



A Patient-Safe Future

A Patient Safety Learning Green Paper

September 2018

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Introduction

Patient Safety Learning is a new independent organisation. Established as a not for profit company, at the time of writing we are awaiting approval of our application for charity status from the Charity Commission.

We believe that there is a need for an independent voice for improving patient safety, drawing on and harnessing the knowledge, enthusiasm and commitment of healthcare organisations, professionals and patients for system wide change.

We have written this paper for two reasons: to help ensure that the work we do is focused on areas that will make the biggest difference; and to help us develop a clear, consistent message about the wider need to reduce avoidable patient harm, moving us towards a patient-safe future.

Executive Summary

Despite global efforts and good work by many people, healthcare services around the world are still characterised by an uncomfortable but glaring truth: every day people are harmed and killed not because of their underlying condition but because of avoidable problems in how their healthcare is delivered.

We argue that despite valiant efforts and considerable progress in some areas, significant challenges remain. Patients today are subject to unacceptable variation in the systems and strategies that manage risks to their safety. Patients may suffer harm in one healthcare setting, despite the fact that others have knowledge, systems and processes that could have avoided it.

“...healthcare provides an extraordinary mixture of wonderful achievements and humanity which may be rapidly followed by serious lapses and adverse effects.”

– Charles Vincent

This Green Paper has six sections:

1. **Patient safety today:** An overview of the patient safety landscape.
2. **The persistence of patient harm:** A diagnosis of why problems remain.
3. **The future:** What a patient-safe future might look like.
4. **Patient Safety Learning’s role:** How Patient Safety Learning proposes to help facilitate, enable and make a difference.
5. **System wide proposals:** The changes that we believe are needed in the wider healthcare system.
6. **Consultation:** We want to hear what you think and in this section we set out how.

The factors that influence safe care are complex and multidimensional. In this paper, we focus on five key areas that we believe are crucial: *data, leadership, culture, shared learning and a professionalised approach*.

Patient Safety Learning will consult widely on this paper until the end of November 2018. We will listen to feedback from patients, healthcare professionals, academics, leaders and policy makers. We will use this to develop a White Paper to inform our work and, we hope, influence change across the wider system.

We believe that the principles and proposed actions contained in this Green Paper are relevant to wherever healthcare is practiced around the world. While this paper draws mainly on examples from the acute sector in the NHS in England, we believe that these principles apply to all healthcare settings.

1 Patient safety today

The scale of unsafe care

People around the world are living longer and have better quality of life than ever before, due in no small part to a steady improvement in the provision of healthcare.

Yet patients continue to die or suffer serious harm, not from their illness or condition, but by the very healthcare that was supposed to make them better.

This isn't new. *An organisation with a memory*¹ was published in 2000. The expert group convened by Sir Liam Donaldson reported that every year in the NHS:

- 400 people die or are seriously injured in adverse events involving medical devices.
- Nearly 10,000 people are reported to have experienced serious adverse reactions to drugs.
- Around 1,150 people who have been in recent contact with mental health services commit suicide.
- Nearly 28,000 written complaints are made about clinical treatment in hospitals.

Patient harm and death as a result of adverse events is reported to be about 10% among hospitalised patients worldwide. Half of these are considered avoidable².

The human consequence of this toll, the impact on families, staff and even whole communities, cannot be overstated.

Furthermore, the harm caused to patients and families is often made worse by the response they receive from the healthcare provider. The difficulty they face in obtaining an honest explanation of what happened, and why, often adds insult to injury.

It's not just patients who suffer

Too often, healthcare organisations investigating patient safety incidents focus on assigning blame. In most cases, however, patient safety problems happen because of failures in the systems, procedures, conditions, environment and constraints that staff face³. Blame isn't just damaging to staff, it's usually wrong.

A focus on blame can result in the wrong causes of unsafe care being identified, placing future patients at risk. A blame culture stifles learning and improvement.

Avoidable harm

In 2015 Helen Hogan, Nick Black and Ara Darzi⁴ estimated that 3.6% of hospital deaths in acute hospitals in the UK had at least a 50% chance of being avoidable. In the NHS, that represents more than 150 deaths a week.

If we want healthcare to be as safe as possible, healthcare organisations must treat their patients with empathy and their staff with fairness. They must seek out and address systemic causes of failures in patient safety.

The financial cost of unsafe care

The NHS makes financial provision for clinical negligence. Almost always, this is predicated on medical error – in other words, it refers to avoidable patient safety incidents. Total NHS balance sheet provision for clinical negligence claims for 2017/18 is estimated as £77bn. Annual payments to compensate patients and families with associated legal costs are £2.2bn per year (2017/2018 costs)⁵.

Patient harm of course affects patients themselves, but it also affects patients' families, loved ones and even employers. These people too suffer loss, disruption and damage, causing lost productivity and diversion of resources to provide extra support. We do not know what these costs are.

The financial costs of unsafe care are immense and are unsustainable at a time of increasing demands on healthcare providers.

Failing to learn

The healthcare industry has known about and studied unsafe patient care for a long time. Yet the problem persists.

The 2001 Bristol Royal Infirmary Inquiry⁶ into the deaths of babies undergoing heart surgery identified five key themes:

- Isolation: professionals in Bristol did not know about improvements in practice elsewhere.
- Inadequate leadership: managers and senior clinicians exhibited a lack of vision, a lack of shared or common objectives, a weak or bullying management style and were slow to act on evidence of problems.
- System and process failure: organisational systems and processes were either not present or failed and the checks and balances needed to prevent problems were absent.
- Poor communication: stakeholders knew something of the problems, but not the full picture.
- Disempowerment of staff and service users: those who could have raised concerns were discouraged from doing so, either because of a sense of helplessness in the face of organisational dysfunction or because the prevailing organisational culture discouraged such action.

A billion pounds a year

In 2014, the UK Department of Health estimated the costs of unsafe care in the NHS at more than £1 billion per year; they accepted that it might be as much as £2.5bn⁷.

The same factors were also identified in the Mid Staffordshire report in 2013⁸ and the Morecambe Bay Investigation⁹ in 2015.

The very same factors were identified in the Ely Hospital Inquiry¹⁰ – in 1969.

In *An organisation with a memory*, Sir Liam Donaldson proposed four areas for improvement.

1. Unified mechanisms for reporting and analysis when things go wrong.
2. An open culture where errors or service failures are reported and discussed.
3. Mechanisms to turn lessons learned into practical change.
4. A systems approach to prevent, analyse and learn from errors.

Yet, despite significant efforts by many people since 2000, the same recommendations could be made today.

In the last few years there has been an unprecedented focus on patient safety at all levels of healthcare. To take the next step, the whole system needs to work together and create a tipping point towards a patient-safe future.

2 The persistence of patient harm

Blame doesn't make us safe

A past view of patient safety that still prevails in many organisations can be characterised as follows:

- People are unreliable, the weak link in systems, and human error is the primary cause of adverse events.
- Individual healthcare professionals are solely responsible for the quality and safety of care they deliver.
- Human error is the person's fault through negligence or carelessness.
- Accident investigations seek to identify who is to blame: 'name, blame, shame and retrain'.

Yet adverse events rarely have a single or 'root' cause. Healthcare professionals go to work each day to do the best they can for their patients. Blaming or removing an individual rarely improves safety. Instead, it simply sets up the next person to fail in the same system.

From a patient perspective, there is a disparity between the sometimes punitive consequences for an individual healthcare practitioner following a patient safety event, and what can feel like a complete absence of accountability at an organisational level for serious lapses in supporting staff to deliver safe care.

