An independent review of the effectiveness of the Trust's safety procedures

A report for
Great Ormond Street Hospital for Children NHS Foundation Trust

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Authors:
Kieran Seale
Ed Marsden
Chris Brougham

Verita is an independent consultancy that specialises in conducting and managing investigations, reviews and inquiries for regulated organisations.

Verita
338 City Road
London EC1V 2PY

Telephone 020 7494 5670

E-mail enquiries@verita.net
Website www.verita.net

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1. Introduction

1.1 Dr Sanjiv Sharma, medical director, at Great Ormond Street Hospital for Children NHS Foundation Trust[1] asked Verita to undertake an independent review of how the trust responds when things go wrong, and how the responses could be improved. The work was commissioned after a number of families raised concerns with the trust about how particular patient safety incidents were responded to. The families' unhappiness was so great that they felt they had no choice but to engage with the media to raise their concerns. One of the outputs of this engagement was a BBC radio programme which questioned whether GOSH properly investigated when things went wrong. The trust would like to learn from these events and improve their current systems and processes. In this report we focus on practical improvements which we believe can help Great Ormond Street to move forward in a positive way.

1.2 Verita is a consultancy specialising in the conduct of investigations and reviews and helping organisations to improve. The team consisted of Ed Marsden, the founder of Verita, Chris Brougham and Kieran Seale, both directors of Verita. Jo Gillespie, a safety expert and Verita associate, acted as peer reviewer. We also liaised with Helen Hughes, chief executive of Patient Safety Learning who is carrying out work for the trust. Scarlett Whitford Webb provided administrative support. The team will be referred to in this report as 'we'. Biographies are in appendix A.

[1] Variously referred to in this report as 'Great Ormond Street', 'GOSH', 'the hospital' or 'the trust'

2. Terms of reference

2.1 The following is a summary of the terms of reference for this work. The full terms of reference are at Appendix B.

2.2 The Verita team will undertake a review of the following matters:

- How hospital staff engage with families following an incident which has caused significant harm.
- Whether there are effective and timely processes in place for managing serious incidents from reporting, investigation and approval through to learning/system improvement to avoid recurrence, including incorporation of feedback from external stakeholders such as NHS England/Improvement.
- Whether there are effective processes in place for managing safety risks in red complaints from identification, investigation and approval through to learning/system improvement, to avoid recurrence.
- Whether there are effective processes in place for managing safety risks in claims and inquests from identification through to learning/system improvement, to avoid recurrence.
- Whether the level of investigation undertaken by GOSH is proportionate to the incident/complaint raised.
- To understand if the processes for investigation enable and support GOSH to identify and act on critical safety issues in a timely way.
- To identify if there is sufficient evidence of the 'golden thread' of safety in the governance and reporting processes from 'ward to board' and with key external stakeholders.
- To identify if processes are supported by a sufficient culture of openness, curiosity and transparency; this includes compliance to Duty of Candour obligations.
- To evaluate whether appropriate support systems are in place for patients, families and staff.
- How GOSH are progressing their action plans following the Care Quality Commission focussed inspection on Serious Incidents and Red Complaints.

3. Executive Summary and Recommendations

3.1 Verita were commissioned to undertake an independent review of how Great Ormond Street responds when things go wrong, and how the responses could be improved. The main focus of our work has been to come up with practical ideas for how things can be changed for the better.

3.2 There were three main elements to or work:

- Conversations with people both inside and outside the hospital
- Attending internal trust meetings (virtually)
- Reviewing documentation.

3.3 The terms of reference asked us to look at a number of specific areas:

- Safety culture
- Serious incidents
- The 'Golden Thread' of safety
- Engagement, support for patients and families and the duty of candour
- Safety risks - in complaints, claims and inquests.

3.4 Patient Safety Learning's 'Blueprint for Action' provides a benchmark against which organisations can measure their 'patient safety maturity'. The document gives a framework for reviewing the trust on the following scale:

- Minimal – aiming to meet statutory and regulatory requirements
- Reactive – plans in place to meet statutory and regulatory requirements
- Active – actively seeking to improve patient safety
- Proactive – reducing harm, supporting staff, plans to deliver a patient-safe future
- Patient-safe future – patient safety in integrated care, minimal avoidable harm, safety is a core purpose, safe for staff

3.5 Our estimate would be to put Great Ormond Street at the 'Reactive' level. In our experience, the key steps for improvement are:

- recognise the problem
- accept responsibility
- develop solutions
- implement
- embed.

3.6 We believe that the leadership at Great Ormond Street accepts that that it can learn and improve, and that doing so is a priority for the organisation. We hope that what follows will help with implementation and embedding change.

Building the patient safety culture

The role of the Board

3.7 Culture starts at the top. The first step in building the patient safety culture is therefore for those in leadership positions to demonstrate that it is a priority for them. While it is not the role of the board to get involved in management of the organisation they can help to deliver the trust's strategy by setting the tone. The following are some ideas of how that could be done:

- Demonstrating that safety is a priority by talking about it. For example, by issuing a board statement about the importance of safety and ensuring that it is talked about in board meetings.
- Bolstering the role of the non-executive who has the specific remit for patient safety, enhancing their role as patient safety champion to support the board's executive patient safety lead.
- Visibility – the presence of non-executive directors 'on-the-ground' demonstrating that they care about safety and setting out the trust's ambitions can send a powerful message.

Strengthening the golden thread

3.8 Communication is key to the effective flow of information from 'ward to board'. That includes both formal and informal channels.

3.9 For the formal channels, patient safety should be considered in all business decisions. Board papers currently have to state whether there are risk, legal or financial implications – patient safety should also be considered.

3.10 For informal channels, safety concerns emanating from lower down the organisation must be able to reach board members. It is welcome that the trust has a Freedom to Speak Up Guardian. The trust should ensure that it takes the full benefit from this resource and that the role is widely understood throughout the organisation. Another way of demonstrating the importance of patient safety is ensuring that it is included in job roles for staff across the organisation.

3.11 Technology should be used to support these changes e.g. electronic screens in theatres.

Openness about risk and safety

3.12 Human beings make mistakes – that is a fact of life. The best systems sometimes fail. The only question is how organisations respond to these facts. A starting point would be for people at the hospital to talk more about when they have made errors, what they did about it and how they felt. This should start from the top – chair, board members, chief executive and senior clinicians.

Directorate risk & safety champions

3.13 Giving people specific responsibility for promoting risk management and patient safety can be an effective way of promoting good practice. These individuals can help drive the safety management function deeper into the organisational structure and provide informed safety support to the chiefs of service and the patient safety team.

Developing the role of the patient safety team

3.14 Strengthening the patient safety function will be an important part of developing the culture of patient safety at Great Ormond Street. We think that the 'fix it' element of the patient safety function should be increased so that the work of the team is more dynamic and rewarding and is able to help deliver improvement more directly.

Creation of a central patient safety hub

3.15 The focus of much safety work is often on the past – looking back at things that have already gone wrong. Safety, however, is about the 'here and now' – making sure what happens today is the best it can be. A central patient safety hub and database with live data about safety issues should be developed. This would not only ensure that the full learning value is drawn from the data that the trust collects but enable things to be put right.

Openness and family engagement

3.16 Family engagement is seldom easy. Everyone involved in a case may have a different perspective. It can be challenging for those who spend their lives in a clinical environment to really understand what things look like for those coming to the experience fresh.

3.17 The key to good family liaison is listening. Understanding what is important to families and to engaging with their priorities is crucial. Asking families what they would prefer – and responding to it – demonstrates respect and helps to build a positive relationship. Some issues can be difficult to focus on simply because they are not a priority for professionals. Creating a listening culture is the way to address this.

3.18 Complexity is a feature of many cases at Great Ormond Street. Many children cared for by the trust have numerous co-morbidities - the simultaneous presence of other diseases/medical conditions. We heard of cases with up to eleven co-morbidities. The trust could do much more to help patients and families with this complexity. The

trust should consider the development of a 'system navigator' function for children with complex needs, so that families have a single point of contact despite being engaged with multiple specialities. We suggest that the trust considers setting up a working group to determine how this sort of role might work best. The group should draw on the experience of the International & Private Care directorate who already have a similar role.

3.19 We recommend the trust works with a small number of families to pioneer a more active role for them in the safety of care and treatment. This could be supported by technology.

Improving investigations

3.20 The main purpose of investigations should be to find out what happened and why, so that there can be learning. Senior management needs demonstrate that learning and improvement are priorities and the starting point for investigations.

3.21 Often it is also important to find out what happened to inform those affected – both a moral, and legal, duty. Declaring a serious incident should therefore be seen as a 'neutral act', with the aim of finding out what really happened, not an exercise in apportioning blame.

3.22 Investigating serious incidents is important. The trust needs to demonstrate that it is a priority by allowing time in job plans for investigation and safety improvement.

