Datix®
Software for patient safety

Good Governance Institute

What every healthcare director needs to know about patient safety

Good Governance Institute

Final report
November 2015

What every healthcare director needs to know about patient safety

Document name:	**What every healthcare director needs to know about patient safety**
Version:	**Final Report**
Date:	**November 2015**
Authors:	**Hilary Merrett, Senior Associate, GGI**
	Donal Sutton, Service Development Executive, GGI
	Dorothea Baltruks, Knowledge Management Analyst, GGI
	Erin Cheston, Policy Analyst, GGI
	Cassie Hill, Programme Delivery Executive, GGI
Reviewed by:	**Andrew Corbett-Nolan, Chief Executive, GGI**
	Jonathan Hazan, Chief Executive Datix
	Christopher Smith, Knowledge Management Team Leader, GGI

This report is part of a growing series of reports developed by the Good Governance Institute (GGI) that consider issues contributing to the better governance of healthcare organisations. GGI is an independent organisation working to improve governance through both direct work with individual boards and governing bodies, and by promoting better practice through broader, national programmes and studies. We run board development programmes, undertake governance reviews and support organisations develop towards authorisation.

Other recent GGI reports and board development tools have considered board assurance, patient safety, clinical audit, quality and safety of telehealth services for people with long-term conditions, diabetes services, better practice in treatment decision-making, productive diversity, the board assurance framework, integrated governance, governance between organisations and of course good governance.

GGI is committed to develop and promote the Good Governance Body of Knowledge

 ISBN: 978-1-907610-36-3

GGI Limited, Old Horsmans, Sedlescombe, near Battle, East Sussex TN33 0RL is the trading entity of the Good Governance Institute

info@good-governance.org.uk

www.good-governance.org.uk

Contents

Foreword

Since the publication of the Good Governance Institute's 2010 report much has happened that has added a striking sense of urgency for acceleration in quality and safety improvement efforts. The publication of the Francis report, addressing concerns regarding insufficiencies and failures in governance in the Mid Staffordshire NHS Foundation Trust, highlighted the dramatic system-wide catastrophes that can and will result from failures in governance. One of the notable findings of the report was the disassociation of the board's strategic governance role from its obligation to enhance and enable successful operations, and that had tragic consequences.

Governance is all about setting priorities, establishing goals and enabling operational managers and subordinate staff to achieve these goals while also working to modulate financial risk. In the healthcare industry the product that is provided to patients should not merely be a range of healthcare services but rather the achievement of optimal health, highest quality healthcare outcomes and enhanced patient safety through the prevention of healthcare associated harm. These must be the goals at the beginning and at the end of each day, every day! This is, and must assuredly be, the agenda of governance.

In order to accomplish these enormously important objectives, transparent trusting communication between operational staff, management and governance leadership must be the norm, never the exception. Caring for patients is an enormous and humbling responsibility that has been assumed by highly qualified professionals committed to service to others. The relationship between clinical staff and patients embodies a sacred trust, and the focus of this trust must always be on achieving the best outcome for each patient, even when the best outcome may only be palliation at the end of life. This is enormously sacred "stuff," and the quintessential responsibility of governance is to acknowledge the inviolability of this obligation and to facilitate this trust.

If the role of governance is to assure health, quality outcomes and safety, governance leaders must coincidently recognise their obligation to enable staff to be as effective as possible. Morale, particularly among doctors and nurses is low, some have said dangerously low. Many are no longer experiencing joy and meaning in their chosen professions, and when people do not experience joy and meaning in their work, their attention to detail may suffer. Practicing medicine and nursing is all about attention to detail, and mistakes can have serious, even fatal, repercussions; as has become so sadly, tragically and repeatedly apparent.

So how does one put all this together? The key element in governance is the absolute requirement to create and sustain a culture of safety where principles of high-reliability industries, such as a preoccupation with human and system failures, become the norm; operating within a just culture reporting framework for identifying risks and errors. Engagement with clinical leadership, as key stakeholders, will be necessary. Governance leaders must work diligently to value these efforts and to instil a new sense of joy and meaning in the workplace.

Dr Daniel L. Cohen
International Medical Director, Datix

Datix®
Software for patient safety

Introduction

It is now four years since the publication of our report for healthcare board members on patient safety – "What Every Healthcare Board Needs to Understand About Patient Safety"[1]. This second report is again aimed at helping existing and new board members understand what the key challenges are for boards on ensuring and improving safety for their patients.

NHS boards have both a duty of care and a duty of quality to those who seek and use their services. There is also now a duty of candour, which applies to NHS provider organisations. Everyone, whether an NHS employee or not, would agree that we should expect high quality and safe services and that Florence Nightingale's maxim *'first do no harm*[2]', should form the foundation of all clinical practice and be upheld across the board. It is perhaps discouraging to reflect that we still feel the need to resort to imposing statutory duties to reinforce what should be second nature to all involved with healthcare.

Ensuring that the culture, structures, systems and processes in our complex institutions are able to deliver safe and high quality care consistently continues to be a significant challenge that demands both vision and skill. Boards are accountable for ensuring that arrangements are in place for monitoring and improving the quality of the health care that is provided. It follows that board members need to understand the importance of patient safety, and what constitutes good practice in both patient safety and governance terms.

Two significant developments since our original report are the Health and Social Care Act 2012, (with its creation of Clinical Commissioning Groups (CCGs) and the abolition of the National Patient Safety Agency (NPSA)), and the public inquiry into the events at Mid Staffordshire NHS Foundation Trust. In light of these developments, we are conscious of the risk of adding to a mountain of reports and commentaries, which may not be practically helpful to our target audience. Consequently, this report does not rehearse in detail the background to patient safety in healthcare. However, we can direct readers to helpful and succinct resources that do this[3],[4]. What we aim to do here is to revisit the themes of the original report and identify:

- any relevant characteristics of organisations known to be performing well or which can be characterised as "highly reliable"[5]
- what has changed in both the patient safety context and field since 2010
- the known and likely implications of these changes for board members
- the essential information board members need to know to ensure that their focus is on the safety and wellbeing of their service users

We have consulted with colleagues, our expert witnesses, to help us in this task, by identifying a short learning message from their experience on safety in healthcare. We have tried to ensure that these people include those working at all levels and settings of healthcare as well as those on the receiving end. If there is one lesson from recent events for those of us committed to improving safety, it is to listen to others. This report is about how to ensure we know both how to listen and how to respond.

Our initial report included a Maturity Matrix as a means by which a board can self-evaluate where its patient safety efforts stand in relation to our recommendations and what actions it could institute. We will be updating this and publishing it separately in due course.

1. Current imperatives in patient safety for boards

Background

The term patient safety is a relative newcomer to the healthcare lexicon. Burgeoning negligence claims and a developing focus on how to assure the quality of patient care towards the end of the 1980s and early 1990s helped to introduce the notion of clinical risk management. Prior to this, concerns about safety and attempts to learn from accidents and incidents were the remit of the health and safety field. This is not to say, of course, that healthcare professionals or indeed, managers, were not concerned with the safety of their patients and the risk that health care might actually cause harm, as well as benefit. The potential for iatrogenic harm had been highlighted as far back as 1863 by Florence Nightingale, where in Notes on Hospitals, she begins with the declaration,

"It may seem a strange principle to enunciate as the very first requirement in a hospital that it should do the sick no harm[6]."