A culture for safety

In healthcare we need a culture that promotes learning. We need people to want to share what they know because they can see how it will help identify real, systemic, causes of patient safety lapses. We need everyone involved to be supported and treated with respect and fairness.

Failure is usually complex and will have multiple causes. The basis of any solution will almost always be systemic. Organisations need to understand these key points:

- Human error is inevitable. Systems and processes are in place to maintain safety through understanding of human behaviour and performance (human factors).
- Punishment/retraining/hiring & firing usually won't solve the problem – doing so may instead hide it and cause it to recur.

“Culture is often seen as a nebulous and non-quantifiable concept even though it can be defined – and thus measured and improved. Historically it has been under-researched and slow to emerge as a root cause of adverse events. This lack of attention to culture is problematic, given the role it plays in fostering safety.”

– Yu *et al.*¹¹

- A finding of ‘human error’ may be the starting point of an investigation but should never be the end point.

Some organisations have made good progress towards such a culture¹². These are the exception.

Furthermore, a blame culture can extend beyond the local organisation. Healthcare staff involved in patient safety events need to trust wider systems of professional regulation to seek the right answer rather than to assign blame. Recent high profile events¹³ suggest that we have some way to go before this is the case.

For a safe organisation, staff need to be confident that doing the right things – reporting incidents, near misses and concerns, being candid about mistakes and talking openly about error – are all welcomed and encouraged. They need to know that the organisation will focus on system learning, not individual blame. Of course, there must always be accountability in the rare cases where individual healthcare staff have acted recklessly or have covered up. The term ‘just culture’ describes a culture which successfully achieves this balance.

In 2016, the advisory group established to help set up the new Healthcare Safety Investigation Branch¹⁴ called for:

“...a shared set of values in which healthcare professionals trust the process of safety investigation; and are assured that any actions, omissions, or decisions that reflect the conduct of a reasonable person under the same circumstances will not be subject to inappropriate or punitive sanctions.”

If we are to create a culture that prioritises safety over fear, this shared set of values must be embedded in every part of the healthcare system.

Patient safety lacks a professional approach

Healthcare is complex and getting more so. What happens on the ground (the ‘work as done’), with its workarounds and compromises may be very different to the formal procedures and guidelines that describe the work in theory (‘work as imagined’)¹⁵. If we don’t understand and reflect this reality, our patient safety efforts have little chance of success.

Blame corrodes trust

The 2017 NHS Staff Survey¹⁶ for example, found that only 45% of NHS staff believe that their organisation treats people fairly after a safety incident. In another survey¹⁷ 70% of GPs said that they felt unsafe writing reflective notes relating to patient safety events.

“There is always an easy solution to every human problem — neat, plausible, and wrong.”

- H.L. Mencken¹⁸

The complex and dynamic nature of healthcare delivery and associated patient safety risks demands a professional and expert approach to all aspects of patient safety and improvement. But this is not what we see.

In 2016 the Care Quality Commission (CQC) audited a random sample of 74 investigation reports from 24 NHS trusts¹⁹. The audit found:

- Only 12% of reports offered clear evidence that the patient or their family had been involved in the investigation.
- Only 39% included interviews with members of staff who were involved in, or who had a perspective on, the incident.
- Only 28% followed investigation guidance and recorded a risk assessment.
- Often reports did not show that the reasons for the failure had been fully explored.
- 75% left unanswered questions or unexplained issues, placing an undue emphasis on staff failure.

If investigations are carried out by people who lack appropriate training, experience and support, we waste everyone's time. Such investigations are unlikely to identify the real contributory factors. Conclusions and recommendations may not be valid or actionable. Underlying systemic risks could remain. Further, such investigations have a real chance of inflicting unnecessary psychological damage on patients, their families and the staff involved.

We need to invest in the right people, skills and expertise.

But we lack a national framework describing the skills and competencies that are needed to enable everyone — carers, clinicians, ancillary workers, managers and board members — to support and contribute to crucial patient safety related activities.

“...at present there are shortfalls in the skills needed at the most senior levels of organisations to provide effective leadership. More needs to be done to support trust boards, senior executives and clinical leads to develop their awareness and capabilities.”

– Health Foundation²⁰

A skills gap

We see a patient safety skills gap:

- Board members lack an understanding of their roles and responsibilities in relation to patient safety and what good patient safety governance looks like.
- Clinicians and managers tasked with investigations lack a common, structured and rigorous process for investigation and the skills to follow it up.
- Those required to contribute to an investigation do not understand what is needed of them.
- Those with patient safety roles lack a common, structured and rigorous multi-modal approach to design and implement solutions to improve patient safety (eg human factors, ergonomics and system factors expertise).

As a consequence, we see that the improvement capacity of individual healthcare organisations varies widely.²¹

If we are serious about improving the safety of healthcare to consistently high standards, we must recognise the importance of safety science by professionalising patient safety as a discipline.

“Safety science is one of the toughest games in town... There are not enough trees in the rainforest to write a set of procedures that will guarantee freedom from harm. To progress this most difficult of areas needs a subtle combination of modern psychology, human factors and deep understanding of the philosophy of technology.”

– James Reason²²

In other safety critical industries, safety is seen as a highly regarded professional discipline. This is reflected in workforce models identifying key roles and activities and supported by a nationally recognised skills and competency framework (see *Learning from the nuclear industry* overleaf).

We do not see this in healthcare. Instead, crucial patient safety related tasks such as incident investigation are often viewed as ‘add-on’ activities to be distributed to staff (sometimes on a ‘whose turn is it next?’ basis) with little or no training or support.

Learning from the nuclear industry

In the nuclear industry, training is a fundamental mechanism through which personnel acquire and maintain the skills and knowledge needed to perform a job to defined standards. It is viewed as instrumental in developing and sustaining competence.²³

Competence is defined as "...the ability to put skills and knowledge into practice in order to perform a job in an effective and efficient manner to an established standard"²⁴

The Office for Nuclear Regulation (ONR) has the responsibility for regulating the safety of nuclear installations in Great Britain and granting licences to nuclear sites to operate. Nuclear sites are required to meet certain conditions relating to training and competency of staff:

Licence Condition 10. Training:

The licensee shall make and implement adequate arrangements for suitable training of all those on site who have responsibility for any operations which may affect safety.

Licence Condition 12. Duly authorised and other suitably qualified and experienced persons:

The licensee shall make and implement adequate arrangements to ensure that only suitably qualified and experienced persons perform any duties which may affect the safety of operations on the site.

In practice, to meet these requirements, nuclear sites must put in place a well-designed training and competence management system that adequately addresses the following elements:

- Identification and analysis of safety related roles and associated competencies.
- Identification of learning objectives and training needs.
- Training programme design.
- Assessment of competence.
- Evaluation of training effectiveness.

This framework ensures that all nuclear operators in the UK understand the competencies required by staff to undertake activities that impact on safety and that a system is in place to ensure staff are suitably qualified and experienced before they are authorised to carry out work.

We're failing the *Orange Wire Test*

In 2004, Sir Liam Donaldson considered safety in aviation²⁵:

“Imagine that a Boeing 757 aircraft engine contained an orange-coloured wire essential to its safe functioning. Imagine that an airline engineer doing a pre-flight inspection spotted that the wire was frayed in a way that suggested a systematic fault rather than routine wear and tear. Imagine what would happen next. It is likely that most 757 engines in the world would be inspected — probably within days — and the orange wire, if faulty, renewed.”

