue alerts, and make sure that they set out clear and effective actions that providers must take on safety-critical issues.

- It should set out guidance on how to develop patient safety alerts, including expectations on involving front line clinicians, patients and others

- It should develop clear standards for the format and content of the alerts, including SMART (specific, measurable, achievable, relevant and time-bound) actions and more use of supporting resources, such as the use of personal stories and case studies and examples of good practice to make the case for change.

- It should oversee an improved method for dissemination of patient safety alerts from central bodies to providers, to make sure that alerts reach all organisations that need to take action and they can record the action they have taken.

- It should support development of mechanisms for providers to share information on their experience of alert implementation between themselves and with central bodies, to make sure that we can all learn from each other's experiences.
- It should describe in detail what good implementation looks like as part of good clinical governance, highlighting a system that plans and coordinates implementation in organisations and ensures continuing compliance. This should include guidance on the tools that might be needed by providers, and the role of patient insight.
- NaPSAC should intervene when bodies issuing national patient safety alerts produce materials that do not meet required standards.
- NaPSAC should consider national trends in how providers implement and respond to national patient safety alerts and support CQC to inspect actions required.

6. Never Events framework

NHS Improvement should review the Never Events framework and work with professional regulators and royal colleges to take account of the difference in the strength of different kinds of barrier to errors (such as distinguishing between those that should be prevented by human interactions and behaviours such as using checklists, counts and sign-in processes, and those that could be designed out entirely, such as through removing equipment or fitting/using physical barriers to risks). This review should focus on the leadership and culture needed to underpin safety. It should take into account the different settings in which Never Events occur, including acute, mental health and community settings.

CQC should work with NHS Improvement to assess compliance with the Never Events framework in a fair and proportionate way that will drive the right behaviours at national and local levels.

7. CQC will also improve our assessment of safety across all sectors

The Care Quality Commission also commits to change that will support patient safety becoming a top priority for all.

- We will improve our patient safety expertise, ensuring we have a patient safety lead who can advise on our processes and methodologies to make sure that regulation does not stifle new systems thinking and innovation
- We will work with NHS Improvement and Health Education England to:
  - ensure that the entire NHS workforce has a common understanding of leadership and just culture, and the skills and behaviours necessary to make safety a priority
  - assess how we can improve patient safety knowledge for all staff, including human factors and ergonomics and systems thinking
  - review our approach to the way we regulate safety in NHS trusts, including how we react to Never Events and engage providers in any changes we make
  - review specific patient safety alerts as part of our ongoing inspections and take regulatory action where implementation is not appropriate – starting with NHS trusts and expanding to other sectors as appropriate.
- We will work with the public and people who use services to make sure that processes are clear and transparent and where possible involve patients in their design.
- We will consider how we can apply the findings in this report to how we regulate adult social care services, primary medical care services and newly emerging integrated care systems.
- We will work with others to make sure that patient safety is a priority for all and, as these recommendations are delivered, reflect them where necessary in our approach.

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Appendix A: Never Events list

This list of Never Events was published by NHS Improvement in January 2018:[47]

1.   Wrong-site surgery

2.   Wrong implant/prosthesis

3.   Retained foreign object post procedure

4.   Mis-selection of a strong potassium solution

5.   Administration of medication by the wrong route

6.   Overdose of insulin due to abbreviations or incorrect device

7.   Overdose of methotrexate for non-cancer treatment

8.   Mis-selection of high strength midazolam during conscious sedation

9.   Failure to install functional collapsible shower or curtain rails

10. Falls from poorly restricted windows

11. Chest or neck entrapment in bed rails

12. Transfusion or transplantation of ABO-incompatible blood components or organs

13. Misplaced naso- or orogastric tubes

14. Scalding of patients

15. Unintentional connection of a patient requiring oxygen to an air flowmeter.

Appendix B: How we carried out the review

We carried out fieldwork in 18 NHS trusts (combination of acute and mental health trusts). Twelve of these trusts were selected as they had a core service inspection scheduled during our fieldwork window (16 April to 8 June 2018). A further six were selected to fill gaps in the sample of planned inspections, or because local intelligence suggested the trust may have challenges to implementing safety requirements or may have examples of good or innovative practice.