The Imperial Patient Safety Translational Research Centre (PSTRC) is funded by the National Institute for Health Research (NIHR) and, through a specialised set of research groups linked to the Imperial Centre for Patient Safety and Service Quality (CPSSQ), drives improvements in patient safety and in the quality of delivered healthcare services[7]. Professor Charles Vincent is Director of the CPSSQ and the Clinical Research Unit. He is also the author of Patient Safety (2nd edition 2010 and the editor of Clinical Risk Management (BMJ Publications, 2nd edition, 2001). Professor Charles Vincent has advised on patient safety in a number of inquiries, including the Berwick Review, and defines patient safety as:

"the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare[8]".

The term 'patient safety' began to emerge in the NHS in the mid 1990s, largely as a result of well-publicised failures in service. The most influential of these involved the avoidable deaths of children at the Bristol Infirmary[9]. Another term entered the health vocabulary around this time: clinical governance[10]. Again, there should be no doubt that clinicians held themselves to account for the safety of their patients before the need to define this responsibility arose. What is interesting to note, especially from the board member's perspective, is that the idea of defining and assuring good governance from the top of an organisation to the front line has been directly linked with the safety of patients; that is, with the very purpose of the service itself.

The challenge for board members is significant. How can any small group of people know that standards are maintained in a complex organisation, delivering care in hundreds of different specialties and settings? How can they be assured that the systems and structures they have put in place to help maintain standards have been implemented and are working properly? How do they know that when, inevitably, incidents happen and failures occur, staff will be able to report and learn from them? How do they decide what adjustments and changes to make to improve safety and the patient outcome and experience? And just how do they set the tone for the magical thing we refer to as a safety culture?

The scale of the safety challenge over the lifetime of the NHS has not diminished as one might have expected. Payments made by the NHS Litigation Authority (NHS LA) in respect of clinical negligence claims against NHS trusts totalled £1.04 bilion[11] in the financial year 2014/15. For the same period, the legal costs incurred by the NHS LA relating to clinical negligence claims closed in 2014/15 with damages paid totalled £2.79 million.[11]

There has been a steady rise in reported incidents since the National Reporting and Learning System (NRLS) was introduced in England and Wales. During the period January 2015 to June 2015, the number of incidents

reported from England was 873,207[12], which is an increase compared to the same quarter in the previous year. However, incident reporting statistics need to be analysed with care: rising numbers are to be expected when a system is first introduced and the movement one seeks is an increase in the reporting of low harm incidents and near misses and a reduction in the more serious occurrences.

The introduction of national incident reporting, a systematic process for investigation and learning from incidents, complaints and claims are all examples of a move to understand better the scale and nature of the problem. We should take heart that the problem is acknowledged and measured (in most settings) more effectively and systematically than ever before.

A recognition that the problems causing harm to patients arise largely from failure in our healthcare systems, rather than from negligent or wilful failures of individual healthcare professionals, has changed the way we think about finding lasting remedies for unsafe healthcare. Making these remedies measurable, acceptable and sustainable should be fundamental to a board member's task.

Ignaz Semmelweis, who pioneered handwashing in the 1840s in Hungary, only achieved recognition years after his death[13]. His work to establish the connection between poor hand hygiene (cross contamination from staff undertaking post mortems) and the incidence of puerperal fever amongst women post delivery was met with indifference by the medical establishment. Semmelweis's career and mental health suffered dramatically as a result, and it is only now that he is recognised as one of the heroes of safety in health care. The treatment of those who have raised concerns about poor practice and poor care[14] indicates that the system as a whole can still militate against the openness and self-examination required to protect patients from harm. It takes courage as well as knowledge and skill to ensure that boards contribute to a safer healthcare system.

In response to the Mid Staffordshire NHS Foundation Trust Public Inquiry chaired by Sir Robert Francis QC, the government commissioned a report from a specially convened national advisory board on the safety of patients in England, led by the American Professor Don Berwick. The report was released in August 2013[15] and focused on the culture of the NHS, making a number of recommendations on openness, transparency and learning. Berwick reflected,

"The most important single change in the NHS in response to this report would be for it to become, more than ever before, a system devoted to continual learning and improvement of patient care, top to bottom and end to end."

That the NHS still has some way to go to move from a punitive culture of blame to an open, just culture, was an important acknowledgment.

Similarly, Sir Bruce Keogh, Medical Director of NHS England, offered this concise message to boards in his report on hospital care in fourteen trusts found to have high mortality rates[16],

"Our NHS is the only healthcare system in the world with a definition of quality enshrined in legislation. It is simple. An organisation delivering high quality care will be offering care that is clinically effective, safe and delivering as positive an experience as possible for patients. These are not unreasonable expectations. The NHS should be good in all three. Being good in one or two is simply not good enough."

Much progress has since been made. The report *Culture Change in the NHS: Applying the lessons of the Francis Enquiry*[16], published in February 2015 by the Department of Health, examines the steps the NHS has taken towards building a patient-centred service and importantly, the steps that still need to be taken to prevent the occurrence and re-occurrence of failures in care. The report notes how through significant improvements to the

regulatory framework and inspection regime, through the launch of a new national drive to improve patient safety and through placing emphasis on the importance of fostering an open, transparent and honest reporting culture, there has been a landmark shift in the way that the NHS prevents the occurrence and reoccurrence of unsafe care.[17]

The introduction of the statutory Duty of Candour marked a significant step towards improving patient safety and counteracting the defensive 'blame and shame' culture that was evident in Mid Staffordshire, instead facilitating the creation of an open and honest culture in which mistakes are recognised, apologised for and learnt from. In support of this, the NHS Litigation Authority (NHS LA) published guidance around how to apologise to patients who have encountered harm. The MyNHS[18] website, hosted by NHS Choices, enables the comparison of health and care organisations on 132 different measures important to patients, including safety measures and open and honest reporting, and was set up as a tool to assure the care quality across the NHS. While The Sign Up To Safety campaign, a national drive to halve avoidable harm, saving 6,000 lives in the process, marks an important step in putting patient safety at the forefront of healthcare to ensure safer care and reduce harm.

Moreover, in response to a survey[19] led by the Health Foundation, Monitor and the NHS Trust Development Authority (TDA) in 2014 to which 40% of NHS providers responded, 93% agreed or strongly disagreed with the statement *'we are making progress towards a continual reduction in harm'*.

Indeed, there is much to celebrate and we believe, encouraged by the progress that is being made by many NHS organisations, that culture change will at last lead to real improvements in safety. There is still, however, a long way to go.

Professor Don Berwick, in a 2008 report commissioned by the Department of Health, argues that a significant barrier to improvement is *"a culture of fear and top-down control rather than shared learning*[20]*"*.