He argued that when an inadvertent death of a patient in a hospital in one country triggers a response that saves the lives of other patients around the world, the healthcare industry will have passed this orange wire test.

We doubt healthcare would pass this test today.

The quality of local investigations varies widely. So when tragic events do occur, contributory factors and causes may not be correctly identified. Even if they are, the strategies we take to prevent reoccurrence and protect future patients often remain trapped at a local level.

“Lessons learnt on a local level are not widely disseminated either within or between trusts...There is a need to improve sharing of solutions by all organisations.”

- National Audit Office²⁶

Patient safety persists as a problem for healthcare services around the world. Despite much good work by many people and organisations, the evidence for the effectiveness of these efforts is weak²⁷. While some people work in pockets of good practice and innovation, we lack a systematic approach to sharing learning across healthcare. Progress remains slow and fragmented.²⁸

Vincent and Amalberti²⁹ propose that we need to

“...observe, identify and collate safety relevant strategies and interventions at all levels of healthcare organisations and the wider system...”

and

“...develop a more robust taxonomy of approaches and begin to assess which might be applicable in different contexts.”

Doing so would help healthcare organisations learn from each other and, over time, could reduce variation in the patient safety strategies of individual organisations and accelerate adoption of the most effective ones.

Patient safety improvement is compromised by poor data

All healthcare organisations need to have systems in place to monitor their own safety performance to ensure they are sensitive and responsive to emergent problems and can act quickly.

Internationally there are strong examples of how organisations working together to share data and best practice can really improve patient safety³⁰, but health services like the NHS are constrained in how they use data:

- Information collected locally may not be comparable to other organisations because of variation in definitions, sensitivity of reporting and detection systems and organisational culture.
- Organisations may limit information sharing because they are concerned about the implications of publishing and sharing safety performance data, for example reputational risk and concerns relating to how such data may be used by regulators.

As a consequence, healthcare organisations are often unaware that other organisations (sometimes as close as a neighbouring trust) have safer patient outcomes because they have adopted different systems and strategies.

Further, patients are usually unaware of the risks that result from such variation. For example, two patients undergoing elective surgery in neighbouring trusts may be given exactly the same estimates of risk for their procedure during the consent process. Yet one may be at significantly higher risk than the other of additional problems, such as post-operative infection, because each trust has adopted different strategies and processes for managing such risks.

We lack sufficient clear, relevant standards for data collection, integrity, benchmarking and reporting. We don't have independent patient safety key performance indicators. Nor do we value outcome data that is useful for patient safety. For instance, data analysis shows that BME patients are more likely to have poorer maternity outcomes. Such information should be a trigger for further research and action.

These issues are compounded by a lack of trust between providers, regulators and the public in sharing data for the benefit of improvement.

Risk and consent

Patients and clinicians usually discuss risk as part of the consent process but patients have little visibility of local patient safety strategies.

The information used is typically the same no matter where the care is being provided. Each organisation has its own systems, processes and strategies for managing patient safety risks. This means that the actual risk exposure for a patient will vary depending on the organisation providing the treatment. These risks are generally not discussed with the patient. This raises questions about the rights of patients to information about risks that affect them and how patients are involved in decisions and choices about their care.

Different clinical settings demand different approaches to safety. For example, the safety model adopted in radiography, a relatively controlled environment, is likely to be quite different to the model needed by the flexible and unplanned demands of trauma care – see the box alongside: *Approaches to Safety*.

A different model of safety

In the NHS, patients' rights in relation to safe healthcare predominantly lie with the civil, legal processes around whether the care provided meets the definition of negligence. This contrasts with many other safety critical industries.

Outside healthcare in the UK, organisations are regulated by the Health and Safety Executive (HSE). Section 3 of the Health and Safety at Work Act 1974 (HSWA)³¹, obliges organisations to take all 'reasonably practicable' steps not to expose people (employees and those affected by the activities of the organisation) to safety risks.

A comprehensive framework specifies what 'reasonably practicable' means in particular contexts. For example, an organisation that requires employees to carry out work at elevated heights must comply with a clear set of requirements. Crucially, these requirements are designed and apply nationally and aren't subject to local variation.

These are underpinned by a skills and competency framework that includes accredited training and a process of ensuring that those carrying out such work are always suitably qualified and experienced.

Approaches to safety: one size does not fit all

Safety is approached very differently in different environments. In some environments and professions, risk is embraced, in some it is managed, and in others, it is controlled.

Vincent and Amalberti propose three classes of safety models:

- An ultra-adaptive approach associated with embracing risks
- A high reliability approach to managing risks
- An ultra-safe approach which relies heavily on avoiding risks

We must also recognise the demands healthcare leaders and managers face. The decision to press the 'stop' button on a car manufacturer's assembly line is not the same as shutting down a busy emergency department. Unlike in other industries, the option of closing a service that is perhaps operating with an undesirable risk has to be weighed against the possibly more serious risks to patients that closing the service could cause.

Nevertheless, compared to other high-risk sectors, healthcare lacks a common understanding of the minimum things all organisations should be doing to manage safety effectively.

This means that even the most serious patient safety risks are managed inconsistently such as, for example, how organisations adhere to good practice guidance to prevent 'never events'.

From the patient's point of view, the NHS can be seen to be very slow to address safety risks, even when there have been avoidable deaths and the risks are understood and known.

A regulatory gap in healthcare

We recognise that the route to safer healthcare should not primarily be through a punitive approach and threat of sanction. However, it is clear from the experience of other industries that effective regulation has an important role to play.

The Francis report⁸ and the Morecambe Bay Investigation highlighted the HSE's own assessment that there is a 'regulatory gap' in healthcare:

"HSE recognises that the lack of a comprehensive set of powers by other regulators, who may otherwise be better placed to act, often leaves it as the 'regulator of last resort', to whom those affected by provider failures look to secure justice.

Because HSE can only enforce where there has been a breach of the legislation it enforces, and because HSE needs to follow its policies and procedures as to when it should investigate, there is effectively a 'regulatory gap'. Providers may escape prosecution, even if their failures and the consequences have been very serious, because of this regulatory gap."

– The Report of the Morecambe Bay Investigation⁹

The UK Government's response to the Francis Inquiry, *Hard Truths*³³ led to the development of new 'fundamental standards' for the CQC. These standards give the CQC powers to prosecute registered providers where there have been serious failures to provide safe or satisfactory care.

Regulation 12³⁴ (overleaf) specifically applies to 'safe care and treatment', requiring that all healthcare organisations should do 'all that is reasonably practicable' to mitigate risks to the health and safety of service users.

In healthcare, unlike other sectors where HSE legislation applies, we lack a clear framework that underpins what 'reasonably practicable' means in terms of what organisations should be doing to mitigate patient safety risks, as well as the responsibilities of healthcare organisations, leaders and staff.

CQC Regulation 12 – Safe care and treatment

1. Care and treatment must be provided in a safe way for service users.
2. Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include—
 - a. assessing the risks to the health and safety of service users of receiving the care or treatment;
 - b. doing all that is reasonably practicable to mitigate any such risks;
 - c. ensuring that persons providing care or treatment to service users have the qualifications, competence, skills and experience to do so safely;
 - d. ensuring that the premises used by the service provider are safe to use for their intended purpose and are used in a safe way;
 - e. ensuring that the equipment used by the service provider for providing care or treatment to a service user is safe for such use and is used in a safe way;
 - f. where equipment or medicines are supplied by the service provider, ensuring that there are sufficient quantities of these to ensure the safety of service users and to meet their needs;
 - g. the proper and safe management of medicines;
 - h. assessing the risk of, and preventing, detecting and controlling the spread of, infections, including those that are health care associated;
 - i. where responsibility for the care and treatment of service users is shared with, or transferred to, other persons, working with such other persons, service users and other appropriate persons to ensure that timely care planning takes place to ensure the health, safety and welfare of the service users.