3.23 The new national Patient Safety Incident Response Framework (PSIRF) sets out how healthcare providers should respond to patient safety incidents. The framework puts an emphasis on the quality of investigations, rather than the quantity of them. This offers an opportunity for Great Ormond Street to develop a new approach to patient safety incident investigation. We believe that the response to an incident should be seen in terms of a range of possible interventions, the aim being to get the one that fits the needs of each incident best. Possible interventions include:

- After-action reviews - discussion by clinical teams followed by a write-up of what has been discussed. A prerequisite of an after-action review is that everyone feels able to contribute without fear of blame or retribution. Those affected by the incident (patient or family) can be invited to attend alongside the clinical team so that their views and perspective can be heard and considered. Following the discussion, a facilitator will record actions identified and a learning log. An action plan is then developed to put any solutions in place. The process has many benefits – they can happen quickly, they can help to promote an open and just culture and reduce the burden of carrying out traditional investigations. Another benefit of the process is that staff involved in the incident can actively participate in the review and those affected by the incident hear first-hand about what went wrong (if anything) are listened to and supported. Reviews can also be used to discuss good care to better understand how it was delivered.
- Structured judgement reviews - initial reviews are carried out by front line reviewers with a second stage review if any care problems are identified which rate care as 'poor' or 'very poor'. The approach contributes to the promotion of an open and just culture, while reducing the burden of investigations. Staff involved in the incident also actively participate in the review and the solutions, and families can be provided with the outputs.
- Fault tree analysis - this approach identifies the causes of system failure and helps to proactively minimise risk in the future.
- Thematic reviews – these can be used where there are a number of incidents to consider. They focus on identifying common elements for improvement and can be perceived by staff as being less intimidating than other approaches.
- Full patient safety incident investigation – under the PSIRF framework, these will be called 'Patient Safety Incident Investigations'. The new approach may lead to fewer investigations, but it will be even more important to ensure that those that are carried out are done well. Any activity which people carry out only intermittently can be challenging and sometimes frustrating. In our experience, people who are asked to carry out an investigation after a long gap often struggle to remember much about the process. It is therefore sensible to look for tools which can support investigators and guide them through the process [d*eclaration of interest – Verita is currently working with Microsoft to develop a tool of this sort*].

3.24 In common with many organisations, we believe that Great Ormond Street could further improve their process for collecting, organising and analysing data from incidents and investigations to make it more systematic. This is a rapidly developing field, but one that presents great opportunities for helping decision making around what to learn and how to respond to incidents.

Improving risk management

3.25 Risk management is an important part of patient safety. The consistent measurement of future and current risk exposure is an essential part of the process. We have identified several methodologies, models and tools for risk management, each with specific applications. They include:

- Tabular risk matrices
- Event risk classification
- Bow-tie modelling
- Observational safety audits
- Hazard logs

3.26 Each have a role to play, and we set out in the report how they could be used to improve patient safety at Great Ormond Street.

Improving safety training

3.27 High quality training is essential if many of the changes in this report are to be delivered. The Learning Academy is an important asset for the trust and we believe it should be central to the trust's ambitions to improve and professionalise patient safety. The academy should be asked to develop a patient safety syllabus covering areas such as human factors, leadership and communication. Training could be another way of addressing the difficulty of acknowledging that thing go wrong even in an organisation that provides the best care, through sessions that address the issue of being *"Exceptional but Fallible"*.

Conclusion

3.28 Great Ormond Street has great strengths as an institution and a reputation for taking on the hardest cases and challenges that other hospitals can't meet. But it also faces significant challenges. Some of these challenges are shared across the NHS and are exacerbated by COVID. Others arise out of the characteristics of the hospital and its patients. We believe that a concerted organisational effort to address the safety of care and services will have a significantly positive impact on patients and families, aid staff recruitment and retention and serve to enhance the trust's reputation as a world-class provider.

4. Methodology

4.1 Our first step was to gather evidence. There were three main elements to that work:

- Conversations with people both inside Great Ormond Street and outside
- Attending internal trust meetings (virtually)
- Reviewing documentation.

4.2 We used a number of benchmarks, including those produced by Patient Safety Learning in their document *Patient Safety: A Blueprint for Action*. The benchmarks have helped inform our assessment, conclusions and recommendations and are discussed in the next section.

Interviews

4.3 We were keen to make sure that we had input into our work from a wide range of voices. Within the trust we spoke to:

- Senior managers, including the chief executive, medical director, (out-going) chief nurse and chief operating officer
- Those responsible for the management of quality and safety, including associate medical directors and the interim head of quality and safety
- Staff responsible for patient experience, bereavement and freedom to speak up
- Patient safety managers (meeting them in groups)
- Chiefs of service
- Heads of nursing
- Non-executive directors.

4.4 Outside the trust, we spoke to three people in NHS England who have direct experience of working closely with Great Ormond Street. We also spoke to the safety team at Titan Airways about their use of technology to assess past, present and future risk.

4.5 In addition, we had a conversation with the parents of a patient who had a difficult experience with the trust. We are very grateful for them taking the time to speak to us. This is not the place to review their individual case, but what they told us has important lessons for the hospital and we hope will contribute to the development of Great Ormond Street.

4.6 With the agreement of the trust, we exchanged views and ideas with Helen Hughes, chief executive of Patient Safety Learning during our work. She held a development session with the Board in April 2021 and kindly shared the outputs with us. We would like to thank Helen Hughes for her input. Any errors or omissions, however, are entirely our own.

4.7 We would like to thank all those who spoke to us, whether inside the trust or outside. Those we spoke to are listed in Appendix C.

Meetings

4.8 We observed internal meetings relevant to the issues of safety and quality. These were:

- **Quality Safety & Experience Assurance Committee** – a committee of the board, which provides assurance on issues relating to quality and safety
- **Patient & Family Experience & Engagement Committee** – which is responsible for giving the Quality, Safety and Experience Assurance Committee assurance on compliance with legislative and regulatory requirements around patient experience and giving oversight of the trust's patient and family experience agenda
- **Patient Safety & Outcomes Committee** – which aims to monitor compliance relating to clinical governance and provide assurance that issues contributing to quality, safety and effectiveness in the trust are effectively managed
- **Closing the Loop** – a sub-committee of the Patient Safety and Outcomes Committee which aims to ensure that actions from previous incidents, complaints and learning from death reviews are implemented

- **Risk Assurance & Compliance Group** – which monitors risk and compliance issues, including the GOSH Board Assurance Framework and progress with recommendations from the Care Quality Commission
- **Executive Incident Review Meeting** – whose role is to review incidents to decide on an appropriate response, e.g. whether a Serious Incident should be declared, and an investigation carried out
- **Clinical Quality Review Group** – a liaison meeting with the NHS England, the commissioner of GOSH's services, about current clinical issues.

4.9 We met with the trust's medical director and the associate medical director for safety to give them an initial idea of our proposals and we refined our approach based on their comments.

Documents

4.10 We requested, and were provided with, many documents, which we subsequently reviewed. They included:

- Papers for committee meetings
- Trust policies, including incident reporting, complaints, duty of candour, raising concerns and risk management
- Job descriptions
- Safety Strategy
- Framework for Patient and Family Experience
- Patient Safety Strategy.

4.11 More details of the documents are given in Appendix D.

4.12 We also reviewed a number of the trust's SI reports. An analysis of those is in Appendix E.

4.13 We discuss the current situation in section 5. Our proposals for further improving patient safety are outlined in section 6.

5. The current situation

5.1 The terms of reference asked us to look at a number of specific areas:

- Safety culture
- Serious incidents – the process of managing incidents and investigations and implementation of actions
- The 'Golden Thread' of safety
- Engagement, support for patients and families and the duty of candour
- Safety risks - in complaints, claims and inquests.

5.2 We were also asked to look at inquests and claims but were advised that there were no ongoing cases at the time of our review.

Being 'world-class' and its implications

5.3 We start by highlighting that the hospital is a world-renowned institution which provides care and carries out research to the highest standards. Staff who work at GOSH have a highly specialist skill base. We were struck by the deep complexity of many of the cases we heard about. We heard that it is common for Great Ormond Street to take on cases that other hospitals simply cannot, including cases from other parts of the world.

5.4 There are important implications of this status.

The danger of the 'superstar' reputation

5.5 Having a reputation as a world-leading institution can be double edged. In our work over the years looking at examples of where things go wrong in health providers across the country, the 'cult of the superstar' is a recurring issue[2]. Across the NHS we have seen a number of instances where the status of individuals is so high that others

[2] Verita's work on the subject of doctors with superhero status has previously been published in the Guardian, see - https://www.theguardian.com/society/2017/aug/26/rogue-doctors-use-superhero-status-abuse-patients-ian-paterson-myles-bradbury

are afraid to challenge them or to raise concerns if things go wrong. This is no criticism of the organisation concerned, it is simply a fact of life – the greater someone's expertise, the harder it can sometimes be to question their decisions. In cases we have seen in other places this reticence can lead to serious lapses in safety with harm to patients and reputational damage resulting. In contrast, effective teamwork in health-care delivery has an immediate and positive impact on patient safety. Being in an effective team means any worker should feel empowered to admit a mistake or speak up about something that gets in the way of delivering safe, high quality care.

5.6 A world-leading reputation raises wider questions about when things do go wrong:

- Can things ever go wrong in a world-class institution?
- Can highly skilled individuals with world-wide reputations ever make mistakes?

5.7 The answer to both these questions is, yes. Things go wrong in all systems – especially where people are involved. And Great Ormond Street is a particularly complex environment – providing children who have challenging conditions with innovative treatments. Mature organisations know that things sometimes go wrong, put systems in place to minimise the number of times they occur, and mitigate the damage that this causes when they do. Mature organisations also have good systems in place to learn from such errors which feed into the preventative actions. Organisations that don't recognise that things sometimes go wrong foster a culture of denial. This ultimately leads to worse patient care.

Patient safety culture at Great Ormond Street

5.8 Creating a culture of safety is an essential foundation to delivering safe and reliable care. Ensuring that patient safety is at the heart of all care delivered can minimise the chances of things going wrong. A strong patient safety culture will have the following characteristics:

- Individuals and teams have a constant and active awareness of the potential for things to go wrong.