Similarly, Sir Robert Francis QC carried out an independent review[21], in 2015, looking at how to create an open and honest reporting culture in the NHS. The report cites one trust where 30% of those who had raised a concern felt unsafe afterwards, while, of those who had not raised a concern, 18% expressed a lack of trust in the system and 15% the fear of victimisation as reasons for not doing so[21]. Not speaking up means missed opportunities to improve patient safety and it is crucial that NHS bodies work to eliminate fear amongst staff to speak up, instead working to encourage the disclosure of concerns.

The independent investigation into maternity and neonatal services in Morecambe Bay[22] made a number of robust recommendations, which, if successfully implemented, will go far in preventing future unnecessary and tragic deaths. The report found that errors were made at almost every level, including a failure to investigate and learn from such mistakes and a failure to be open and honest with patients. It is crucial that NHS organisations do not allow the key messages and recommendations from previous failures in care to simply sit on the shelf. We must not become complacent.

Thankfully, the NHS is beginning to nurture a culture of shared learning. A national programme, coordinated by NHS England and NHS Improving Quality (NHS IQ), has established a network of 15 patient safety collaboratives[23], led by the 15 Academic Health Sciences Networks (AHSNs), to facilitate improvement in safety across NHS organisations nationally. The collaboratives will each focus on their respective priority areas, based on local need, with a particular emphasis placed on patient safety 'leadership' and the 'measurement' of patient safety. Once tested locally, successful solutions will then be shared with other collaboratives. The programme endeavours to facilitate the adoption of successful solutions across the health service in England whilst creating a health system that is wholly committed to continual learning and improvement.

We must continue to maintain this level of momentum towards quality and safety improvements and, as articulated in Professor Don Berwick's review into patient safety and Sir Robert Francis QC's freedom to speak up review, work to embrace a culture of learning where staff are encouraged to speak up on safety issues and are not afraid to do so.

2. Changes to the healthcare system

Structure

Since our last report, there have been significant changes to the healthcare system in England. While the challenges for safety are the same across all countries making up the UK, differences between the structures are becoming increasingly marked. Despite this, all countries have identified national patient safety campaigns and all have systems in place to capture data on safety at a national level. The systems for setting and monitoring standards and for managing and learning from incidents, claims and complaints do vary and therefore this report focuses in particular on the system in England.

Since April 2013, the Department of Health (DH) is responsible for the strategic leadership of both the health and social care systems, but will no longer be the headquarters of the NHS, nor will it directly manage any NHS organisations. Commissioning of healthcare in England has became the responsibility of both NHS England (formally known as the NHS Commissioning Board) and of Clinical Commissioning Groups (CCGs). Healthcare is then provided through various forms of primary care and larger NHS and independent-sector healthcare providers. The role of Chief Executive of the NHS no longer exists, so the direct chain of command to this position has been broken. People will, however inevitably look to the Chief Executive of NHS England, currently Simon Stevens, for strategic leadership.

CCGs were created through the Health and Social Care Act 2012 to be the fundamental commissioning unit of the NHS, replacing the previous system of primary care trusts (PCTs). Each of the 211 CCGs serves a median population size of around 226,000 people. CCGs have been designed to be clinically led and responsive to the health needs of their local populations. They are membership bodies made up of GP practices in the area they cover, with the idea being that local GPs have a well-grounded understanding of the health needs of their population and, consequently, they should take the leadership in deciding how and where care should be commissioned and delivered. All GP practices are required to be a member of a CCG. The requirement for CCGs to be clinically led and to have direct influence from clinicians from both primary and secondary care settings marked an important step in ensuring that the interest of patients is considered first and foremost where decisions about the redesign of care are concerned.

CCGs have responsibility for commissioning urgent and emergency care, elective hospital care, community health services, maternity and newborn, mental health and learning disability and through co-comissioning, have recently been given the opportunity to assume greater powers for commissioning some GP services. NHS England, an executive non-departmental body at arm's length to the government, established as the NHS Commissioning Board in October 2012, works in close collaboration with CCGs. NHS England is responsible for the direct commissioning of services which are more appropriate to commission at a national level, as opposed to locally. Such services include specialised services, healthcare for offenders, some healthcare for the armed forces and those primary care services not delegated to CCGs. NHS England also holds responsibility for the authorisation, development and oversight of CCGs, provides resources and information to CCGs and holds CCGs to account.

In seeking this assurance, they will continue to draw from the guidelines of the National Institute of Health and Care Excellence (NICE) in terms of standards of care and by the reports and findings of the Care Quality Commission (CQC).

What has not changed is the requirement for all boards, both commissioners and providers, to have a Board Assurance Framework (BAF) in place which gives them (and thus their stakeholders) confidence that risks and concerns about the quality or safety of patient care are detected, reported and managed at the appropriate level of the organisation. As many of the functions previously provided by PCTs are now being undertaken by Commissioning Support Units (CSUs) under contracts, it is vital that CCGs put in place systems to ensure that risk is being effectively handled and reported. Research shows that the more "handoff" points there are in a system, the more risk will exist[24].

Regulation

The regulation system still incorporates the CQC, Monitor, individual professional regulators (e.g. General Medical Council, Nursing and Midwifery Council etc.) and other regulatory bodies. In June 2015, the government announced that Monitor and the Trust Development Authority (TDA) will move to single leadership to facilitate the delivery of increased support to hospitals[25]. The combined provider regulator will be called NHS Improvement and will be in operation from April 2016. The CQC has an enhanced role in regulating and the performance of all providers against fundamental standards of care and recommending remedial action or sanctions where necessary. Most recently in 2014, the duty of candour regulations were introduced. The regulation states that by law a healthcare provider must alert the service user of an incident and all relevant information pertaining to the incident that occurred during their care.

Healthwatch England operates at national and at local level and is the independent consumer champion, gathering and representing the views of the public about health and social care services in England. It has significant statutory powers to ensure the public and patient voice is strengthened and heard by those who commission, deliver, and regulate health and care services. All board members should be aware that both NHS England and CCGs have a duty to involve their members and the patients, carers and the public in decisions about the services they commission.

Patient safety

NHS England's responsibility for setting the patient safety agenda for the NHS has become particularly apparent in the post-Mid Staffordshire environment. The identification of common clinical risks and patient safety incident types based on data provided by all healthcare organisations in the country, is a key responsibility of NHS England's Patient Safety Domain. Beyond that, NHS England needs to ensure that all commissioners have processes in place for monitoring patient safety incidents, investigations of the latter and the implementation of action plans resulting from these[26].

The NPSA has been abolished and many of its duties transferred into NHS England. A critical resource for monitoring data about patient safety is the NRLS[27]. This arm of the former NPSA remains part of NHS England and comprises what is acknowledged to be the world's most comprehensive database of patient safety information. It publishes regular reports compiled from information submitted by healthcare organisations on incidents, as well as Patient Safely Alerts on specific safety concerns and risks (e.g. Venous Thromboembolism, naso-gastric tube placement) and associated guidance.

NHS England as well as CCGs are obliged to involve patients and carers in their strategic development of prevention, care planning, and treatment as well as commissioning of services, and guarantee their access to information required to make an informed patient choice between different providers. In response to the recommendations for patient safety that have been put forward, NHS England has established several Patient Safety Expert Groups around the specialities of women's health, children and young people, mental specialties, primary care, medical specialities and surgical specialties. These groups are made up of multiple stakeholders and their findings and recommendations will be used to aid commissioners and providers on patient safety initiatives.