We need a new perspective

The challenge of how to make positive change for patient safety is an evolving field. To make further progress we need to embrace new perspectives.

In the past, the view of what constitutes an incident has often been from the eyes of clinicians or healthcare professionals.

In the future, to improve patient care, we believe it is essential to look from the patient's perspective across the whole care pathway. Doing so opens the door to recognising different incidents, such as harm caused by longer-term failures or an avoidable hospitalisation due to undetected deterioration in a chronic condition.

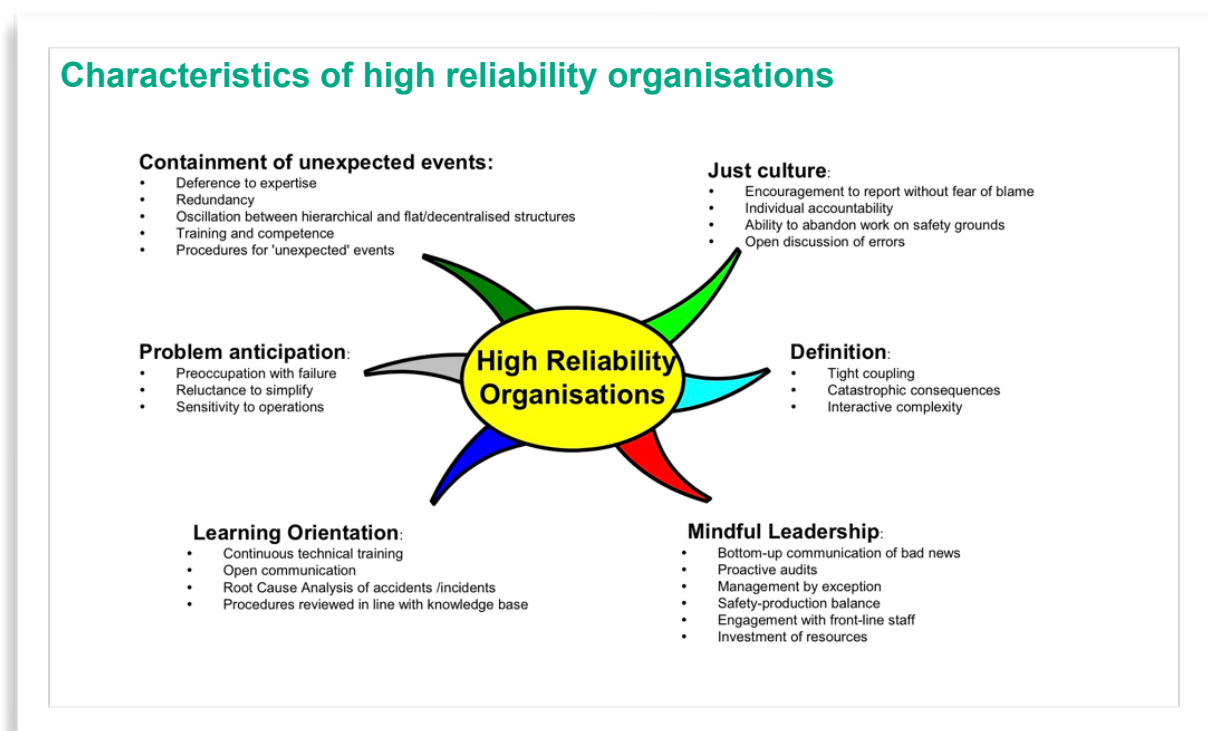
In *Safer Healthcare, Strategies for the Real World*²⁹, Charles Vincent and Rene Amalberti discuss the importance of seeing safety 'through the patient's eyes'. Closer integration of care services provides an opportunity to take this wider view and identify opportunities to improve patient care that could otherwise be missed.

Erik Hollnagel's paper, *Safety I to Safety II*³⁴, provides powerful concepts for thinking differently about patient safety. As well as learning from things that go wrong, we need to be learning from what goes right and our systems need to support sharing this learning across healthcare.

Crucially, safe healthcare can only be achieved with a committed, motivated workforce. The Lucian Leape Institute³⁵ writes about the importance of joy and meaning at work. We need to create the conditions to support healthcare staff to flourish and recognise improvement isn't possible if we don't create the conditions, time, resources and culture to allow it.

Staff can only flourish when the organisation is equipped to think differently, proactively creating the conditions needed to support staff to work safely and not just responding to adverse events and incidents.

Other high-risk industries which manage to sustain high levels of safety performance are known as High Reliability Organisations (HROs)³⁶. Many of the characteristics of high reliability organisations are relevant to healthcare. A High Reliability Organisation (HRO) is characterised by the ability to sustain high levels of safety despite operating in hazardous conditions where the consequences of errors could be catastrophic.



In this section we've identified some key reasons why we believe patient safety is a persistent problem. In our view, changes in a number of key areas are essential.

We now look at what the key features of a patient-safe healthcare system might look like.

3 A patient-safe future: Thinking about tomorrow

A vision for a patient-safe future

“In our view, a safer care system is conceived from the perspective of the patient, following his or her journey through different care settings, irrespective of organisational boundaries. It is networked, so that successes and failures identified in one part of the system can be readily accessed, understood and built on in another. And it is judged not by the prevalence of adverse events, but by the ability to proactively identify hazards and risks before they harm patients.”

– Health Foundation³⁷

We believe that the following five areas are crucial for a patient-safe future: *data, leadership, culture, shared learning* and a *professionalised approach*.



Shared learning

Patients, clinicians, managers and healthcare system leaders share learning about safety practice and performance to make care safer.

Professionalise patient safety

Clinicians, managers and leaders are professionally skilled to track, investigate and prevent incidents and take measures to improve patient safety.

A safe culture

Organisations have a culture that promotes learning and transparency, with patients and staff experiencing a culture that prizes and encourages safe practice.

Safety data

Organisations understand how to measure their own safety performance and accurate, comparable data is collected and used intelligently within organisations to identify problems and prioritise improvement efforts. Performance data is routinely shared to enable the identification and sharing of best practice and new safety strategies and innovations.

Leadership

Healthcare organisations know how to lead and manage patient safety. There are clear expectations as to what organisations need to do to design and implement the delivery of safer care and organisations take all 'reasonable and practical steps' to improve patient safety.

We discuss each in more detail below.

Learning is shared

In a patient-safe-future:

- When a new strategy, technique, tool, finding, method or process helps make patients safer, healthcare organisations and individuals find out about it easily.
- When people working on patient safety want to discuss a problem or they want some new ideas, they can do so quickly and easily with peers.
- Organisations can compare their patient safety performance with other similar organisations.
- Researchers can find bodies of information about investigations, incidents, strategies, tools or solutions.
- Patients have access to patient safety information and the processes around patient safety, such as how investigations work, and what to expect, and how good their healthcare organisation is at managing patient safety.
- People can assess and compare different strategies and know which ones have been proven to be effective.
- When a healthcare organisation develops and implements a new patient safety strategy that is shown to be effective, they can share the 'what' and the 'how' with others.

What might shared patient safety learning look like in practice?