- A culture that is open and just, one that encourages people to speak up about mistakes – being open and just means sharing information openly with patients and their families balanced with fair treatment for staff when an incident happens.
- Both the individual and organisation can acknowledge mistakes, learn from them and take action to put them right.

5.9 We asked Jo Gillespie, the peer reviewer of this report and a well-known safety expert from aviation, to describe organisational safety for Great Ormond Street. This is drawn from literature and his own extensive experience. It is as follows:

> *'Organisational safety is a by-product of experience gained from every element of the organisation – people, equipment, facilities, procedures, leadership, tasks, successes and failures – that informs a resilience to recognise the unsafe and correct it before harm is done, at the same time acknowledging and promoting good practice. It is directly related to the culture or 'common law' of the organisation.'*

5.10 We are pleased to report that the people we spoke to explained that there is a widely shared view that Great Ormond Street has come a long way in recent years in improving its safety culture, and that there is strong commitment from the leadership to continuing that progress. We heard and saw many specific instances of things that have been improved in recent years – notably through the leadership team's commitment to patient safety and its communication of that commitment. Having spoken to them, we are convinced of the desire of the leadership team to improve things further.

5.11 Many people agree, however, that there remains some way to go if the trust is to have a strong patient safety culture. We have heard a number of people telling us the following:

- Some clinicians haven't been given enough protected time to deliver the patient safety aspect of their job.
- There is a concern that patient safety issues are only taken seriously if there is a metric or target attached to it.

- Issues that have been placed on the risk register don't always get monitored or mitigated.
- Staff with patient safety responsibilities don't always feel that they are being listened to.

When things go wrong

5.12 We reviewed the trust's incident reporting and management policy. We looked at whether there are effective and timely processes is in place for managing serious incidents. This includes reporting, investigation and approval, through to learning and system improvement to avoid recurrence.

5.13 Many people that we spoke to within Great Ormond Street understand that a positive patient safety culture acknowledges that there is always the potential for things to go wrong. Systems can therefore be put in place to minimise the chances of that happening. However, we believe that it is sometimes culturally difficult within Great Ormond Street to accept that things can go wrong and to respond appropriately. We were told that some see the organisation as '*bullet-proof*' in the face of criticism. There is also a view outside the trust that some clinicians at Great Ormond Street can find it difficult to accept that something had gone wrong. Some believe that this reflex is deeply ingrained. This is potentially indicative of a culture of defensiveness. Acknowledging this trait is the first step on the road to changing it.

5.14 In addition, we have seen strong indications that it is often part of the culture at Great Ormond Street to think that something going wrong means that someone must have done something wrong. We have heard comments after an event such as "*this doesn't need to be investigated because no-one has done anything wrong*". We have also seen the mirror image of that argument - a reluctance to declare a serious incident because it will be interpreted as an admission of failure by the individuals concerned. This is unhelpful to creating the right environment for understanding harm and improving systems and processes. The assumption amongst many people that investigation and blame inevitably go together is implicit, but present in the trust.

5.15 In our experience, people who are blamed can become closed and fearful; they will be reluctant to help investigators understand the safety aspects of an incident. This

can create a culture of concealment which limits the opportunity for learning and improvement. NHS policy makes it is clear that inappropriate blame is extremely damaging to individuals and an organisation's safety and culture.

The science lab

5.16 Research is another key aspect of Great Ormond Street's work. Some describe this as "*GOSH as half hospital, half a science lab*". The cultures of research and clinical practice are not the same, not least because in clinical practice the need for clinicians to be in dialogue with patients and families is a priority.

5.17 We were told that some practitioners at Great Ormond Street see a focus on safety conflicting with innovation. Others told us that they feel that the hospital sometimes puts too much emphasis on pushing the boundaries of science. They are concerned may lead to a culture where some prioritise innovation over safety in their practice.

5.18 We heard indications that there are some clinicians for whom an interest in research is their primary motivation. They may therefore put less emphasis on the communication aspects of their role.

5.19 Getting the right balance between safety and innovation is an issue across the NHS. It is particularly important in an institution like GOSH where the proportion of innovative research work is much higher than in most UK hospitals.

Incident investigation at Great Ormond Street

The process

5.20 The trust policy defines an incident as:

> *"Any unintended or unexpected incident that could have, or did, lead to harm for one or more patients receiving healthcare".*

5.21 The policy states:

> *"Those incidents which meet the threshold of a serious incident will be investigated following the National Serious Incident Framework".*

5.22 The process used at the trust is similar to those used across the NHS, but one aspect that we found different is that investigators rely on the staff involved in serious incidents to provide written statements, rather than carrying out interviews. Whilst this approach is acceptable for less serious incidents, our recommended approach to investigations, is to collect evidence by talking to people. Done well, this should allow people to be put at their ease and to explain things in their own time. Investigators are also likely to obtain more reliable information.

5.23 An external interviewee told us that they felt that the trust appeared to struggle to get reports completed, perhaps because too much of a perfectionist approach is taken to the reports. However, this means that there is often a long gap between initial drafts and reports being sent to NHS England. People in the trust told us that they thought investigation reports could be too long and detailed, rather than getting to the point. We were also told that some people focussed unduly on the process of investigations, rather than the actual learning and clinical improvement that should follow.

Review of a sample of reports

5.24 We reviewed five reports of serious incident investigations carried out by the trust. We found the reports to be good quality. All five reports set out a good description of the incident and provided a readable account of what happened. Each of the reports highlighted at least one care delivery problem (care delivery problems are issues that arise during care – usually actions or omissions by staff).

5.25 The identification of the contributory, influencing, underlying or causal factors that contributed to the incident is also a key part of the process. Although the contributory factors framework was used, more effort could be made to drill down to the underlying causes.

5.26 There may be occasions when nothing could have prevented the incident and no root causes are identified. However, in our experience there are often lessons to learn and safer practice issues may be identified which did not materially contribute to the incident. It wasn't clear from some of the reports whether the term 'lessons learned' was being correctly used. It would be helpful for reports to make clear which lessons learnt are incidental findings and recommendations and which are from something that contributed towards the incident.

5.27 The recommendations in a serious incident report should address all the root causes and any contributory factors. They should be designed to significantly reduce the likelihood of recurrence and/or severity of outcome be clear and concise and kept to a minimum wherever possible. All the reports we reviewed contained recommendations. On the whole these were good and related well to the contributory factors highlighted in the report.

The decentralisation of the management of serious incidents to directorates

5.28 An important question in any serious incident process is the extent to which it is centralised or localised. Under the current approach, investigations are largely carried out by the central patient safety team, with support from directorates. Change to the process to have more local involvement in carrying out investigations is under consideration and was being discussed at the time we were collecting evidence. The proposal is that directorates take on responsibility for incident investigating with a central team able to provide theoretical safety expertise. The drive for 'ownership' of safety to be held by directorates with investigations supported by the patient safety team who have a key coordination and report construction role is welcome.

5.29 The advantage of a decentralised process is that it allows investigations to be carried out by people close to the service where the incident happened. This means that they will have a good understanding of the systems in place and are more likely to be able to tailor recommendations to ensure that they are implementable. However, a decentralised approach relies on staff who might only carry out investigations relatively infrequently. Staff told us of a concern that local investigation risks bias because teams haven't been trained in serious incident investigation and will be "*marking their own*

homework". At the time of writing this remained an issue that many people had real concerns about. We also heard from staff that they were worried that there wouldn't be enough resources allocated to the directorates to take on the responsibility of managing serious incident investigations.

Learning from serious incident data

5.30 Serious incident investigations produce valuable data, but it is important that the data is analysed and then disseminated properly. Safety culture should be visible throughout the organisation, and information should flow from care providers up through the governance structure to the board, and back down to the front line (this linkage is known as "the golden thread").

5.31 The full value of data from investigations will not be realised unless it is collected in a systematic and organised way. Doing so helps to reduce the need to investigate incidents in ways that are burdensome. We do not believe that there is currently a supply of data which is organised systematically to make it easy to interrogate.

5.32 Once data is collected, it is important to ensure that it is properly disseminated. In some ways this is the most important part of the serious incident process – it does not matter how much information has been collected and how much time has been spent investigating if nothing happens to the outputs. Findings of serious incident reports are reported within the trust and the 'Closing the Loop' meeting has specific responsibility for chasing up the actions from investigations. However, it was less clear to us that there was a good system for passing on lessons from investigations to staff more generally.

Disseminating learning from serious incidents

5.33 We were told by a lot of staff that the trust's mechanisms for disseminating learning from incidents do not work well and some have fallen into disuse in recent times. Current mechanisms include:

- Cascade briefings from meetings e.g. PSOC
- Learning events – including lectures and lunchtime sessions
- Email summaries & reminders

5.34 All of them require staff to act to gather and assimilate the information offered.

5.35 One group of senior staff told us that it was most unlikely a band 5 nurse would be familiar with the serious incident process or know about changes to clinical practice recommended in response. They also said that changes to practice often didn't 'stick' and old clinical habits soon re-emerge. In short, safety messages don't easily get to the ward and when they do, don't necessarily result in sustained improvement in clinical practice.

5.36 Several people we spoke to told us that the learning from incidents was very specific to particular teams and didn't have wider application to the hospital. That might be the case in some instances, but generally the learning from investigations has a generic element which might be of use to others. The idea that much learning doesn't have wider applications should be looked at closely. Otherwise there is a danger that wider learning is lost.