The Public Administration Select Committee (PASC) recommended in its report 'Investigating clinical incidents in the NHS'[28] the establishment of an independent national patient safety investigation body with the power to conduct its own investigations into systematic clinical failures and to oversee local investigations. It would publish its own independent reports and recommendations and be accountable directly to Parliament. Vested with expertise in the area of patient safety and the investigation of untoward clinical incidents, we agree that this body could have the potential to also establish and implement much needed systematic learning from incidents and clinical failures across the system.

This investigation body, the Independent Patient Safety Investigation Service (IPSIS), is currently being set up with the oversight of Dr Mike Durkin, Director of Patient Safety at NHS England. IPSIS will be in operation from April 2016 and will provide support and guidance to NHS organisations on investigations in to serious patient safety incidents. IPSIS will also carry out certain investigations itself. The patient safety functions of NHS England, including the NRLS, will be transferred to this new body, which will be responsible for supporting investigations undertaken locally, performing thematic investigations and

responding to concerns raised by the public and the media. The service will focus on ensuring that errors are acknowledged and learnt from and that trust and honesty are become embedded in individual and organisation behaviour.

Between August 25th 2015 to October 31st 2015, an Expert Advisory Group (EAG), established to make recommendations regarding how the IPSIS should function, launched an online call for evidence[29], the purpose of which was to seek views on five key themes around how the investigation service should work. These were:

- independence, governance and accountability
- engagement and transparency
- what IPSIS should investigate
- supporting improvement and learning
- people, skills and operation

The views received as a result of the consultation will feed in to the work of the EAG.
There is also the European Union Network for Patient Safety and Quality of Care centre (PaSQ)[30], which has been established to map and identify good practices in patient safety and quality of care across the European Union through 2015. This initiative will enable the exchange of information around patient safety within the EU through conferences, online courses, and other events.

Social media

Improving patient safety requires professionals and clinicians to be better connected and also for patients themselves to be empowered. Dr Janet Williamson and Dr Mike Durkin assert that social media tools can facilitate the effectiveness of Patient Safety Collaboratives and patient equity partnerships by enabling wider participation, and also foster mechanisms through which healthcare professionals are held accountable by patients[31]. Following the recommendations of the Francis report, online platforms enabling patients, relatives and staff to raise safety concerns can be an important step towards placing greater priority on patient safety, as long as confidentiality is preserved and abuse prevented.

The patient safety campaign Cure the NHS, founded by Julie Bailey, is a prominent example of this kind of patient empowerment facilitated by social media tools including Twitter, Facebook, and blogs. Social media can also be effective in facilitating the collaboration of patients and relatives over a very specific issue. This was successfully achieved by the Twitter campaign #hellomynameis, initiated by Dr Kate Granger, which has brought healthcare professionals all over the country to remember the importance of the relationship with their patients and colleagues[32].

Birmingham Children's Hospital is an example of a trust who, having previously struggled with engagement on social media, have since dedicated themselves to maximising the strategic use of social media to cultivate engagement and raise the hospital's profile, revolutionising their social media presence and changing the way the public interact with the hospital. A social media strategy was created with a number of outputs including a platform strategy, social media policy, content calendar and many other ideas around Twitter, Facebook, YouTube, Instagram and LinkedIn. The trust provides platforms of communication and interacts with people online, responding to posts to facilitate greater engagement. A daily content diary posts topical and emotive messages at times shown to engage the largest audiences. When selected to be part of the national campaign The Big Give, the trust based their campaign around Twitter, which marked the first time that Twitter was strategically used to raise funds.

Unlike other professions, NHS GP practices offering to communicate with patients via email or social media are still rare, and information available to patients through NHS organisations' websites is often scarce. Online patient reviews on professionally administered and transparent yet confidential websites can be a powerful facilitation for public engagement and transparency. Sharing anonymised feedback and outcome data online contributes to accountability and trust between practitioners and patients, Dr Neil Bacon, founder of Doctors.net.uk and iWantGreatCare.org, argues[33]. Legitimate concerns about misuse and confidentiality should be addressed with transparency, so as not to overshadow the potential of social media to play an important role in enhancing patient safety.

Standards and compliance

The NHS Litigation Authority (NHS LA) is a Special Health Authority (part of the NHS), responsible for handling negligence claims made against NHS bodies in England. The NHS LA developed risk management standards[34] to reflect issues which arise in clinical and non-clinical negligence claims. However, following an extensive review by the NHS LA of the standards and assessment process used, a decision was taken to revise the approach in order to facilitate a more outcomes focused, and fit for purpose, process[35]. Accordingly, as of April 2014, the NHS LA no longer updates the standards and no longer assesses NHS trusts against these standards. However, the standards continue to reflect good risk management practice and therefore can still be used by trusts in addressing areas of risk.

In place of the standards and assessment process, the NHS LA has developed a Safety and Learning service delivered by NHS LA Safety and Learning Leads[36]. This service aims to support the NHS in reducing harm and improving patient safety through learning from litigation claims and clinical assessment cases, therefore helping to build a safety and learning culture across the NHS through saying sorry when things go wrong and through adherence to the Duty of Candour. Members of the NHS LA are provided with information and analysis in relation to their respective organisations claims on the secure NHSLA Extranet as well as a Safety and Learning Library of best practice guidance, local network events and targeted workshops. In addition, the Safety and Learning service aims to work closely with clinicians, risk managers and other stakeholders to reduce harm in maternity and surgery and two Safety and Learning Advisory Groups have been established specifically for these areas to provide best practice guidance and specialist knowledge and advice.

The Care Quality Commission (CQC), the independent regulator for health and adult social care in England, checks whether services meet national standards of quality and safety. The indicator on NHS Choices shows whether a particular hospital is meeting safety standards as expected. Hospitals are rated as either meeting the required standards or not. This is the most authoritative view of the safety of a hospital.

All providers registered with the CQC, are required in line with the Care Quality Commission (Registration) Regulations 2009: Regulation 18, to notify them about certain safety incidents that have an effect on their service or those who use it. As demonstrated through the Morecambe Bay Investigation and the report of the Public Administration Select Committee, the NHS as a whole does not have a strong capability with regards to reporting[44]. This demonstrated the need for standards and guidelines for incident reporting across the NHS.

Accordingly, a revised Serious Incident Framework[37], published by NHS England in March 2015 in collaboration with healthcare providers, commissioners, regulatory bodies, patients, patient safety experts and other stakeholders, emphasises the need to take a whole-system approach to quality improvement. The Framework supports NHS bodies to ensure that robust systems are embedded within the organisation for reporting, investigating and responding to incidents. The aim of the Framework is to facilitate learning through eliminating a 'blame and shame' culture that can result in the concealment of mistakes and thus missed opportunities to learn. Acting in line with the Framework will aid in preventing future occurrences that result in harm. Frequent reporting of both serious and low/no harm incidents is indicative of a sound reporting culture.