- A healthcare organisation identifies a patient safety problem or an improvement opportunity (e.g. through a case note review, an incident or a near miss investigation).
- Rather than designing a solution from scratch, the patient safety team learn about other healthcare organisations around the world that had a similar issue. They also learn which strategies and techniques have been evaluated as effective.
- They learn how these strategies were implemented, how they were customised locally and how effectiveness was measured.
- They have access to proven, relevant tools, templates and guidance on implementation.
- The patient safety team connects with teams in other organisations for advice and support on how they have implemented the solution.
- As a result the organisation quickly implements a patient safety strategy that has already been shown to be effective, instead of taking longer to develop a bespoke local solution that may be less effective.
- In turn, the safety team shares their experience of implementation and further learning with other organisations.

Patient safety is a professional discipline

A patient-safe future includes:

- Processes to train all healthcare workers in foundation principles of patient safety.
- A common competency framework that defines the skills and levels needed for everyone whose work affects patient safety. This includes clinicians, care-givers, ancillary staff, managers, chief executives and board members. It may also include professional and national regulators, commissioners and policymakers.
- A syllabus of training to address these competences and levels of performance.
- Standards for training delivery. A range of training providers offer appropriate, high quality training/qualifications. These providers are professionally accredited so that patient safety training meets these standards.
- Systems at healthcare organisations to ensure that only suitably qualified and experienced persons perform activities which are crucial to patient safety.

Professionalising patient safety

All healthcare staff whose activities could affect patient safety can demonstrate that they are suitably qualified and experienced (SQEP) to carry out their jobs.

What might professionalised approach to patient safety look like in practice?

- Healthcare organisations have access to better expertise and qualified resources. As a result, they adopt more proactive approaches to improving patient safety.
- Organisations monitor leading patient safety indicators to identify improvement opportunities and pre-empt incidents that might lead to patient harm.
- Techniques such as Failure Mode and Effects Analysis (FMEA)³⁸ are routinely used by specialist staff to make all aspects of care safer.
- Organisations use robust, scientific approaches to design and implement patient safety improvement strategies.
- Every level of the organisation makes better decisions by using reliable patient safety performance information.
- Core competencies crucial to safety, such as patient communication, are embedded in staff training and CPD programmes.
- Incident investigation, implementation of improvement strategies are led by professionals who have undertaken recognised, accredited training which includes systems and human factors expertise.
- Patients and families feel engaged and supported whenever there is a patient safety incident. Investigations fully involve them and openly and transparently provide explanations and restorative justice.
- When patients or families who experience harm because of patient safety problems, healthcare systems should respond to provide an apology, support, involvement in investigations and an open and honest explanation for what happened and why.
- Patients and families should only have to turn to the complaints system if these systems fail.

Organisations adopt a just culture that supports learning

In a patient-safe future:

- Following a patient safety event, there is open and honest disclosure to patients and their families.
- Communication with harmed patients and their family members is prompt, complete, sustained, kind, supportive and empathetic. Patient safety events are investigated consistently and rigorously by suitably qualified, accredited and experienced personnel.
- Investigations begin with an initial intent to determine the systemic causes of an incident, rather than assuming assignment of liability or blame.
- Clinicians and other affected staff are given appropriate support. They are confident that the organisation, professional bodies and the wider system will treat them fairly and consistently with the principles of a just culture.
- Successful improvements in patient safety are celebrated appropriately and shared widely.
- Staff feel safe and secure in reporting patient safety concerns, near misses, and incidents knowing they will be actively welcomed and thanked.
- The working environment allows challenge and encourages raising concerns by anyone.
- Healthcare organisations measure organisational culture to identify opportunities to sustain and progress an improved safety culture.
- A national charter of principles and standards sets fair expectations for how healthcare professionals involved in a patient safety incident are supported and treated.
- Healthcare professionals understand their responsibility for patient safety.
- Organisations 'take all reasonable and practicable steps' to improve the safety of patients.

A safe culture

Healthcare organisations embrace the principles of a just culture where patients and staff are treated with respect and empathy.

How a just culture responds

David Marx, in his book *Whack-a-Mole: The Price We Pay For Expecting Perfection*³⁹ argues that a 'just culture' distinguishes between different types of 'unsafe' acts as follows:

- Human error
- At-risk behaviour
- Reckless behaviour

Marx proposes that in a 'just culture, the response:

- to *human error* should be to **console**
- to *at-risk behaviour* should be to **coach**
- and to *reckless behaviour* should be to **punish**.

What might a patient-safe culture look like in practice?

1. **Leadership:** Leaders acknowledge that healthcare is a high-risk environment. They align vision/mission, staff competency, and fiscal and human resources, from the boardroom to the front line. Leaders show they understand the science of safety and the power of data. They have insight into safety problems and make patient safety a continuing priority.
2. **Teamwork:** Executives, clinicians and their colleagues in patient care share a spirit of collegiality, collaboration, and cooperation. Relationships are open, safe, respectful, and flexible.
3. **Evidence-based care:** Patient care practices are based on evidence. Processes are designed to achieve high reliability and standardised to minimise variation.
4. **Communication:** Individual staff members, no matter their job description, have the right and the responsibility to speak up on behalf of a patient. Front-line staff see that communications with managers are heard and acknowledged. Providing feedback and closing the loop builds trust and openness.
5. **Learning:** The organisation learns from its mistakes and seeks to improve safety performance. Learning is valued by all staff, including the medical staff.
6. **Just:** The organisation's culture recognises errors as system failures rather than individual failures. At the same time, it does not shrink from holding individuals accountable for their actions. Staff at all levels see raising patient safety concerns and report near misses as a professional duty and this is supported and welcomed, formally and informally.
7. **Patient-centred care:** Patient care is centred on the patient and family. Patients are valued as equal partners in their care. When things go wrong, they are fully involved in investigative processes and have the opportunity to help improve patient safety.

(Adapted from Stavrianopoulos, 2012⁴⁰)

Organisations collect and use data to improve patient safety

In a patient-safe future:

- Incident and near miss reporting is adopted widely within the organisation, in the context of a culture that encourages the reporting of concerns.
- As well as incidents, information on complaints and litigation claims is analysed regularly to learn lessons to improve safety.
- Information systems are integrated as far as possible to ensure that all opportunities for learning from the data are explored.
- Data from information systems is mined for insights, using the latest data mining and analysis techniques.
- Up to date information on safety is published to all staff and can be easily accessed electronically to ensure that the latest information is available. The information should be relevant to the type of staff and as near to contemporaneous as possible.
- Standards for safety information will ensure that information can be shared as widely possible between organisations.
- Sharing of safety information between healthcare organisations takes place routinely in order to improve patient safety.

Safety Data

Healthcare organisations routinely collect data related to patient safety and make full use of all relevant sources of data to monitor safety and inform patient safety improvement strategies.

Using data to drive patient safety improvement in practice

- Organisations set and use quality standards for leading and lagging patient safety indicators (including outcome and experience measures) across all care services.
- Organisations routinely collect and monitor patient safety data to defined data quality standards. This data highlights patient safety problems and identifies improvement opportunities.
- The effectiveness of improvement strategies is monitored to aid decision making.
- Organisations routinely benchmark their performance data with other comparable organisations, nationally and internationally, and use the results to identify improvement opportunities.