5.37 We saw indications that the board is remote from patient safety issues. While to some extent that is natural – it is not their role to get involved in the day-to-day running of the trust – we think that the board can play a major role in demonstrating the importance of the patient safety agenda. We will address this further in the next section.

Family engagement and the duty of candour

5.38 The terms of reference for this review ask us to see how hospital staff engage with families following an incident which has caused significant harm. Great Ormond Street has always worked in a complex social environment, but we heard from a number of people about how that environment is evolving. One interviewee commented to us that there is generally less willingness in society to accept mortality, particularly when it involves children. While some people may have less respect for authority, others may have higher expectations about what those in authority can deliver. The greater

willingness of some people to speak up, facilitated by social media, is also an important trend. Together these societal factors make Great Ormond Street's role increasingly challenging, especially if things go wrong.

5.39 We recognise also from our interviews with staff that staff work hard to ease the burden on families, and support children and young people through complex and sometimes life-saving treatment on a daily basis. Many families are happy with the care and treatment provided.

5.40 Apart from interviewing staff, we met with a family who had experienced problems with how the trust had managed a serious incident. We also listened to the BBC radio programme that led up to our appointment.

5.41 Staff in the trust acknowledged that there were problems at times with family engagement. They also recognised that this is a significant issue for Great Ormond Street as public confidence is important to uphold.

5.42 The duty of candour is an important aspect of this communication agenda.

5.43 The legislation relating to duty of candour[3] states:

1. *Registered persons must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.*

2. *As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a registered person must— a) notify the relevant person that the incident has occurred…*

5.44 It goes on to discuss notifiable safety incidents and how they should be handled.

5.45 We saw evidence that duty of candour is not consistently understood within Great Ormond Street. Some staff interpret duty of candour as meaning that if there is a notifiable incident, they have a duty to be open and transparent, but if there isn't, they don't. We saw instances where staff thought said that they needed to "*check if*

[3] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20

anyone did anything wrong" before deciding on whether the duty of candour applied to that case, rather than it just being part of their everyday job. Clearing up any ambiguity in this area is important – all regulated healthcare staff have a duty to be open and transparent and that should be their first instinct, whatever the circumstances of the case. The trust may have additional processes for when there has been harm, but this shouldn't be confused with the general duty all staff have to be open with patients and families.

Risk appetite

5.46 No procedure, or decision not to carry out a procedure, is risk free. Organisations must consider what level of risk is acceptable to them and how that level is calculated.

5.47 One driver of the acceptability of taking a risk is the consequence of not taking an action. When the life of a child is in the balance, a high level of risk may be acceptable. Great Ormond Street might therefore be expected to have a risk appetite that is relatively high.

5.48 There is no objective level of risk that is correct, however. The risk that is acceptable will vary with the circumstances and people involved. What is essential is that there is dialogue between clinicians and families so that families know what risk is being taken and that choices are being made consciously. Working through that dialogue can take time and effort, but it is essential if long term issues are to be avoided.

5.49 Alternatively, significant new diagnostic tests, procedures or treatments could be subject to risk assessment in advance of implementation. Prospective investigation of this sort could be of significant benefit when new tests, technology or procedures are a feature.

The patient safety team

5.50 The patient safety team have a responsibility to lead, develop and implement patient safety systems, processes and initiatives within the trust. They also act as lead investigator on complex/serious incident investigations and are responsible for ensuring that investigations are carried out within the allocated time.

5.51 The time of our review coincided with a period of change for the patient safety team. We did not therefore look closely at how the team currently operates as anything we would have said may be out of date.

5.52 Going forward we believe that it is important that the team continues to focus on improving the patient safety culture in addition to carrying out/supporting serious incident investigations. If these are to be carried out within the directorates, they will have important role to play in supporting the process of investigation however it is delivered in future.

Committee meetings

5.53 In common with much of the NHS, Great Ormond Street holds many meetings in relation to patient safety – internal executive meetings, board assurance meetings, and meetings with external bodies such as NHS England. We were stuck by the length of the papers for meetings – often 300 pages long. Meetings were long with large numbers of people involved. We also noticed that on occasion there were large numbers of deputies attending, often without saying much or anything in the meeting.

5.54 Meetings can have many functions:

- Exchanging ideas
- Generating ideas
- Disseminating information
- Providing assurance that things are being done as agreed.

5.55 In some instances, it wasn't immediately clear to us what some of the meetings we observed were trying to achieve. We doubt whether some of the meetings would really achieve their objectives, even if they were clear. There is a concern that having a meeting itself was considered to be '*action*' in response to a problem.

5.56 More thought is needed about what the current committees are trying to achieve and, and whether the current range of meetings is the best way of achieving them. This process should start by defining a list of objectives – gathering information, sharing information, agreeing conclusions, dissemination of conclusions – and identifying the best way of achieving them (which may not always include a meeting).

Communication, communication, communication

5.57 Communication is key to finding an acceptable way forward on many of the issues that we have discussed.

5.58 Communication with staff is important both to show why investigating incidents is important and, more generally, to demonstrate the importance that the trust places on having a good safety culture and systems. As well as good clear communication coming down from the leadership, junior staff need to feel empowered to raise issues with those higher up in the organisation. A culture of openness and good communication between staff is a key feature of a safe organisation.

5.59 Communication with families is also crucial. Choices about care are often complex and involve trade-offs. There may simply be no objectively 'right answer' to how much risk is acceptable in the choice between one action and another, or of not acting at all. Ensuring that families feel empowered and listened to is essential, so that they give their backing for whatever decision is ultimately made.

5.60 We were told that there are some staff who struggle with the communications aspects of their role and admit that they are not a "*people person*". Even if all involved are effective communicators and have a desire to be open, the complexity of cases makes good communication a challenging task. This task is only going to get harder as the advance of medical science makes treatment options ever more technically complex and the resulting moral issues grow. The task of engaging with patients and families and explaining what is happening and what choices need to be made has to be priority within the trust. Staff should be supported and incentivised to be as open as possible, with time set aside for them to do so.

Overall comment

5.61 Patient Safety Learning's 'Blueprint for Action' provides a benchmark against which organisations can measure their 'patient safety maturity'. It covers the following areas:

- Shared learning for patient safety
- Professionalising patient safety
- Data and insight for patient safety
- Leadership for patient safety
- Patient engagement for patient safety
- Culture for patient safety.

5.62 The document gives a framework for reviewing the trust on the following scale:

- Minimal – aiming to meet statutory and regulatory requirements
- Reactive – plans in place to meet statutory and regulatory requirements
- Active – actively seeking to improve patient safety
- Proactive – reducing harm, supporting staff, plans to deliver a patient-safe future
- Patient-safe future - patient safety in integrated care, minimal avoidable harm, safety is a core purpose, safe for staff.

5.63 Our estimate would be to put Great Ormond Street at the 'Reactive' level.

5.64 In our experience, the key steps for improvement in any organisation are:

- recognise problem
- accept responsibility
- develop solutions
- implement
- embed.

5.65 We believe that the leadership at Great Ormond Street accepts that that it can learn and improve and that this is a priority for the organisation. Some solutions have

been developed internally and in the next section we propose some additional ones. We also hope that what follows will help with implementation and embedding change.

6. Proposals for change

6.1 The focus of our work has been on developing ideas for further improvement. We recognise that the trust is implementing the patient safety strategy, however we have some practical ideas of what could be done to build on this work.

a) Building the patient safety culture

6.2 As we have described earlier in this report, patient safety culture is an essential base on which to build safety improvements. There are a number of elements to growing such a culture.

The role of the Board

6.3 As a world-class hospital, Great Ormond Street's excellent care and treatment should be matched by world-class patient safety. This ambition should be the goal of the trust over the next five years.

6.4 Culture starts at the top. The first step in building the patient safety culture is for those in leadership positions to demonstrate that it is a priority for them. An observer who attended NHS board meetings across the country would probably reach the conclusion that the top priority for most trust boards is finance - because that is what they appear to be most interested in. They would probably be right![4].

6.5 While it is not the role of the board to get involved in management of the organisation they can help to deliver the trust's strategy by setting the tone. There are a number of ways in which that could be done. The following are some ideas:

- Demonstrating that safety is a priority – the most obvious ways in which the board can show that safety is a priority is by talking about it. That might begin by issuing a board statement about the importance of safety and continue by ensuring that it is talked about in board meetings. The statement should invite

[4] Board meetings begin with hearing about patient experience at the trust. This is welcome but is not a substitute for having a patient safety focus.

staff to see their daily work as having two parts: delivering excellent care and improving the safety of the trust's systems and processes. It should emphasise that the two go hand in hand.

- Bolstering the role of the non-executive with the specific remit for patient safety, enhancing their role as patient safety champion to support the board's executive patient safety lead. This role could bring a degree of independent, supportive challenge to the oversight of patient safety.

- Visibility – specialty/directorate visits have obviously been curtailed by Covid, but the presence of non-executive directors 'on-the-ground' demonstrating that they care about safety and setting out the trust's ambitions would send a powerful message to the organisation. All specialties should be visited over the next eighteen months and on a planned, regular basis for the future.

6.6 The trust has initiated a patient safety network with the five children's hospitals with which it works most closely. This is welcome and should be prioritised to ensure that it is used to share information and discuss key safety challenges.

Strengthening the golden thread

6.7 Communication is key to the effective flow of information from ward to board. That includes both formal and informal channels.