The Clinical Negligence Scheme for Trusts, administered on behalf of the Secretary of State by the NHS LA, handles all clinical negligence claims against member NHS bodies where the incident in question took place on or after 1 April 1995 (or when the body joined the scheme, if that is later). The scheme is voluntary, although all NHS trusts in England are currently members of the scheme.

In almost all organisations, good reporting practice, incident investigation and incident management were supported by the use of information technology to a greater or lesser degree. The most widely used of these systems is Datix, which is used by around 80% of all NHS organisations.

Improving quality

Quality and safety are interdependent in healthcare, and the creation of NHS Improving Quality (NHS IQ) forms a central part of NHS England's efforts in this regard, with quality improvement priorities aligned to the NHS Outcomes Framework[38]. As of 1st November 2015, NHS IQ have transferred into NHS England as their new Sustainable Improvement Team, who will continue to support the NHS by providing improvement and change expertise[39].

The Professional Standards Authority lays down the standards for members of NHS boards and CCG governing bodies in England[40]. Within these, it is stated that members have a duty to ensure that effective procedures are in place for whistleblowing and complaints and that members are responsible for addressing and learning from harmful behavior, misconduct or systems weakness as well as for raising any concerns identified. Making a disclosure in the public interest[41], i.e. whistleblowing, has become a central component to improving patient safety. In 2014, Rt. Hon. Jeremy Hunt MP announced the "Sign up for Safety" hospital campaign[42], aimed at reducing avoidable harm by 50% and save 6,000 lives over the course of three years. Moreover, the Whistleblowing Helpline has reported to receive over 8000 calls annually[43].

The Department of Health's *Learning not blaming* report[44], published in response to the Freedom to Speak Up Review consultation, the Public Administration Select Committee's report *Investigating clinical incidents in the NHS* and Dr Bill Kirkup's report on failings in care at Morecambe Bay, lays down several requirements of NHS trusts. The report recommends that the Chief Executive of all NHS trusts should

'appoint a Freedom to Speak Up Guardian, to encourage and enable staff to raise concerns over patient safety in a confidential setting'.

Boards need to ensure that all employees are aware of the organisation's whistleblowing policy, and feel safe to report concerns about risks to patient safety arising from possible wrongdoings that are being covered up, criminal offences, or colleagues who are neglecting their duties. Patients First[45], a network of professionals committed to protecting whistleblowers and reducing harm caused by unsafe practices, continue to raise concerns about the lack of support and protection whistleblowers receive. Patients First was founded by Dr Kim Holt, and the organisation claims that the NHS, as well as the CQC, needs to do more to combat the silencing and bullying of whistleblowers across the health and social care landscape[46].

As Jennie Fecitt, Patient's First's Nursing Advisor and Managing Director of Primary Healthcare Training Ltd says,

"Failure of employers to provide robust support, correctly characterise those who raise concerns and follow policies appears to be the norm rather than the exception."

Failures in safety and implications for boards

The effects of the failures in care at Mid Staffordshire NHS Foundation Trust[47] and the implications of the subsequent inquiry and reports has impacted on the health landscape significantly since our last report.

Rosemary Hittinger, former President and Council Member of the Quality in Healthcare section at the Royal Society of Medicine notes,

"in my experience it is the organisation that creates the 'whistleblower'. It is not usually an ambition of the person who is trying to expose poor practice to become one. Therefore maybe boards should be concerned about the cultural health of their organisation as well as the actual incident/episode if any allegation of whistleblowing is made."

An investigation by the Healthcare Commission in to high mortality rates in patients admitted to Mid Staffordshire NHS Foundation Trust as an emergency admission and the care received by these patients was carried out in between March 2008, and September 2008, with findings published in 2009. The ensuing scandal was fuelled by the claim that between 400 and 1200 more patients died between 2005 and 2008 than would be expected for the type of hospital, though in fact such 'excess' death statistics did not appear in the final Healthcare Commission report.

On 21 July 2009, the then Secretary of State for Health, Andy Burnham, announced an independent inquiry, chaired by Robert Francis, QC, into care provided by Mid Staffordshire Hospitals NHS Foundation Trust. The generally critical inquiry report was published on 24 February 2010 and made 18 local and national recommendations. In June 2010, the new coalition government announced that a full public inquiry would be held. The inquiry began on 8 November 2010, again chaired by Robert Francis QC, with the specific purpose of considering why these (i.e. identified problems and failures) issues had not been detected earlier, and to ensure that the necessary lessons were learned.

The final report was published on 6 February 2013, outlining 290 recommendations. Francis concluded that patients were routinely neglected by a trust that was preoccupied with cost cutting, targets and processes and which lost sight of its fundamental responsibility to provide safe care.

Key messages from the inquiry include:

- for NHS trust boards: "failures resulted from a tolerance of poor standards and a disengagement from managerial and leadership responsibilities"
- for CCGs: "there was a plethora of agencies, scrutiny groups, commissioners, regulators and professional bodies, all of whom might have been expected by patients and the public to detect and do something effective to remedy non-compliance with acceptable standards of care"
- for regulators: "The story of Stafford shows the importance of not ignoring trusts which have failed to appear on the radar of concern"

The Summary Hospital-level Mortality Indicator (SHMI) is the ratio between the actual number of patients who die following hospitalisation at the trust and the number that would be expected to die on the basis of average England figures, given the characteristics of the patients treated there. It covers all deaths reported of patients who were admitted to non-specialist acute trusts in England and either die while in hospital or within 30 days of discharge and is available online via the Health and Social Care Information Centre[48] (HSCIC).

It is important to realise that the focus of attention on events at Stafford Hospital is relevant to only part of the picture of safety for healthcare users: patients and their families do not see boundaries between providers of health and social care, nor should they. The issue of what constitutes a resilient safety culture must be addressed across the whole provider landscape.

Fortunately, the critical elements of safe care and high reliability apply to providers of care across primary and secondary care and for the users of acute, community and mental health services.

Francis made 290 detailed recommendations in his report. The government responded to the report by accepting a number of the recommendations, rejecting others and accepting the remainder in modified form. The government also commissioned a further review by Don Berwick of the Institute for Healthcare Improvement to determine how the NHS culture could be transformed into one of learning.

Well-led healthcare providers

Together with the CQC and the NHS Trust Development Authority (TDA), Monitor has developed the 'well-led framework for governance reviews'[49]. They define well-led care providers as those with "leadership, management and governance that assures the delivery of high quality care for patients, support learning and promote an open and fair culture"[50]. The framework is used to assess how trusts and foundation trusts are governed establishing greater consistency between the three regulators, but it is also intended as a self-assessment tool for providers to evaluate their governance structures and improve them.

The Framework sets out four domains indicating whether an organisation is well-led by the board:

- strategy and planning - how well is the board setting direction for the organisation?
- capability and culture - is the board taking steps to ensure it has the appropriate experience and ability, now and into the future, and can it positively shape the organisation's culture to deliver care in a safe and sustainable way?
- process and structures - do reporting lines and accountabilities support the effective oversight of the organisation?