Trusts visited as part of our business as usual inspection schedule	Additional trusts visited
• City Hospitals Sunderland NHS Foundation Trust • East Kent Hospitals University NHS Foundation Trust • Essex Partnership University NHS Foundation Trust • Kingston Hospital NHS Foundation Trust • London North West Healthcare NHS Trust • Medway NHS Foundation Trust • Northamptonshire Healthcare NHS Foundation Trust • Northumberland, Tyne and Wear NHS Foundation Trust • Portsmouth Hospitals NHS Trust • Salford Royal NHS Foundation Trust • Sherwood Forest Hospitals NHS Foundation Trust • The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust	• Gateshead Health NHS Foundation Trust • Leeds Teaching Hospitals NHS Trust • Moorfields Eye Hospital NHS Foundation Trust • The Queen Victoria Hospital (East Grinstead) • University Hospitals Bristol NHS Foundation Trust • University Hospital Southampton NHS Foundation Trust

We held one-to-one interviews, visited different services, and reviewed policies and procedures. At the business as usual inspections, we held one-to-one interviews with two to three people, who were leads for safety at the trust, and the board representative for safety at the trust. In addition, we spoke with safety representatives at the local clinical commissioning groups (CCGs) for each trust we visited. We also spoke with staff working across services and reviewed documents and policies to understand how the trusts implemented alerts, learned from incidents and involved people who use services in those processes. For the planned inspections, our review teams included one CQC inspector and one member of NHS Improvement's patient safety team, and one Expert by Experience. NHS Improvement's patient safety team acted as specialist advisors on this review. Specialist advisors are a senior health or social care professional who brings their specialist expertise to assist us with inspections and reviews. An Expert by Experience is someone who has personal experience of using services or caring for someone who uses services. The additional trust visits were conducted by the relationship owner for the trust (at a minimum).

Following fieldwork, we held a focus group with all Experts by Experience involved in the trust visits and patient representatives from our expert advisory group. The focus group discussed their experience and what was learned during the visits. In addition, we discussed possible recommendations that would improve safety from a patient's perspective.

In addition to our fieldwork, we reviewed existing knowledge and evidence about safety in health settings as well as in other organisations. We reviewed findings from NHS Improvement about the implementation of National Safety Standards for Invasive Procedures (NatSSIPs) nationally. We spoke with various key organisations to understand their role in the wider patient safety system. We spoke with individuals who have experienced Never Events as a patient and as a clinician, patient safety experts and safety experts in other organisations. We visited various organisations to observe implementation of safety requirements and training in action, for example observations of surgeries and

maternity care (involving briefings, WHO checklists and swab counts), and safety training for pilots. We also ran a number of workshops and focus groups as part of the review.

- Forum focusing on what we can learn from other industries by bringing together people working in other industries as well as patient safety experts and individuals working in NHS acute and mental health trusts.

- Forum focusing on what we can learn from outstanding trusts by bringing together people working in core services with CQC outstanding ratings for safe.

- Workshop focusing on human factors by bringing together human factors experts and people working in NHS acute and mental health trusts and other industries.

- European Partnership for Supervisory Organisations (EPSO) in Health Services and Social Care workshop focusing on what we can learn from other countries by bringing together people working in health care from countries across Europe and beyond, including attendees from Bulgaria, Denmark, Estonia, Iceland, Kosovo, Latvia, New Zealand, Portugal, Sweden and Turkey.

- Focus groups focusing on different safety scenarios and challenges of implementing safety procedures by bringing together frontline staff from the various clinical groups, including inpatient mental health managers; surgeons and anaesthetists; theatre practitioners; and ward managers.