Healthcare organisations know how to lead and manage patient safety

In a patient-safe future:

- Leaders and managers achieve and sustain high standards of patient safety and operate high reliability organisations.
- Leaders and managers at all levels equip the organisation to take all reasonably practicable steps to minimise patient safety risks.
- Safety decisions at all levels of the organisation are informed by accurate data and are rational, objective, transparent and prudent.
- Leaders and managers understand the factors that are critical to their organisation's capacity to secure and maintain patient safety standards.
- Leaders and managers seek learning from internal and external sources to improve patient safety.
- Leaders and managers receive competency assessment, supportive training and leadership development for patient safety.
- Leaders and managers proactively assess patient safety risk and take opportunities to design patient safety improvements into clinical and management systems and processes.
- The insights and knowledge of patients, staff and safety system experts in human factors is used to design out unsafe care.
- Opportunities to use technology to improve patient safety are embraced, including aids to diagnostic decision-making, automatic systems to red-flag patient safety risks and improved communication across care pathways.

Leadership

Healthcare organisations have the mindset, skills, processes, systems, governance and leadership to manage patient safety actively.

Managers at all levels of the organisation have a part to play in this.

What might leadership and management for Patient Safety look like in practice?

In a patient-safe future, we believe leaders and managers:

- Role-model behaviour consistent with a good safety culture, are open and transparent about mistakes and demonstrate humility, self-reflection and learning.
- Define clear patient safety objectives at strategic and service-specific levels: what improvement is needed; how implementation is to be delivered and resourced; and when and how success will be measured.
- Set and communicate clear values and expectations for patient-safe behaviour, ensuring that these are cascaded and understood throughout the organisation.
- Empower and listen to front line staff. Champion an environment that ensures staff views and concerns are freely shared, listened to and acted on, with reporting of near misses and incidents encouraged.
- Visibly welcome and act on safety concerns raised by staff at all levels, from porters to senior consultants.
- Are visible and approachable. They spend time on the 'shop floor' and see the work 'as done' as opposed to 'as imagined'.
- Champion the principles of 'just culture'. This includes the use of human factors in systems when responding to patient safety events.
- Ensure that staff are treated fairly and consistently if a patient safety event happens. When patients and families are involved, they are supported and are given an open and honest account of what happened and why.
- Are open and transparent about safety and quality and publish relevant data and results.
- Measure patient safety data to make decisions and monitor results.
- Celebrate successes and learn from errors and initiatives that don't work.
- Recognise the value of the patient voice and involve patients as partners in patient safety improvement.
- Recruit for the values and behaviours that contribute to safe care.
- Ensure that roles that are critical to patient safety have the resources and quality training they need.
- Continuously seek ways to improve patient safety.
- Encourage the sharing of patient safety learning within the organisation and across the wider system.

In a patient-safe future, organisations take all ‘reasonably practicable steps’ to minimise patient safety risks

Regulation 12 of CQC fundamental standards concerns safe care and treatment. Regulation 12 2(b) requires healthcare providers to do “...all that is reasonably practicable to mitigate any such (patient safety) risks,” but offers little on what that might look like.

From our perspective, we think such ‘reasonably practicable’ actions might include:

- A skills and competency framework to ensure key patient safety roles are undertaken by suitably qualified and experienced staff.
- A proven system of monitoring organisational culture, linked to a programme of continuous improvement.
- Robust systems both to track patient safety performance with leading and lagging indicators and to act on identified patient safety risks.
- Systems that benchmark safety performance against other organisations and use this to identify new standards, strategies and interventions where evidence shows a real patient safety advantage.
- Organisations sharing their learning – both successes and failures - with others.
- Robust systems to learn from reported near misses and incidents. This includes having the right number of staff, the necessary skills to carry out systemic investigations and reviews, to engage with harmed patients, to ensure staff are treated consistently and fairly and to design, implement and evaluate new patient safety solutions and strategies.
- Patients and service users can easily access information about patient safety risks and how these are being managed.

Serious failures in any of these should trigger a regulatory response.

4 The role of Patient Safety Learning

Who we are

We are an independent organisation with expertise and focus on patient safety. We will initiate, facilitate, inform and propel thinking and action to make patient care safer, to help create a patient-safe future. Patient Safety Learning has been set up with philanthropic funding and we will source funds from foundations, grants and delivering paid-for services.

Our aim is to be an authoritative source of knowledge to improve patient safety worldwide. We will support the implementation of safer care with resources such as training and toolkits.

The consultation on this Green Paper will help inform our priorities and how we work together for safer healthcare.

Why we exist

We believe that there is a need for an independent voice for improving patient safety, working with patients, healthcare professionals and organisations. Patient Safety Learning will champion a whole system approach to take action to improve patient safety.

Shared learning for patient safety remains a challenge in many healthcare systems. Currently, people and organisations have few ways to share practical knowledge, strategies and lessons about safety improvement.

We believe that more is needed to support widespread sharing of learning for safety. We will deliver a Learning Platform to catalyse and inspire collaboration for improved patient safety globally.

How we will work

We are an independent voice for patient safety, informed by evidence and expertise in practice and theory. We will create opportunities for collaboration and will:

- Focus our work on action, supporting and empowering front-line clinicians, staff, managers and leaders to provide safer care.
- Ensure that the experience and the voice of patients and their families are at the heart of what we do and how we champion improvements in patient safety.
- Be a thought leader, using research and evidence for safety improvement to inform our work and that of others.
- Promote a learning culture.
- Bring people together across the whole of healthcare to collaborate, act and make a difference.
- Source and share knowledge and insights on how to improve safety, whether from health and social care organisations in the UK, internationally or other safety systems.

- Work in partnership with whomever can drive patient safety improvement.
- Be an independent voice for patient safety. When we need to, we will call for change and speak ‘truth to power’.

What you can expect to see from Patient Safety Learning

Over the next year you can expect to see from us the start of an ambitious delivery programme. The engagement with partners through consultation on the Green Paper will help us develop short, medium and long-term strategic goals for Patient Safety Learning.

Shared Learning

Our Learning Platform will enable front line clinicians, managers, patient safety and quality improvements experts and system, researchers, policy makers, patients, academics and organisational leaders to easily share and find relevant and practical tools, advice, guidance and support for improving patient safety. This resource will be available worldwide.

Professionalising Patient Safety

We will support the development of patient safety as a professional discipline, working with partners to design healthcare where all staff and leaders are qualified and experienced in delivering safer care. We will design and deliver world-class training to support this.

A Just Culture that Learns

We will promote a just culture that treats patients and staff with fairness and respect. We will share best practice through our Learning Platform, award those that are making great progress, create programmes for listening to, and supporting, patients who use their insight and experience to work with healthcare for safety improvement.

Leadership and management of patient safety

To deliver a patient-safe future, healthcare must design and deliver safe systems. We will develop practical resources and tools to support healthcare organisations, deliver board governance and patient safety strategies, support staff including in responding to incidents and the proactive design of safer care, and share all this knowledge on our Learning Platform.

Effective use of data

We will promote the development of data, evaluation and performance measures for patient safety for clinicians, managers and Boards to use to assess patient safety and drive improvement. We will take a leading role in convening experts to drive innovation and catalyse change.

The impact we aim to have

We will work in three key areas:

1. Support front-line improvement for patient safety

- We are developing the world's first Learning Platform for Patient Safety that will share knowledge and establish communities of practice. The Learning Platform will be a shared resource for the patient safety community, enabling the sharing of knowledge and become a space for patient safety communities to work together. It will be a source of practical information, with a repository of knowledge from centres of excellence in patient safety and links to resources such as web conferences and social media. Our aim is for the Learning Platform to be the first port of call for any patient safety query. We would also like to see it become a resource for benchmarking patient safety information. We are developing the Learning Platform in partnership with a wide range of people, including clinicians, patient safety specialists, patients and academics.
- We are developing world class training in incident investigation, leadership for patient safety and engaging and supporting patients and families.
- We will advise and support organisations seeking to transform patient safety.
- We will commission research into patient safety issues and best practice. A key focus for us will be how we best address the implementation gap, where we know why we need to make changes and what we need to do, but don't yet fully understand how to address the barriers to dissemination and implementation of good practice.
- Promote and create 'how to' resources and toolkits that improve patient safety including those for proactive risk assessment, data and measurement, patient engagement, design for safety, just culture and patient safety improvement including the more effective use of technology to better understand and design what a 'high reliability organisation' looks like for healthcare.