- measurement - does the board receive appropriate, robust and timely information and does this this support the leadership of the trust

The framework provides 'good practice' outcome examples and 10 assurance questions for each domain for foundation trusts to assess their board's governance practices and capabilities. Monitor's 'risk assessment framework'[51] provides assurance to NHS foundation trusts that they are well-led measured by clearly described criteria that foundation trusts should measure their quality of care against, unless they have a plausible reason for non-compliance.

With a coherent set of indicators for all providers, it is easier to align assessments and data analysis for governance, including clinical, staff, financial, and information governance, thereby ensuring that provider organisations are held accountable internally and externally on a regular basis. The key lines of enquiry in the new framework will focus on whether an organisation's services are:

a) safe in terms of protecting people from abuse and avoidable harm
b) effective in achieving good outcomes, evidence-based and promoting good quality of life
c) caring in the way patients are involved and treated
d) responsive to people's needs, and
e) well-led, assuring the delivery of high quality person-centred care as well as supporting learning and innovation, and an open and fair culture[52]

Professor Sir Bruce Keogh carried out a review on the quality of care and treatment being provided by fourteen hospital trusts in England that had persistently higher than average mortality rates over the two years preceding the review. Eleven out of the fourteen hospitals investigated during the review were subsequently placed in special measures. The need for a framework focussing on the effectiveness and quality of governance became apparent with the Keogh Review that identified poor governance as a major factor responsible for poor care. Regular assessment of governance structures and leadership is essential but complex and often difficult at the same time. Analysing and evaluating governance is not just a management-level activity, and needs to incorporate feedback from staff, patients, stakeholders and the community in the form of surveys, regular engagement of staff and patient representatives in board meetings and strategic development, or other engagement activities.[53]

Co-commissioning initiatives

The co-commissioning of primary care, as set out in the NHS Five Year Forward View, is still a new mechanism in England, intended to ease the integration of care between hospitals and community care providers, and in larger geographical areas to decrease health inequalities. Co-commissioning, meaning partnership working and delegation in commissioning, has the potential to enable greater investment, for instance in a cross-organisational IT system, and innovation as well as the exploration of alternative, more sustainable allocation of financial resources. Such collaboration can form a key element in the transformation from an organisation-centred to a patient-centred approach to the provision of primary, secondary, and social care, and of broader patient safety efforts.

Furthermore, co-commissioned contracts can enable CCGs and NHS England to set new standards against which performance and quality of care could be measured in areas currently evaluated insufficiently. To make providers more accountable for their quality of care in comparison to others, commissioners can make performance and quality indicators and outcomes available to patients and the public. Incentivising providers to improve the quality of their care in this way can prove more effective under a collaborative co-commissioning framework that covers a wider range of providers. Better transparency and accountability can also help overcome potential conflicts of interest faced by CCGs, ensuring that the focus always lies on the interest of the patient.

CCG's were invited by NHS England to assume an increased role in the commissioning of General Medical services via one of the three co-commissioning models[54] detailed below:

1) **Greater involvement** whereby CCGs collaborate more closely with local NHS England teams in decisions regarding primary care services. This aims to facilitate greater strategic alignment across local areas
2) **Joint commissioning**, which enables one or more CCGs to jointly commission general practice services with NHS England through a joint committee
3) **Delegated commissioning** whereby CCGs take full responsibility for commissioning general practice services.

A document published[55] in November 2014 by the joint CCG and NHS England Primary Care Commissioning Programme Oversight Group, in partnership with NHS Clinical Commissioners, provided clarity around each of the commissioning models listed above and the arrangements for their implementation. This publication was supported by a suite of tools to aide CCGs in the implementation of co-commissioning arrangements.

Over 70% of CCGs (150 in total) are taking on greater responsibility for the commissioning of primary medical care services in 2015/16. Whilst offering the opportunity for CCGs to commission services in a more joined up manner, co-commissioning increases the potential for both real and perceived conflicts of interest. Indeed, a recent joint investigation by the British Medical Journal (BMJ) and the Times has revealed that a total of 437 out of 5671 contracts worth at least £2.4 billion were awarded by CCGs in England to providers in which one or more CCG board member had declared an interest[56]. The majority were to NHS trusts or similar organisations and 50 CCGs were found to have awarded contracts where a conflict was present. The findings of the investigation reveal the degree to which CCG boards are conflicted and uncovered extensive variations in the ways in which conflicts of interest were managed by respective CCGs. CCGs are accountable for public money and the investigation spoke of concern amongst doctors, patients and MPs that conflicts of interests pose.

In acknowledgment of the additional conflicts of interest co-commissioning of primary medical services creates, in December 2014, NHS England published the *Managing conflicts of Interest: statutory guidance for CCGs*[57], which built on, strengthened and replaced existing NHS England guidance. In addition, statutory guidance states that CCGs taking on co-commissioning of primary medical services must do so through arms length committees whereby GPs form the minority.

In terms of evaluation, the measure of success of co-commissioning will be how far the new arrangements improve care and outcomes. A three-year formal evaluation programme, (June 2015 – December 2017), commissioned by the Department of Health and led by the Policy Research Unit in Commissioning and Healthcare System (PruCOMM) will provide NHS England with evidence to support them in working with CCGs as they take on enhanced responsibilities for primary care commissioning.

New care models

As noted in the Five Year Forward View[58], together with clinical effectiveness and patient experience, patient safety is integral to the definition of quality in health care. The Five Year Forward View sets out how and why the NHS needs to change in order to meet the fundamental challenges facing our health system and to ensure sustainability in to the future. One such challenge is the care and quality gap. Without implementing changes to reshape the delivery of care, maximise the use of technology and reduce unacceptable variation in the quality and safety of care received, the changing needs of the population will not be met and ultimately, patients will be harmed. In light of the many challenges facing the NHS, the Five Year Forward View sets out a number of care models to help dissolve the traditional divide between primary, community and acute care services and instead foster an integrated patient-focused healthcare system. When considering the increase in demand for GPs and the core workforce challenges facing primary care, such as one fifth of GP's approaching retirement in the next five years, the successful implementation of these new models of care will be fundamental to ensuring the robustness and sustainability of primary care in to the future.

A prominent first step in the delivery of the Five Year Forward View came in January 2015, when NHS organisations and partnerships were given the opportunity to apply to become a vanguard site for the new care models programme to address national challenges and support the integration and thus improvement of care services. The programme looked to turn the range of models outlined in the Five Year Forward View, including integrated Primary and Acute Care Systems (PACS), enhanced health in care homes, Multispeciality Community Provider (MCP) vanguards as well as urgent and emergency care networks and acute care collaborations, in to practice[59]. A total of 50 vanguard sites were selected and are currently taking the lead on the development of the new care models, which will form the blueprints for shaping the future NHS.

The House of Care framework[60] is used as a metaphor to illustrate the integrated, whole-system person-centred approach to tackling the management of long-term conditions, and puts patients at the heart of the delivery of care. The growing development of MCPs and a number of integration initiatives around the 'house of care' model facilitated by the NHS England Vanguard sites are key to the development of primary care integration. Indeed, the commitment of all CCGs involved to successfully use co-commisioning to foster integrated care, especially for the most disadvantaged patients, is promising.