6.8 For the formal channels, patient safety should be considered in all business decisions. Board papers currently have to state whether there are risk, legal or financial implications. They could be required to state whether there are patient safety implications as well. This will help to ensure that patient safety is considered and included in all decisions. There are already formal trust meetings whose role is to discuss patient safety - Quality, Safety & Experience Assurance Committee at board level and Patient Safety Outcomes Committee. These meetings tend to have a mass of paperwork and might benefit from time spent discussing patient safety issues in a freer way than just reviewing a series of reports. Other meetings about routine matters should start with a brief discussion about the pressing safety issues of the day e.g.

'what safety concerns are there today in the trust?'. Executives should ensure this happens.

6.9 In terms of informal channels, safety concerns emanating from lower down the organisation must be able to reach board members. It is welcome that the trust has a Freedom to Speak Up Guardian. The trust should ensure that it takes the full benefit from this resource and that the role is widely understood throughout the organisation. Another way of demonstrating the importance of patient safety is ensuring that it is included in job roles for staff across the organisation.

6.10 The trust should establish a baseline assessment of the current culture – ideally from existing resources. Progress should be monitored regularly. Time should also be taken to celebrate successes when they occur.

Openness about risk and safety

6.11 Human beings make mistakes – that is a fact of life. The best systems sometimes fail. The only question is how organisations respond to these facts.

6.12 A starting point would be for people in the organisation to talk more about when they have made errors, what they did about it and how they felt. This should start from the top – chair, board members, chief executive and senior clinicians. Talks could be given to groups of staff about human performance, safety and blame. These events should be organised to make it easy for staff to attend. They could be badged *'Exceptional but fallible'* - that is, making it clear in the title that even the best hospital can have incidents of avoidable harm. An external speaker, such as an eminent psychologist, clinician or a human factors specialist, could also be invited to speak on the same topic.

6.13 It would be beneficial to encourage dialogue when things go wrong. Experience of senior people talking about such circumstances should help, together with alternative approaches to investigation which encourage dialogue – both internally and externally (see discussion of alternatives to investigation, below). The trust should start to examine what leads to so much good care. How is it achieved? Are there key ingredients? How are these best incorporated into good clinical practice?

6.14 More generally, the trust should accept that it is inevitable that it receives criticism from the media and, from time to time, from families. It should ensure that it responds to this proactively and is prepared to be open with people when things go wrong. Admitting mistakes should be seen for what it is – a strength – not as a weakness.

Directorate risk & safety champions

6.15 Identifying people with responsibility for promoting risk management and patient safety can be an effective way of promoting good practice. These individuals will help drive the safety management function deeper into the organisational structure and provide informed safety support to the chiefs of service and patient safety team. These roles could be taken on by deputy chiefs of service or by people who report to them. They should be provided with additional training in some or all the risk management tools described in this report.

Developing the role of the patient safety team

6.16 Strengthening the patient safety function will be an important part of developing the culture of patient safety at Great Ormond Street. We were told that in the past the patient safety function concentrated too much on process. We think that the 'fix it' element of the role should be increased, so that the work of the team is more dynamic and rewarding and is able to help deliver improvement more directly. The team should be trained in a range of patient safety techniques to facilitate this.

Creation of a central patient safety hub

6.17 The focus of much safety work is often on the past – looking back at things that have already gone wrong. Safety, however, is about the 'here and now' – making sure what happens today is the best it can be. Data and technology offer great opportunities for developing this perspective. A central patient safety hub and

database with live data about safety issues should be developed to ensure not only that the full learning value is drawn from the data that the trust collects, but to ensure that things can be put right. This would help move safety onto a dynamic footing and refocus it from the past to the present.

6.18 The trust should trial new ways of ensuring that safety messages reach clinical staff and teams quickly. These messages should be specific, simple and targeted. Eye-catching infographics would be a good medium. Importantly, they should be timed to arrive at a time that they can readily influence the clinical task. They could include, for example:

- reminders about prosthetic packaging changes at the beginning of a theatre list
- prompts to label syringes after drugs have been drawn up
- reminders to read diagnostic test results
- safety messages to support ward huddles.

6.19 The trust should build on how other industries routinely communicate and impart important information to 'deskless workers' with a view to learning from them.

6.20 Technology should be used to support these changes e.g. electronic screens in theatres. Dissemination of knowledge should eventually be run by directorates with the support from their directorate safety partner. Initially, key messages should be gathered from the last ten serious incident investigations and any national safety alerts and be used as the basis for this work. This work should be formally evaluated by research commissioned by the charity. The research should focus on establishing, for example, what impact on behaviour the messages have and how that varies depending on the nature of the message and the time at which it is sent.

b) Openness and family engagement

6.21 Family engagement is seldom easy. Everyone involved in the process may have a different perspective and it can be challenging for those who spend their lives in a clinical environment to really understand what things look like for those coming to the experience fresh. We heard evidence that some at Great Ormond Street sometimes find family engagement difficult. We think that the reasons for this lie partly in the

cultural issues we identified earlier. Striking the right balance between being an authoritative expert while open to the possibility of error and the need to learn, is a difficult one. Some of our foregoing suggestions about changing the safety culture will address this issue, but there are further steps that can be taken.

6.22 Changing attitudes of the public to health, and the availability of social media which can bring together groups of people with concerns make this issue increasingly complex. The trust needs to be prepared to respond to these issues in an open and receptive way.

6.23 The key to good family liaison is active listening. We were told that not enough time at Great Ormond Street is spent sitting down with families and listening to them. Identifying what is important to families and to engaging with their priorities is crucial. For example, we heard discussion about whether patient names should be used in Serious Incident reports. There is no right or wrong answer to that question. Many may not think it is an important issue. But it can matter to some families. Asking families what they would prefer – and responding to it – demonstrates respect and helps to build a positive relationship. Issues can be difficult to focus on simply because they are not a priority for professionals. Creating an active listening culture is one way to address this. When there has been engagement with families about their concerns, keeping a good record in the patient notes is particularly important in ensuring that families are provided with clear and consistent information.

6.24 Complexity is a feature of many cases at the hospital and we heard a great deal of evidence to this end. Many children cared for by the trust have numerous co-morbidities i.e. the simultaneous presence of other diseases/medical conditions (we heard of cases with eleven co-morbidities). That is significant for staff, but an even more so for patients and families. Although complexity is something that has to be dealt with across the NHS, it is a bigger issue in Great Ormond Street given the particular case mix. The trust could do much more to help patients and families in this area. We propose that Great Ormond Street considers the development of a 'system navigator' function for children with complex needs, so that families have a single point of contact despite being engaged with multiple specialities. We think this may be a responsibility suitable for an experienced senior nurse. While this will involve extra work for the person dealing with an individual patient, across the system as a whole it should be more efficient than having multiple people providing information to families.

We suggest that the trust considers setting up a working group to determine how this sort of role might work best.

6.25 We were told that there is currently a two-month waiting list for bereavement counselling. There may be good reasons behind why the backlog has built up but addressing this as a priority to demonstrate that the needs of families are being prioritised.

6.26 We recommend the trust works with a small number of families to pioneer a more active role for them in safety of care and treatment. This could be supported by technology.

c) Improving investigations

6.27 As with many processes in the NHS, there is a danger that serious incident investigation focuses on the process itself, rather than on what it is trying to achieve. The first step with investigations should be to establish what the objective is and what can be gained from the investigation to help move the organisation forward.

6.28 The main purpose of investigations should be to find out what happened and why, so that there can be learning. Often it is also important to find out what happened to inform those affected – both a moral, and legal, duty.

6.29 Declaring a serious incident should therefore be seen as a 'neutral act', not an exercise in apportioning blame. It is rare for investigations to form the basis for disciplinary action, but if this is an issue in a particular case, communication with the relevant staff should be prioritised. It is important for senior management to demonstrate that learning and improvement are priorities for the organisation (as discussed above). The trust also needs to demonstrate that investigation is itself a priority - by allowing realistic time in job plans for investigation and safety improvement. Talking to staff across the NHS we hear of people who carry out investigations in their spare time or at weekends. If investigations are treated as a spare time activity, they will be perceived as such.

6.30 Investigations can be big or small: some events need in-depth detailed study; others would benefit from a quick review, allowing learning to be captured immediately and all involved to move on. The new NHS Patient Safety Incident Response Framework (PSIRF) sets out how healthcare providers should respond to patient safety incidents and how and when an investigation should be conducted. The framework puts an emphasis on the quality of investigations, rather than the quantity of them. This offers an opportunity for Great Ormond Street to develop a new approach to patient safety incident investigation. We propose that the response to an incident should be seen in terms of a range of possible interventions, the aim being to get the one that fits the needs of each incident best. Possible interventions include:

- After-action reviews
- Structured judgement reviews
- Fault tree analysis
- Thematic reviews
- Full patient safety incident investigation

After-action reviews

6.31 We suggest that the trust adds after-action reviews to its repertoire. The technique relies on discussion by clinical teams followed by a write-up of what has been discussed. NHS England describe after-action reviews as "*a structured approach for reflecting on work of a group and identifying strengths, weaknesses and areas for improvements*". The approach involves getting as many people as possible who were involved in an incident together so they can discuss their viewpoints on what happened with the support of an independent external facilitator. After-action reviews can be used in many circumstances:

- An incident
- A near miss
- A complaint
- At the end of a project.

6.32 A prerequisite of an after-action review is that everyone feels able to contribute without fear of blame or retribution. They are about learning, not holding

people to account. The role of the facilitator is to guide the group through the discussion and help create a safe and open atmosphere. Discussions tend to last a maximum of an hour. The facilitator will take the group through a series of questions:

- What happened that we want to learn from? - creating a common understanding of the experience under review
- What did we set out to do?
- What happened?
- Why were there differences?
- What went well and why?
- Reflecting on the successes and failures: what could have gone better? Why?