2. Guide the direction of patient safety with an independent voice

- We have developed this Green Paper for improved patient safety with clear recommendations for action. We will consult widely on this Green Paper during 2018 and will report formally in early 2019. Consultation through events and face to face meetings will be limited to the UK but online consultation will be global.
- We will stimulate thinking with blogs and comments, research reports, anonymised thematic feedback from our Learning Platform, conferences and events. Our web site already contains blogs and commentaries on important current and topical issues on patient safety. We will ensure that resources developed in the UK and internationally are easily accessible on our new Learning Platform.
- Hold an annual conference and work with other events to inform, engage and collaborate.

- We are calling for the Professionalisation of Patient Safety and will support the development of governance models, a competency framework for patient safety, training, standards and accreditation. We will develop a framework for engaging all partners and delivering a Concordat for Professionalising Patient Safety.
- We will promote the development of data, evaluation and performance measures for patient safety including benchmarks and patient safety data sheets for clinicians, managers and boards to use to assess patient safety and drive improvement. We are planning an International Symposium on Patient Safety Data and Measurement with leading experts to drive innovation and catalyse change.
- We will promote an organisational focus on risk transparency so that all health and social care organisations committed to and are regulated in taking all 'reasonable and practical steps' to meet explicit standards for patient safety.
- We will publish a 'State of Patient Safety' report with analysis of patient safety issues, initiatives, strategies, successes and ongoing concerns from the previous year.

3. Promote Just Culture

- We have established an annual awards programme that supports cultural change. Our first award winners will shortly be announced at our Inaugural Conference in September 2018.
- We will seek out the patient voice in everything we do and give patients and families a platform to advocate for change.
- We will run programmes to actively support staff and patient engagement in improving patient safety.
- We will initiate and manage active relationships with patient safety partners in the UK and internationally.

5 System-wide proposals

Progress to improve patient safety needs the whole system to pull in the same direction.

Many organisations and roles will contribute to a patient-safe future. Below, we outline some initial thoughts on what might help make it happen.

We recognise, however, that many people will already be doing some or all of these. We also recognise that we may have missed some or that a number of our suggestions may be incorrect. Let us know how these can improved.

Organisation	Recommendation
System regulators	<ol style="list-style-type: none"> 1. Promote a just culture 2. Clearer framework for regulation 12, 'all reasonable and practical steps' 3. Support the professionalisation of patient safety 4. Implement a competency framework for own staff 5. Inspection model aligned to a strengthened view of key components of a patient-safe future: <ul style="list-style-type: none"> • Leadership and standards • Data and measurement • Safe culture • Shared learning • Professionalised approach to patient safety 6. Promote the sharing of knowledge and learning 7. Be a role model of openness and transparency 8. Take a system view of patient safety and work in collaboration with others to achieve this

Organisation	Recommendation
Professional regulators	<ol style="list-style-type: none"> 1. Promote a just culture 2. Apply open, transparent and trusted processes for investigating Fitness to Practise (FtP) 3. Support the professionalisation of patient safety 4. Implement a competency framework for own staff 5. Design a competency framework for patient safety into education and training standards (training curricula, revalidation etc) 6. Promote standards in postgraduate education and training to give greater focus on clinical leadership and patient safety skills and awareness. 7. Be a role model of openness and transparency 8. Listen and respond empathetically to the voice of patients and families 9. Take a system view of patient safety and work in collaboration with others to achieve this
Policy makers	<ol style="list-style-type: none"> 1. Take a system view of patient safety and work in collaboration with others to achieve this 2. Ensure that patient safety policy is evidence based and sufficient resources and conditions are in place for implementation 3. Evaluate patient safety initiatives to inform effective dissemination and spread 4. Be a role model of openness and transparency 5. Listen and respond empathetically to the voice of patients and families

Organisation	Recommendation
Commissioners and providers of health and social care	<ol style="list-style-type: none"> 1. Take a system view of patient safety and work in collaboration with others to achieve this 2. Listen and respond empathetically to the voice of patients and families 3. Design and deliver health and social care with the key components of a patient-safe future: <ul style="list-style-type: none"> • Leadership and standards • Data and measurement • Safe culture • Shared learning • Professionalised approach to patient safety
Politicians	<ol style="list-style-type: none"> 1. Treat patient safety as a healthcare priority 2. Provide leadership in taking a system view of patient safety 3. Ensure decisions are driven by evidence 4. Be fearless in acknowledging and tackling patient safety problems 5. Protect the independence of systems of regulation to ensure that issues that relate to patient safety are highlighted and addressed effectively, free from political interference. 6. Be a role model of openness and transparency 7. Listen and respond empathetically to the voice of patients and families

These are our initial thoughts. Let us know how we can improve them.

6 Our Green Paper Consultation

From proposals to commitment

This Green Paper focuses on:

Patient safety today

An overview of the patient safety landscape.

The persistence of patient harm

A diagnosis of why problems continue.

The Future

What a patient-safe future might look like.

Our role

How Patient Safety Learning proposes to help facilitate, enable or make a difference.

System-wide proposals

Our thoughts on changes that we believe are needed in the wider healthcare system.

Between now and the end of November, we will be engaging widely with as many people as we can. We really want to find out what you think.

We will use your contributions to inform a White Paper that we will publish in January. This White Paper will build on the ideas in this Green Paper and will set out the goals, activities and deliverables needed to achieve a patient-safe future.

To find out more about the consultation process or to take part, please go to our website at <https://www.patientsafetylearning.org/> where you will find more details.

Thank you.

References

1. Department of Health. An organisation with a memory: report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer. London: Department of Health, 2000
2. de Vries, E. N., Ramrattan, M. A., Smorenburg, S. M., Gouma, D. J., & Boermeester, M. A. (2008). The incidence and nature of in-hospital adverse events: a systematic review. *Qual Saf Health Care*, 17(3), 216-223
3. National Advisory Group on the Safety of Patients in England. A promise to learn - a commitment to act. Improving the Safety of Patients in England. [Internet]. 2013 [cited 2016 Jan 29]. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf
4. Hogan, H., Zipfel, R., Neuburger, J., Hutchings, A., Darzi, A. and Black, N. (2015). Avoidability of hospital deaths and association with hospital-wide mortality ratios: retrospective case record review and regression analysis. *BMJ*, p.h3239.
5. NHS Resolution (2018). Annual Report and Accounts 2017/18. [online] Available at https://resolution.nhs.uk/wp-content/uploads/2018/07/NHS-Resolution-Annual-Report-2017-2018_digital.pdf [Accessed 13 Sep 2018]
6. Webarchive.nationalarchives.gov.uk. (2018). Learning from Bristol. [online] Available at: http://webarchive.nationalarchives.gov.uk/20090811143822/http://www.bristol-inquiry.org.uk/final_report/the_report.pdf [Accessed 19 Aug. 2018].
7. Evidence.nhs.uk. (2014). Exploring the costs of unsafe care in the NHS: A report prepared for the department of health. Available at: <https://www.evidence.nhs.uk/document?id=1801416&returnUrl=Search%3Fq%3Dunsafe%2Bpractice&q=unsafe+practice>[Accessed 9 Sep. 2018].
8. Francis R. The Mid Staffordshire NHS Foundation Trust Public Inquiry. HC 947. London: The Stationery Office, 2013. www.midstaffpublicinquiry.com/ (accessed 14 August 2018). The previous independent inquiry is available at: www.midstaffpublicinquiry.com/previous-independent-inquiry
9. Kirkup B. The Report of the Morecambe Bay investigation. London: The Stationery Office, 2015. www.gov.uk/government/uploads/system/uploads/attachment_data/file/408480/47487_MBI_Accessible_v0.1.pdf (accessed 15 August 2018).
10. Socialist Health Association. (2018). Report on Ely Hospital. [online] Available at: <https://www.sochealth.co.uk/national-health-service/democracy-involvement-and-accountability-in-health/complaints-regulation-and-enquiries/report-of-the-committee-of-inquiry-into-allegations-of-ill-treatment-of-patients-and-other-irregularities-at-the-ely-hospital-cardiff-1969> [Accessed 19 Aug. 2018].