In total, across our work, we have spoken with 433 people, including:

- 21 people using services, Experts by Experience or people working in patient groups
- 265 people working in trusts
- 32 people working in clinical commissioning groups
- 54 people working in national bodies
- 26 academics or patient safety/human factors experts
- 16 people working in other industries
- 19 people working in other countries

Expert Advisory Group

Throughout our review, we have worked with a group of people and organisations who have expert knowledge and experience of patient safety. This Expert Advisory Group provided advice and guidance in the development of our methodology, engagement work and recommendations. The membership of our Expert Advisory Group is listed in Appendix C.

Section 48: CQC's special review powers

We carried out this review under section 48 of the Health and Social Care Act 2008. This gives CQC the ability to explore issues that are wider than the regulations that underpin our regular inspection activity. Using these powers, we can do more to understand people's experience of care across settings, through exploring local area commissioning arrangements and how organisations are working together to develop personalised, coordinated care. The purpose of this thematic work is to encourage improvement in the quality of care.

Appendix C: Organisations involved in the thematic review

Organisations represented at our Expert Advisory Group

- Action against Medical Accidents
- Behaviour Insight / UCL
- Behavioural Insights Team
- Clinical Human Factors Group
- Guy's and St Thomas' NHS Foundation Trust
- Health Education England
- Healthcare Safety Investigation Branch
- Imperial College Healthcare NHS Trust
- Medicines and Healthcare products Regulatory Agency
- NHS England
- NHS Resolution
- Patient representative
- Patients Association
- Royal College of Obstetricians and Gynaecologists
- Sign up to Safety
- The Dudley Group NHS Foundation Trust
- The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust
- West of England Academic Health Science Network
- Yeovil District Hospital NHS Foundation Trust

Other organisations involved in various activities

- Bradford Teaching hospital
- British Airways
- Cambridge Engineering Design Centre
- Camden Health Improvement Practice
- Civil Aviation Authority
- Coram
- Defence Safety Authority
- Department of Health and Social Care
- Department of Health and Social Care Collaborate
- Derby Teaching Hospitals NHS Foundation Trust
- Devon and Somerset Fire and Rescue Service
- East Lancashire Hospitals NHS Trust
- European Partnership for Supervisory Organisations (EPSO) in Health Services and Social Care
- Frimley Health NHS Foundation Trust
- General Medical Council
- General Pharmaceutical Council
- GS1 UK
- Health and Safety Executive
- Healthwatch
- Heli offshore
- Human Tissue Authority
- Imperial College London Patient Safety Translational Research Centre
- Jacobs
- Kent Fire and Rescue
- King's College London
- London South Bank University
- Loughborough University
- Maidstone and Tunbridge Wells NHS Trust

- National Guardian's Office
- National Institute for Health and Care Excellence
- National Institute for Health Research Greater Manchester Patient Safety Translational Research Centre
- Needhams
- NHS Business Authority
- NHS Digital
- NHS Regions
- North Middlesex University Hospital NHS Trust
- Northumbria Healthcare NHS Foundation Trust
- Nottingham University Hospitals NHS Trust
- Nuffield Health Brentwood Hospital
- Nursing and Midwifery Council
- Public Health England
- RAF Benson
- Royal Air Force
- Royal Air Force Safety Centre
- Royal College of Anaesthetists

- Royal College of Physicians
- Royal College of Radiologists
- Royal College of Surgeons
- Royal Cornwall Hospitals NHS Trust
- Southern Health NHS Foundation Trust
- Southport and Ormskirk Hospital NHS Trust
- The Health and Care Professions Council
- The Newcastle upon Tyne Hospitals NHS Foundation Trust
- Trimetis
- University College London Hospitals NHS Foundation Trust
- University of Cambridge
- University of Leicester
- University of Oxford
- Warrington and Halton Hospitals NHS Foundation Trust
- Western Sussex Hospitals NHS Foundation Trust

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