6.33 If an after-action review takes place following an incident, those affected by the incident (patient or family) can be invited to attend alongside the clinical team so that their views and perspective can be heard and considered. Following the discussion, the facilitator will record actions identified and a learning log. An action plan is then developed to put any solutions in place. Possible outcomes could be:

- Initiation of immediate action to mitigate further harm
- No action required
- A celebration of excellent care
- Identification of a learning need
- A conventional audit or further investigation is needed
- Sharing the learning.

6.34 The process has many benefits. One is that the reviews can happen quickly. That is both a benefit for learning (as the facts are fresh in people's minds), but it also demonstrates to families that the incident is being taken seriously (the delay within the serious incident process alone is corrosive of many of its benefits). The use of after-action reviews can help to promote an open and just culture as well as reducing the burden of carrying out traditional investigations. Another benefit of the process is that staff involved in the incident can actively participate in the review and those affected by the incident hear first-hand about what went wrong (if anything) are listened to and supported. This helps to ensure that the duty of candour is met.

Structured judgement reviews

6.35 Structured judgement case note reviews can be used for a wide range of incidents and complaints. An important feature of this approach is that the quality and safety of care are evaluated and recorded whatever the outcome of the case, and good care is judged and recorded in the same detail as care that was problematic.

6.36 There are two stages to the review process:

a. Reviews carried out by front line reviewers. These are members of the team who are trained to undertake reviews within their own service or directorate.

b. A second-stage review takes place if care problems have been identified by a first stage reviewer and care has been rated as 'poor' or 'very poor'. This second-stage review is usually undertaken within the hospital governance process and normally uses the same review method.

6.37 The approach has several benefits. Much care is of good or excellent quality and that there is much to be learned from the evaluation of high-quality care. Another benefit of using this approach is that the Child Death Review panel works in an analogous way with any perceived deficiencies in care referred for consideration through a root cause analysis of serious incident (if the threshold is met). It is thus a familiar process to clinical staff.

6.38 The approach also contributes to the promotion of an open and just culture, while reducing the burden of investigations. Staff involved in the incident also actively participate in the review and the solutions, and families can be provided with the outputs.

Fault tree analysis

6.39 Fault tree analysis can be used for all types of system level risk assessment process. The purpose of this approach is to identify the causes of system failure and to proactively minimise risk in the future. This is a useful tool for complex systems that visually displays the logical way of identifying the problem.

Thematic reviews

6.40 Where there are a number of incidents to consider, thematic reviews can be useful. With their focus on identifying common elements for improvement, these can be perceived by staff as being less intimidating. The contributory factors framework provides a model which could be used to provide consistency in approach.

Full investigations

6.41 Under the PSIRF framework, investigations which are now known as 'Root Cause Analysis' will be called Patient Safety Incident Investigations. The new approach may lead to fewer investigations, but it will be even more important to ensure that those that are carried out are done well.

6.42 In our experience, investigations that are poorly conducted in their early stages often result in a much bigger use of management time and resources in the long run.

6.43 The use of staff directly involved in clinical practice to carry out investigations is important as it ensures that both the investigation, and any subsequent action plan, directly addresses the problem from the practitioner point of view. However, a system of this kind often results in long gaps between any individual carrying out one investigation and another as incidents in a particular speciality only come around infrequently. Any activity which people carry out only intermittently can be challenging and sometimes frustrating. In our experience, people who are asked to carry out an investigation after a long gap often struggle to remember much about the process. While training is important, often a long time has passed between the training and the use of the investigation skills. At the same time, providing extensive training on skills which staff use only rarely is not a good use of resources. It is therefore sensible to look for tools which can support investigators and guide them through the process [declaration of interest – Verita is currently working with Microsoft to develop a tool of this sort].

Recognising good practice

6.44 While attention is typically focussed on when things go wrong, there are benefits of a systematic approach to identifying good practice and outcomes and so that there can be learning from them. We recommend that a process should be put in place at Great Ormond Street to capture and share such learning.

Promoting learning from incidents

6.45 Learning from incidents is of no use unless there is a good process in place for getting what has been learnt to those who are on the front line. We do not believe that presenting papers to committees and expecting those present to disseminate the key points is an effective way of promoting learning. We suggest that more attention be given to getting messages out, possibly led by the patient safety team creating a rolling programme of communications. Methods for getting key messages across could include:

- Having electronic boards which displaying key messages, e.g. in theatres before a list
- Sending text messages to selected staff
- Lunchtime learning events
- Talks in academic settings
- Patient safety managers or senior managers carrying out walkabouts
- Setting up a safety hub and database with live data about safety issues which is fed through to staff (as discussed earlier).

Better use of data

6.46 In common with many organisations, we believe that Great Ormond Street could further improve their process for collecting, organising and analysing data from incidents and investigations to make it more systematic. There are currently systems in place which generate a large amount of data - to the point that many people feel overwhelmed by the quantity of it. The difficultly comes in organising it so that it can be easily interrogated. Technology offers a solution to this problem. It can help to identify subtle variations by factors such as time of day, week or year, etc. This is a rapidly developing field, but one that presents great opportunities for helping decision making around what to learn and how to respond to incidents.

Implementing improvements

6.47 The response to an incident should not be seen as a binary issue – serious incident investigation, yes or no. The new world of investigation offers flexibility and choice. That also presents challenges as decisions will need to be made about what it appropriate in what context. Thought will need to be given to what the objective of the response is. All this will require the development of internal policies and training on how it works. Technology could help staff charged with these responsibilities.

d) Improving risk management

6.48 Risk management is an important part of patient safety. The consistent measurement of future and current risk exposure is an essential part of the process. We have identified several methodologies, models and tools for risk management, each with specific applications. They include:

Tabular risk matrices

6.49 Risk matrices in the form of a tabular matrix, often with scales of 1 – 5 along the *x* and *y* axes, using terminology such as *very unlikely* to *very likely* and *negligible* to *catastrophic*, are widely used in the NHS.

Event risk classification

6.50 Event risk classification is used to assess the risk of past occurrences and incidents. It is based around two simple questions:

1. How bad could this have been?
2. What safeguards prevented it being so bad?

6.51 The answers offer insights into the magnitude of risk exposure and into the effectiveness of current mitigations, known as '*barriers*'. Event risk classification is

also based around a type of matrix, which also generates a numerical risk value for organisational risk exposure monitoring.

Bow-tie modelling

6.52 'Bow-tie' models are used to map out and visualise *threats* (root causes), *mitigations* (barriers) and *outcomes*. They derive their name from the shape of the diagram which is used to represent them with threats and outcomes centred on an event. Bow-tie models are best applied to the analysis of new procedures, new equipment or organisational changes, to identify what new risks those changes could introduce, how bad the risk outcomes could be and how effective any mitigations might be in protecting against them. Used retrospectively, bow-ties can also map out the evolution of serious incidents to help determine where existing mitigations failed and where new mitigations should be developed. Because the process is resource demanding it should only be applied to major risk concerns.

Observational safety audits

6.53 This is a process in which trained and knowledgeable 'auditors' observe a number of similar activities or procedures to identify common threats, errors and good practices. The observations are always unattributed and made only with the permission of those being observed. The output is a bank of aggregated data indicating areas of excellence and opportunities for improvement for a service, rather than focusing on any individual. Because of the sensitive nature of the collected data, strong data protection protocols are required.

Hazard logs

6.54 Similar in format and function to corporate risk registers, hazard logs can be raised to catalogue all identified hazards associated with a specific activity, area or procedure. Familiarisation with these hazards and the applied mitigations prior to commencement, allows practitioners to be aware of the level and sources of risk they may encounter.

6.55 These approaches are summarised in table 1 (Appendix F).

e) Improving safety training

6.56 High quality training is essential if many of the changes set out in this report are to be delivered. Delivery of regular training in areas such as serous incident investigation is particularly important (a number of people we spoke to identified the lack of training in recent years as an important issue).

6.57 The Learning Academy is an important asset for the trust and has received significant funding from the charity. We believe it should be central to the trust's ambitions to improve and professionalise patient safety. We propose that the academy should be asked to develop a patient safety syllabus that covers training in the following:

- Human factors
- Human error theory
- Human performance
- Building a safety culture
- Building resilient teams
- Leadership for safety
- Communication, duty of candour and supporting families after incidents
- Investigating incidents using technology
- Interviewing during investigations
- After-action review & other investigative techniques
- Developing solutions after incidents

6.58 Appendix G provides a short description of each of these courses.

6.59 In addition to these measures, the trust should ensure that staff are registered to attend the Healthcare Safety Investigation Branch (hsib.org.uk) programme on investigating.

6.60 As we set out above, training could be another way of addressing the difficulty of acknowledging that thing go wrong even in an organisation that provides the best care, through sessions that address the issue of being *"Exceptional but Fallible"*.

7. Next steps and conclusion

7.1 Using the Patient Safety Learning – A Blueprint for Action maturity index referred to in paragraph 5.59 above, Great Ormond Street should aim to move from Reactive to Active in [X] years and from Active to Proactive in [Y] years [*timescales to be discussed*].

7.2 An Active approach is a healthcare organisation that is '*actively seeking opportunities to improve patient safety*'. The conditions to be met include:

- Patients actively engaged in the safety of their care
- Safe staffing
- Patient advocates
- Staff training on systems and human factors
- Safety culture assessment
- Patient safety impact assessments

7.3 Achieving this first goal will require a considerable effort, including agreeing the details of each condition to be met. The executive and the board should monitor progress regularly.