3. What works to improve safety in healthcare organisations?

Two sides of the safety coin

There has been considerable activity in the patient safety field in the UK over the past 15 years or so. The establishment of the NPSA and its incident reporting system, the NRLS, was lauded internationally. The patient safety campaigns across the UK have shown promising results in specific risk areas (central venous catheter infections, ventilator associated pneumonias etc). Sadly, we still experience both high rates of preventable harm to patients which, given the growing elderly and frail population, risk contributing to an unacceptable level of all round care for significant numbers of our patients.

While we certainly do not have all the answers to our safety challenges, nor the resources to do everything we would like, a more pressing issue is the actual implementation of remedial action. We do not have a good track record in implementing and sustaining the improvements that we do know to be effective, at scale.

In this section we look at the key features of highly reliable organisations and the implications for healthcare boards in terms of what type of issues they need to focus on. In the final section, we align specific recommendations in these areas with examples of good practice in terms of implementation and sustainability.

So what should we be doing?

Current thinking on safety generally, and certainly on patient safety, crystallises the work of safety experts over the last two decades down to two fundamental issues – i.e. two sides of the safety coin:

- Systems design
- Managing behaviours

Both are critical to ensuring a safe system of work. The safe landing on the Hudson River of US Airways Flight 1549 in 2009 following a bird strike that disabled both engines, was heralded as a miracle in the press. Subsequent analysis showed that the pilots followed their training and relied on systems, adaptability and good team working – all features of highly reliable organisations. Jeff Skiles, the First Officer of US Airways flight 1549 and Dr Terry Fairbanks, emergency physician, safety science expert and Director of the National Center for Human Factors Engineering in Healthcare at MedStar Health, reflect on the fact that – as human error is inevitable, good systems design (and therefore redesign, informed by experience) is essential. [61] Turning to managing behaviour, they highlighted the need to ensure that organisations encourage a culture where they will know as much as possible about risks:

"(It is) Vastly more important to identify the hazards and threats to safety, than to identify and punish an individual for a mistake."

"(It is) More important to exchange the ability to reprimand an individual for the ability to gain greater knowledge."

David Marx[62] argues for a revolution in the way we deal with individuals and error, and to design systems which allow for this: "our power is in the systems we build around imperfect human beings and in our expectations of them within those systems."

Using the analogies of both parenting and the sports field, he describes an approach that acknowledges that there is a continuum from error through risky behaviour to reckless behaviour and the best way to manage behaviour is to:

"Console the error, coach the at risk behaviour, and punish the reckless behaviour – regardless of the outcome."

This is an important improvement over the "no blame culture" that is still talked about in healthcare. It is important that people understand that reckless or illegal behaviour will not go unpunished.

Most healthcare organisations have policy statements about incident reporting that purport to encourage openness and to restrict disciplinary action to egregious behaviour – does this happen in practice or - more importantly – do our staff believe and trust that it will happen in practice?

A white paper by Lucian Leape[63] focuses specifically on what organisations and their boards need to understand and do to enable their staff to work safely. He sets out a range of helpful recommendations on supporting continuous learning, improvement, teamwork, and transparency, but perhaps the most critical point he makes is again concerning the confidence, trust and belief that staff have in the organisation – only with these secured can you expect behaviour to change:

"the workforce needs to know that their safety is an enduring and non-negotiable priority for the governing board, CEO, and organisation."

For healthcare boards, the bottom line of safety is knowing that your staff are empowered and encouraged to report concerns without fear of negative consequences. In the next section, we will give some practical suggestions as to how to ensure this is the case.

High Reliability Organisations

Before we turn to solutions, it is worth reviewing the acknowledged characteristics of high reliability organisations (HROs). Karl Weick has written extensively on this topic and has described the concept of "mindfulness": a combination of high alertness, flexibility, and adaptability. He summarises the two outstanding features of HROs in this way: "They constantly confront the unexpected and operate with remarkable consistency and effectiveness"[5]. The five key characteristics identified are:

- **Don't be tricked by your success** – constantly challenge your ways of working, your expected outcomes and the messages coming back to the organisation

- **Defer to your experts on the front line** – your staff are the people who can spot problems, opportunities for improvement and can apply their expertise to tackle changing conditions. Robust assurance does not mean knowing everything about the intricacies of your business - it means knowing that the right people are able to recognise, deal with and report issues when they occur

- **Let unexpected circumstances provide your solution** – resist the temptation to focus on one aspect of a complex problem or what you did last time – new circumstances may provide new solutions and organisations need to be open to this challenge. This, of course, goes hand in hand with deferring to front line experts

- **Embrace complexity** - healthcare staff often bemoan the frequent analogies made with aviation and other industries on safety – "we are different, we are much more complex" etc. While healthcare is certainly different and analogies can only be taken so far, complexity exists in different ways in many businesses and sectors. Complexity should foster adaptability and a culture of listening to the experts and other stakeholders. HROs resist simplification and seek to understand nuance

- **Anticipate - but also anticipate your limit**s – this is where you need to get the balance right between strategy and planning and acting. This is a lesson that organisations need to take on board in the wake of the potential for post–Francis paralysis. Weick and Sullivan recommend focusing on those mistakes you wish to avoid – how do you know what these are? What do systems tell you about them? Secondly, trust your anticipation to enable you to act but check the accuracy of your estimated outcome as soon as you can. Did this change of policy work? Where is the evidence? Do we need to adjust it? And also – how can we build in resilience so that these actions are measurable and reproducible in the future?

Information sharing

A key element in securing quality in healthcare provision is ensuring partnership working and information sharing across organisational boundaries. Developing constructive dialogue in local health and social care economies is fundamental to efforts around improving patient safety and securing quality assurance.

This information sharing across organisations is particularly pertinent to patient safety in relation to the pathway of care, and patient handover. While poor or incomplete handover occurring within an organisation is clearly linked to a heightened prevalence of safety incidents[64], any healthcare director would be remiss in ignoring the value of information sharing across organisations. An organisational boundary of specific importance in addressing patient safety issues is that of commissioner and provider.

Earlier work by the Good Governance Institute in conjunction with NHS South London Commissioning Support Unit[65], found that the theme of 'relationship building' between CCGs and provider organisations emerged as a central concern around information sharing as a means of supporting patient safety. This highlights the importance of 'soft intelligence' throughout the healthcare economy, something that has been highlighted in both the Francis and Berwick reports. This information sharing is fundamentally linked to recommendations of placing transparency at the core of operations in order to foster accountability and the growth of knowledge throughout the health and social care sector.

Genuine quality assurance for patient safety requires an environment of consolidated partnerships and information sharing. This is a major challenge to a complicated health service, and involves the synchronisation of both operational processes and structural designs that need to work efficiently and seamlessly across various care and support services. Nevertheless, this complexity bears testament to the value of healthy information streams both within and across organisations. From best practice examples, to patient handover and operational risk, the importance of information sharing to improving patient safety highlights it as an area in need of continuous development.