11. Yu A, Flott K, Chainani N., Fontana G, Darzi A. Patient Safety 2030. London, UK: NIHR. Imperial Patient Safety Translational Research Centre (2016). Available at: <https://www.imperial.ac.uk/media/imperial-college/institute-of-global-health-innovation/centre-for-health-policy/Patient-Safety-2030-Report-VFinal.pdf> [Accessed 19 Aug. 2018].
12. Vimeo. (2018). Just Culture - NHS MerseyCare Documentary. [online] Available at: <https://vimeo.com/267727392> [Accessed 19 Aug. 2018].
13. Cohen, D. (2017). Back to blame: the Bawa-Garba case and the patient safety agenda. *BMJ*, p.j5534.
14. Healthcare Safety Investigation Branch (2016), Report of the Expert Advisory Group. [Online] Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/522785/hsibreport.pdf [Accessed 13 Sep 2018]
15. European Organisation for the Safety of Air Navigation (2017), Hindsight 25: Work as done and Work as Imagined [Online] Available at: <https://www.eurocontrol.int/sites/default/files/publication/files/hindsight-25.pdf> [Accessed 13 Sep 2018]
16. NHS, NHS Staff Survey 2017: Errors, Near-Misses and Incidents. http://www.nhsstaffsurveys.com/Caches/Files/ST17%20-%20errors_sheet5.xls
17. Gponline.com. (2018). 70% of GPs say writing reflective notes is unsafe following Bawa-Garba case | GPonline. [online] Available at: <https://www.gponline.com/70-gps-say-writing-reflective-notes-unsafe-following-bawa-garba-case/article/1488425>[Accessed 19 Aug. 2018].
18. H. L. Mencken (1917), "The Divine Afflatus", originally published in the *New York Evening Mail* (November 16, 1917); reprinted in *Prejudices: Second Series* (1920), and *A Mencken Chrestomathy* (1949), chapter 25, p. 443
19. Care Quality Commission. (2016). Learning from serious incidents in NHS acute hospitals. [online] Available at: https://www.cqc.org.uk/sites/default/files/20160608_learning_from_harm_briefing_paper.pdf [Accessed 19 Aug. 2018].
20. Health Foundation (2013). Hard Truths: essential actions. [online]. Available at <https://www.health.org.uk/sites/health/files/HardTruthsEssentialActions.pdf> [accessed 13 Sep 2018],
21. J., Boaden, R. and Walshe, K. (2017). Conceptualizing and assessing improvement capability: a review. *International Journal for Quality in Health Care*, 29(5), pp.604-611.
22. Macrae, C. (2014). *Close calls*. Palgrave Macmillan, p.vii.
23. The Office of Nuclear Regulation (ONR). (2017). TRAINING AND ASSURING PERSONNEL COMPETENCE. [online] Available at: http://www.onr.org.uk/operational/tech_asst_guides/ns-tast-gd-027.pdf [Accessed 9 Sep. 2018].
24. Nuclear Power Plant Personnel Training and its Evaluation: A Guidebook. Technical Report Series 380, IAEA, Vienna, 1996

25. Donaldson, L. (2004). When will healthcare pass the orange wire test?. [online] Available at: http://www.who.int/patientsafety/information_centre/articles/en/ [Accessed 19 Aug. 2018].
26. National Audit Office, A Safer Place for Patients: Learning to Improve Patient Safety. [online]. Available at <https://www.nao.org.uk/wp-content/uploads/2005/11/0506456.pdf> [accessed 13 Sep 2018]
27. Landrigan CP, Parry GJ, Bones CB, et al. Temporal trends in rates of patient harm resulting from medical care. N Engl J Med 2010;363:2124–34. doi:10.1056/NEJMsa1004404
28. Shojania KG. Conventional evaluations of improvement interventions: more trials or just more tribulations? BMJ Qual Saf 2013;22:881–4. doi:10.1136/bmjqs-2013-002377
29. Vincent, C. and Amalberti, R. (2016). Safer Healthcare. Cham: Springer International Publishing.
30. Childrens' Hospitals Solutions for Patient Safety. Our Results. <http://www.solutionsforpatientsafety.org/our-results/>
31. Hse.gov.uk. (2018). Scope and application - Health and Safety at Work etc Act 1974 - Section 3: Enforcement. [online] Available at: <http://www.hse.gov.uk/enforce/hswact/scopeapplication.htm> [Accessed 9 Sep. 2018].
32. Assets.publishing.service.gov.uk. (2013). Hard Truths: The Journey to Putting Patients First. [online] Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/270368/34658_Cm_8777_Vol_1_accessible.pdf [Accessed 9 Sep. 2018].
33. Cqc.org.uk. (2014). Regulation 12: Safe care and treatment | Care Quality Commission. [online] Available at: <https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-12-safe-care-treatment> [Accessed 9 Sep. 2018].
34. Hollnagel, E. (2015). From Safety-I to Safety-II: A White Paper. [online] England.nhs.uk. Available at: <https://www.england.nhs.uk/signuptosafety/wp-content/uploads/sites/16/2015/10/safety-1-safety-2-whte-papr.pdf> [Accessed 9 Sep. 2018].
35. Lucian Leape Institute. (2013). Through The eyes of The Workforce creating Joy, Meaning, and safer health care. [online] Available at: <https://c.ymcdn.com/sites/npsf.site-ym.com/resource/resmgr/LLI/Through-Eyes-of-the-Workforc.pdf> [Accessed 9 Sep. 2018].
36. Lekka, C. (2011). High reliability organisations: A review of the literature. [online] Hse.gov.uk. Available at: <http://www.hse.gov.uk/research/rrpdf/rr899.pdf> [Accessed 9 Sep. 2018].
37. Illingworth, J. (2015). Continuous improvement of patient safety: The case for change in the NHS. [online] Health.org.uk. Available at: <https://www.health.org.uk/sites/health/files/ContinuousImprovementPatientSafety.pdf> [Accessed 9 Sep. 2018].
38. Ihi.org. (n.d.). Failure Modes and Effects Analysis (FMEA) Tool. [online] Available at: <http://www.ihl.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx> [Accessed 9 Sep. 2018].

39. Marx, D. Whack-a-mole: the price we pay for expecting perfection, Plano, TX: By Your Side Studios, 2009
40. Stavrianopoulos, T. (2012). The development of patient safety culture. Health Science Journal, 6(2).

Patient Safety Learning

Patient Safety Learning is an independent voice that seeks to make a difference to patient safety.



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