7.4 We have set out a variety of proposals in this report, ranging from culture change across the organisation, to specific measures that could be implemented quickly and will help achieve this first milestone. We would welcome the opportunity to support the trust in the implementation of any of the measures set out here.

7.5 Great Ormond Street has great strengths as an institution and a reputation for taking on the hardest cases and challenges that other hospitals can't meet. But it also faces significant challenges. Some of these challenges are shared across the NHS and are exacerbated by COVID. Others arise out of the particular characteristics of the hospital and its patients. We believe that a concerted organisational effort to address the safety of care and services will have a significantly positive impact on patients and families, aid staff recruitment and retention and serve to enhance the trust's reputation as a world-class provider.

Appendix A

Team biographies

Ed Marsden

Ed Marsden has a clinical background in general and psychiatric nursing and NHS management. He has worked for the National Audit Office, the Department of Health and the West Kent Health Authority where he was director of performance management. He combines his responsibilities as Verita's founder with an active role in leading complex consultancy. He worked with Kate Lampard to provide independent oversight of the 40 or so investigations carried out by the NHS into allegations about Jimmy Savile. He and Kate wrote a lessons learnt report for the Secretary of State for Health arising from the publication of the Savile investigations. Recently, he was appointed by the global board of G4S PLC to investigate the concerns raised by BBC Panorama in their programme about Brook House immigration removal centre at Gatwick airport. The report was published in December 2018. Ed has advised the Jersey government about the inquiry into historical child abuse. He is an associate of the Prime Minister's Delivery Unit where he has carried out three assignments on immigration. He is the founder of a new healthcare tech company called Eva (www.evaapplications.com).

Chris Brougham

Chris has worked for Verita for 12 years. She is an experienced investigator and has conducted some high-profile investigations and reviews over the years. Chris is a qualified mental health nurse and an experienced manager. She has previously worked as a director of nursing in a large mental health trust and has also worked at the National Patient Safety Agency working collaboratively across the whole health community to promote patient safety and improve investigations into serious incidents in the NHS. Recently Chris has been working with Icotech services to develop Eva, a technology to help healthcare organisations conduct patient safety investigations.

Kieran Seale

Kieran Seale joined Verita in 2014 and was appointed a director in 2018. Governance is a particular area of expertise for Kieran. He has led a number of reviews of conflict of

interest and governance issues for NHS England and in the charity sector. He also leads Verita's work in the field of complaints management. He also runs training courses on complaints management and regularly speaks at conferences on the subject. Other notable investigations that Kieran has worked on include an investigation following the suicide of a nurse at Imperial NHS Trust, an investigation into safeguarding concerns for the Green Party and an investigation into whistle-blowing allegations at a charity. He has an interest in health policy and regularly writes blogs on health and technology issues.

Appendix B

Terms of reference

Background

Dr Sanjiv Sharma, Medical Director (MD), at Great Ormond Street Hospital for Children NHS Foundation Trust (GOSH) has asked Verita to undertake an independent review of the Trust's safety procedures, with a view to finding out whether they are effective and fit for purpose.

This follows on from various concerns expressed by parents about how effectively the Trust investigates patient safety incidents. These culminated in a BBC radio 'File on 4' current affairs programme broadcast in March 2020 which was critical of the Trust.

The Trust would like to learn and improve their current systems, processes and approach to investigating the complex care and treatment of children.

Terms of reference

The Verita team will undertake a review of the following matters:

1. How hospital staff engage with families following an incident which has caused significant harm. Verita will establish whether there are appropriate levels of engagement to reinforce comprehensive and open communication with parents, families and carers. Verita will examine the processes for working with families when things have gone wrong and identify if they are clear, compassionate and empathetic. Where national frameworks and guidance exist they will be used as the standard; outside of this opinion and judgement will be used.
2. Whether there are effective and timely processes in place for managing serious incidents from reporting, investigation and approval through to learning/system improvement to avoid recurrence, including incorporation of feedback from external stakeholders such as NHS England/Improvement.
3. Whether there are effective processes in place for managing safety risks in red complaints from identification, investigation and approval through to learning/system improvement, to avoid recurrence.

4. Whether there are effective processes in place for managing safety risks in claims and inquests from identification through to learning/system improvement, to avoid recurrence.
5. Whether the level of investigation undertaken by the Trust is proportionate to the incident/complaint raised.
6. To understand if the processes for investigation enables and supports the Trust to identify and act on critical safety issues in a timely way.
7. To identify if there is sufficient evidence of the 'golden thread' of safety in the governance and reporting processes from ward to Board (including but not exclusive of Trust Board assurance committees) and with key external stakeholders, specifically in relation to Serious Incidents, Red Complaints, Claims, Inquests and Mortality Reviews. This should include consideration of the role of the Patient Safety Specialist, and the plans set out in the Safety Strategy and Operational Delivery Plan.
8. To identify if processes are supported by a sufficient culture of openness, curiosity and transparency; this includes compliance to Duty of Candour obligations.
9. To evaluate whether appropriate support systems are in place for patients, families and staff. This will include an evaluation of confidence amongst all parties in the Trust's ability to be fair, honest and transparent in a culture of learning without blame.
10. How the Trust are progressing their action plans following the Care Quality Commission focussed inspection on Serious Incidents and Red Complaints.

The work will involve consideration of relevant documents, including examples of investigations, correspondence with families, the terms of reference of relevant committees and minutes/agenda as appropriate.

The work will also comprise interviews with families who are/have been through an investigation process, key members of staff and relevant external stakeholders (e.g. NHS England/Improvement - NHSEI, North Central London Integrated Care System – NCL ICS).

This will include one or two investigators/teams who are carrying out 'live' investigations and also talking to investigation 'approvers'. This will give a better understanding of how Trust staff conduct the work and how reports are signed off.

Verita will attend the Trust's Executive Incident Review Meeting (EIRM) and SI panel review meetings. The purpose of this will be to see how investigations are commissioned and quality assured.

There will be attendance of a selection of Risk Action Groups (RAG) and Directorate Governance meetings to evaluate how actions arising from serious incidents and red complaints are implemented at a Directorate level.

Verita will attend a meeting of Trust's Patient Safety Outcomes Committee (PSOC) , Patient and Family Experience and Engagement Committee (PFEEC) and Closing the Loop (CtL) to get an understanding of how learning and actions from Serious Incidents and Complaints are implemented at a broader Trust Level.

Verita will carry out one or two focus groups with families. This could include participants who have no experience of a serious incident (as per previous point this is a narrow reading of what we hope to be looked at - families may have experience of the SI process, red complaints and inquest etc) investigation and others who do.

Findings will be developed with reference to operational delivery plans the Trust has developed for their 2020 Safety and Quality strategies to ensure that these delivery plans are fit for purpose in relation to safety investigations and improvement processes.

Regular feedback will be provided to the Trust. Any patient safety concerns will be raised immediately outside of these regular updates.

On completion of the work Verita will produce a written report, following a factual accuracy check process with the Trust. Verita will also produce a slide-set report outlining findings, with recommendations as appropriate. A workshop-style event will be held to discuss the findings, conclusions and next steps. This will be on two levels – firstly a highlight presentation for the Executive Group and, secondly, a more detailed workshop event for the Safety Team, Complaints Team, Deputy Chiefs of Service (DCoS) and Heads of Nursing (HoN). This will be jointly facilitated by the Trust and Verita.

Verita will engage extensively with the Trust, especially the patient safety and complaints team and the directorate management teams. This will help ensure that the

recommendations meet the needs of the organisation and are shared with those who will need to implement them at the earliest opportunity.

In the interests of transparency, the Executive Summary and Recommendations will be shared at the Public Trust Board and resulting action plans to appropriate designated assurance committee. Contributors to the report, including families, NHSEI and NCL ICS), as well as external regulatory bodies (including the CQC) will also be provided with Executive Summary and Recommendations.

Appendix C

Interviewees

GOSH

- Sanjiv Sharma, medical director
- Alison Robertson, chief nurse
- Matthew Shaw, chief executive
- Anna Ferrant, company secretary
- David De Beer, associate medical director for safety
- Pascale du Pre, death reviews
- Andrew Pearson, death reviews
- Amanda Ellingworth, non-executive
- Kathryn Ludlow, non-executive
- Claire Williams, head of patient experience
- Hussein Khatib, interim head of quality and safety
- Andrew Pearson, clinical audit manager
- Patient Safety Managers (1)
- Patient Safety Managers (2)
- Rachel Cook, head of bereavement team
- Renee McCullogh, associate medical director of welfare
- Dan Sumpton, Freedom to Speak Up guardian
- John Quinn, chief operating officer
- Daljit Hothi, associate medical director for leadership and coaching
- Russel Viner, non-executive

NHS England

- Simon Barton, medical director for NHS commissioning in London
- Angela Lennox, deputy medical director
- Jess Peck, clinical quality manager

Groups

- Heads of Nursing
- Chiefs of Service

Families

- The parents of a child who had been treated at Great Ormond Street.

Appendix D

Documents reviewed

- Papers from internal committees, including:
    - Trust Board
    - Quality Safety and Experience Assurance Committee
    - Patient Safety Outcomes Committee
    - Patient and Family Experience and Engagement
    - Closing the Loop
    - Executive Incident Review Meeting
- Integrated Quality and Performance Reports, and proposed changes to the report
- Safety and Quality Team Restructuring Consultation Document
- Safety Strategy 2020 - 2025
- Framework for Patient and Family Experience
- Trust policies, including:
    - Being Open and Duty of Candour Policy
    - Complaints Policy
    - Incident Reporting and Management Policy
    - Learning from Deaths Policy
    - Risk Management Strategy
- A selection of five trust Serious Incident Reports
- Well Led Review, July 2021
- Job Descriptions
- Reports from the Care Quality Commission
- NHS Patient Safety Strategy 2019.
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Appendix E

GOSH Serious incident/ Red complaint reports

We reviewed five incident investigation reports to find out whether there are effective and timely processes in place for managing serious incidents investigations and red complaints:

- Report 1 - An investigation into a retained guidewire following central line insertion.
- Report 2 - A patient who experienced loss of renal function in their left kidney.
- Report 3 - A portacath (a small device that provides direct central venous access) was inadvertently left in situ.
- Report 4 - a complaint made about the care of a 4-month-old baby.
- Report 5 - The patient suffered a catastrophic pulmonary hemorrhage at home less than two days after discharge.

Analysis of the reports

The reports are written following a template like those used in other trusts. The purpose of using a template is to promote consistency. This template mirrors the NHS Root Cause Analysis investigatory process.

Terms of reference and scope of the investigation

The terms of reference are important because they set out the scope, purpose, boundary and the lines of enquiry of the investigation. This helps the investigation team to keep focused and on track.

All reports explain the scope of the investigation, i.e. what episode of care is being examined. Each report sets out generic terms of reference. These describe the process of the investigation rather than the purpose. There are also specific questions, some of which are from families for the investigation team to answer. The terms of reference could be further improved if specific terms of reference were devised for each incident so that the purpose and lines of enquiry are clear.

Describing what happened

All five reports set out a good description of the incident/ complaint and provide a readable account of what happened.

Identifying care delivery problems

Care Delivery Problems arise in the process of care – usually actions or omissions by staff e.g. care deviated beyond safe limits of practice, failure to monitor, observe, act. Every report highlighted at least one care delivery problem. This section of the report could be further improved by making sure that the description of the care delivery problems is in relation to the failing and not the cause.

Contributory/ underlying factors

A fundamental component of the RCA investigation and analysis is the identification of the contributory/ influencing/underlying and causal factors that contributed to the incident. This can prove to be a difficult part of the investigation, especially when investigating aspects of complex care. There is a framework/taxonomy which was developed to use across the NHS to help the investigators with this part of the investigation. The trust uses the NHS framework and there are references to it in all five reports.

The investigation reports could be further improved by making sure that any analysis in this section is linked to a care delivery problem and not the incident as a whole.

Lessons learnt

There may be occasions when nothing could have prevented the incident and no root cause(s) are identified. There are always lessons to learn and key safer practice issues may be identified which did not materially contribute to the incident. Lessons learned may be described as 'key safety and practice issues identified which did not materially contribute to the incident'.

It wasn't clear from some of the reports whether the term was being correctly used. It would be helpful for the reader of GOSH investigation reports to know that lessons learnt are incidental findings rather than lessons learnt from something that contributed towards the incident.

Recommendations

The recommendations should address all of the root causes and any contributory factors. They should be designed to significantly reduce the likelihood of recurrence and/or severity of outcome, be clear and concise and kept to a minimum wherever possible. All reports contained recommendations. On the whole these were good and related well to the contributory factors highlighted in the report.

Appendix F

New investigation techniques for Great Ormond Street Hospital

Current NHS policy position

The NHS Patient Safety Strategy published in July 2019 says that:

> *'Patient safety is about maximising the things that go right and minimising the things that go wrong. It is integral to the NHS definition of quality in healthcare, alongside effectiveness and patient experience.'*

The NHS Patient Safety Incident Response Framework (PSIRF) 2020 sets out how healthcare providers should respond to patient safety incidents and how and when a patient safety incident investigation (PSII) should be conducted. It is a key part of the overall NHS strategy.

The ambition of PSIRF is improve the quality of PSIIs by:

- *'refocusing PSII towards a systems approach and the rigorous identification of interconnected causal factors and systems issues*
- *focusing on addressing these causal factors and the use of improvement science to prevent or continuously and measurably reduce repeat patient safety risks and incidents*
- *transferring the emphasis from the quantity to the quality of PSIIs such that it increases our stakeholders' (notably patients, families, carers and staff) confidence in the improvement of patient safety through learning'*

The emphasis of the policy change is to make more effective use of current resources and focus on improving the quality of investigations and making a more proportionate response to avoidable harm.

The policy and Great Ormond Street Hospital

We believe that the guidance is sufficiently permissive to offer an opportunity for Great Ormond Street Hospital to develop its own approach to patient safety incident

investigation. This includes having a range of interventions available to provide deep insight into patient safety incidents. Some of the interventions we suggest are based on current methods in healthcare and in use in the trust. Others are drawn from high-risk industries and would need to be adapted to suit healthcare. We believe that this is feasible in partnership with Verita.

Investigation

The current investigative methods in use at the trust focus on events that have already happened and include the comprehensive Serious Incident investigation and root cause analysis.

In this report we have suggested that the trust adds after-action review to its repertoire for the better understanding of selected near—misses and good practice. This technique relies on discussion by clinical teams followed by a write-up. A review seeks to answer five key questions:

1. What was supposed to happen?
2. What did happen?
3. What went well?
4. What did not go well?
5. What should be changed for next time?

After-action reviews are conducted by a person trained in the method. The assessment allows teams and leaders to learn what happened and why, reassess direction and review successes and challenges. It is flexible and focuses on tasks and goals that were to be accomplished. An after-action review can take between 15 minutes and 2 hours to conduct. They have such information readily available and being actively used. It should be able to demonstrate this to families, staff and regulators. All the tools and interventions listed above can be embedded into software

Table 1 - potential safety investigation techniques for Great Ormond Street Hospital

Purpose	Investigation techniques	Application	Resource demand	Training needed	Amenable to being accommodated in software	Questions answered
Measuring and managing future risk	Tabular risk matrices	Analysis of new treatments, procedures, equipment and diagnostic tests	Knowledgeable assessors and SMEs[5]	Half-day training in the methodology	✓	What risk is attendant on proposed activities?
Understanding and managing past encountered risk	Event risk classification	Investigation of clinical near-misses, incidents and Serious Incidents	Knowledgeable assessors and SMEs	Half-day training in the methodology	✓	What was our risk exposure? How well did our mitigations work?
In-depth analysis	Bow-tie model	Improving safety of clinical practice and mapping investigations of serious clinical incidents	Trained practitioners and (ideally) Bow-tie XP or similar software	1 – 2 days training in the methodology and (if used) the software	✓	What does a proposed new activity look like in terms of threats, mitigations and outcomes? What worked and what failed

[5] SME - subject-matter expert

						in the development of an incident?
Good practices and process deviations	Observational safety audits (anonymised)	Identifying strengths & weaknesses in clinical teams and processes	Knowledgeable, trained assessors whom colleagues trust plus full management support	3 days assessor training plus 2 hour brief for managers and short (on-line?) explanation for participants	✓	What are the common threats, errors and good practices embedded in our routine activities?
Cataloguing and tracking hazards, mitigations and risks over time	Hazard logs	Managing hazards and risks associated with organisational changes and high-risk activities	Departmental risk/safety champions	1 day initial training for champions and half-day annual recurrent	✓	How can we be sure no hazards are overlooked and applied?
Embedding safety and investigation deeper into the organisation	Departmental safety/risk champions	Knowledgeable SMEs embedded in departments to support investigations	Motivated existing departmental SMEs	1-day initial training (including hazard logs above) plus half-day annual recurrent	✗	Does the organisational investigation process have enough local informed insight?

Appendix G

Safety training courses

Human performance

Human performance is about how and why people do what they do. If we can understand the motivations, capabilities and limitations of those around us we can help maximise successful performance and safely manage the less successful. This programme would focus on human factors to enhance clinical performance through an understanding of the effects of teamwork, tasks, equipment, workspace, culture and organisation on human behaviour and abilities so that this can be applied in clinical settings

Human error theory

A programme which would focus on the theory behind human error so that clinicians can understand how and why they make mistakes and what can be done to mitigate them.

Building a safety culture

This programme will explore the steps needed to create a culture of safety to promote the delivery of safe and reliable care and ensure that patient safety is at the heart of all care delivered.

Building resilient teams

This course focuses on the importance of developing and maintain resilient teams and how effective teamwork is essential for patient safety.

Leadership for safety

This programme examines how leadership and management styles have an effect on staff, work and work environments which all in turn have an effect on clinical safety outcomes.

Communication, duty of candour and supporting families after incidents

This course helps participants to unpick the elements of duty of candour so that those affected by an incident are properly informed and supported.

Investigating incidents using technology

This course shows participants how digital solutions can be used to carry out patient safety incident investigations in healthcare and make data on safety events easier to access.

Interviewing during investigations

Investigative interviewing is a technique to help the person who has been involved in the incident to remember as much as possible about the incident. This programme focuses on the steps of investigative interviewing and the need for interviewers to provide an enduring record of the interview.

After-action review & other investigative techniques

This programme provides participants with information on how to investigate or review less serious incidents using techniques such as an after-action review or structured judgement reviews.

Developing solutions after incidents

This course looks at learning from patient safety incident investigations and how sustainable solutions can be put in place to reduce the chances of the same thing recurring.