4. Governing for safety: good practice and recommendations

A fundamental purpose of the NHS is to provide services that are of high quality and are safe. NHS England has built on Lord Ara Darzi's three dimensions of quality care[66] to propose this definition:

- care that is clinically effective — not just in the eyes of clinicians but in the eyes of patients themselves
- care that is safe
- care that provides as positive an experience for patients as possible

In governance terms, this means that the organisation must have structures and processes in place to identify and benchmark itself against relevant best practice and to track and report compliance against relevant standards and targets. It must ensure a clear line of sight from the front line of service delivery through to board level on quality and safety. To do that, there must be an explicit framework for:

- delivering and demonstrating accountability for quality of clinical outcomes
- quality improvement activity, including innovation and the delivery of excellence
- measuring improvement and compliance with national and professional standards and tracking performance against national and local targets
- reporting, recording and escalating risks and concerns about quality
- monitoring and evaluating actions to reduce risk, improve quality and sustain improvement

This framework must be designed to work at all levels of the organisation and be a critical part of the governance system as it provides assurance that threats to the organisation's strategic objectives are managed.

Governance should help those leading organisations to provide seamless assurance to patients around quality and safety, as well as around the effective stewardship of resources for the taxpayer. The Health and Social Care Act added duties for those leading healthcare organisations. The developing regulation systems in healthcare are largely designed to use the corporate and clinical governance systems as a means by which they test the quality and safety of patient care.

Governance imperatives

In our previous report, we highlighted the key facets of good governance for boards[67]:

- **vision** - boards or governing bodies of organisations need to ask themselves 'what is the point of this organisation?' Vision is the shared understanding of what the organisation is trying to achieve and the difference it intends to create. It helps provide clarity and a sustainable **strategy**
- **strategy** - the planned means by which the organisation delivers the vision
- **leadership** - how the organisation is able to deliver the strategy over time. In order to achieve the organisation's purpose, those in governing and leadership roles need to also have clarity around their contribution to this and exhibit a set of behaviours that is in tune with the vision. This will support the effective achievement of the organisation's purpose. Boards and governing bodies are less effective if there is confusion around roles and when behaviours are out of tune with the value that good governance brings to an organisation
- **assurance** - that the organisation does what it says it will do and behaves in the manner it has agreed? Assurance refers to the continual vigilance to ensure that plans are delivered and that all relevant compliances are maintained
- **probity** – that the organisation meets standards of openness and transparency, acts with integrity and in good faith. In the public sector, taking note of the Nolan principles of public life[68]
- **stewardship** – that the organisation is responsible with resources, especially other people's resources (such as credit)

In terms of how these responsibilities translate to patient safety, we cannot improve on this summary by Antony Sumara of watchwords for board members:

- be **open and transparent** - hold all meetings in public
- Put **safety and care** at the beginning of the meeting and bear it in mind right through
- challenge each other - "**is this good enough for my family member**?"
- **challenge the good reports** as well as the bad. Achieving a target is good but at what cost?
- seek assurance outside of the boardroom - **is there a clear line of site from board to ward and back?**
- have **integrated information** which pulls operational, safety, complaints, mortality, finance etc. into one report. Use hard and soft data
- **listen to the patients, the public and your staff** – a culture in which staff fear the punitive repercussions of reporting incidents is toxic to effective patient safety – promotion of openness and organisational learning is crucial

The role of foundation trust governors

There are also special additional considerations for foundation trust governors as they have an important role to play in ensuring patient safety in their organisation.

The key role for Governors, whilst representing the interests of their constituency, is to hold the non-executive directors individually and collectively to account for the performance of the Board of directors. There is no one "right way" to hold non-executive directors to account and local approaches are emerging. The Council of Governors acts in an advisory capacity and by doing so contribute to the strategic direction of the Trust. The operational management and decision-making however remains with the executive and the Board.

In addition to holding the non-executive directors individually and collectively to account for the performance of the board, foundation trust governors have a number of other specific duties and responsibilities. Governors are required by law to represent the interests of both members of the NHS foundation trust and of the public.

Specific duties of governors include:

- appoint, and if appropriate remove the Chair and Non Executive Directors
- decide the remuneration and allowances, and the other terms and conditions of office, of the chair and the other non-executive directors
- approve the appointment of the Chief Executive
- approve / remove the Trust's external auditor
- receive the Trust's annual accounts, any report of the auditor on them and the annual report
- be consulted on the Trust's future plans for the Trust and of any significant changes to the way services are provided

In consultation with the council of governors, the board appoints one of the nonexecutive directors as the senior independent director (SID). They are an alternative point of contact for governors (and directors) when:

- they have concerns that have not been resolved through normal channels
- contact with the chair, finance director or chief executive is inappropriate
- discussing the chair's performance appraisal, remuneration or allowances

The Panel for Advising Governors was established in line with the Health and Social Care Act 2012 and was initially setup by Monitor prior to becoming independent. The remit of the panel is to answer questions raised by the governors of an NHS foundation trust about whether the trust has failed or is failing to act in accordance with either its own constitution or chapter 5 of the NHS Act 2006 (which sets out how NHS foundation trusts operate and therefore the Panel also answers questions around healthcare standards).

A governor may refer a question to the Panel only if more than half the members of the council of governors voting approve the referral. Evidence of the vote will need to be provided to the Panel before it can consider a question from governors. The Panel's remit is to support governors in fulfilling their role in representing the interests of their members and the public. Best interests are served by governors seeking to resolve any questions or issues with their trust chair and other nonexecutive directors before posing a question to the Panel. However, the Panel is available as a free resource in the event of continued uncertainty.

A survey[69] published by Monitor in March 2015 of NHS foundation trust governors 2014/15 asked governors about their greatest achievements and the impact of this on the trust and wider community. Responses were received from 1,264 governors and as well as fulfilling statutory duties (12%), engaging with the public and trust members (11%) and holding trust board to account via the non-executive directors (10%), improving the quality, safety and experience of care for patients (9%) was noted as a key achievement.

In the next section, we look at five key activities board members need to engage in, so that they can assure themselves they are governing for safety, and give examples of good practice and developments which can help. Thoughts and advice from our small band of patient safety commentators, healthcare leaders and clinicians illustrate these issues.

Our original recommendations on good practice are still relevant – it is sobering to realise that many of these are clearly still not in place across the system. We show these for information in Appendix 2. Our maturity matrix is also largely unchanged and is in current use as a measure of how boards are performing in terms of patient safety. We have however updated this with the patient involvement and feedback dimension.

5. Governing for safety: Designing systems and managing behaviour

Board safety reporting

Patient safety incidents, as described by the National Reporting and Learning System (NRLS), are any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving NHS-funded healthcare[70]. Boards of NHS organisations have a critical role to play in assuring quality and safety across their respective organisations and for driving quality improvement. However, it is always a challenge for boards to have complete oversight across complex organisations, such as healthcare organisations, of the resilience of patient safety. In addition, it is important that boards do not focus only on negative or problematic issues but aim to disseminate positive messages and best practice with regards to patient safety and incident reporting.

The NRLS notes that there is an emerging evidence base of a stronger culture of patient safety within NHS organisations whose incident reporting rates are higher. This is likely due to the emphasis placed by such organisations on learning from incidents in order to nurture safer patient care. Indeed, data published by NHS England in September 2015 shows a 6% increase in the number of incidents reported compared to the same six-month period during the previous year[71].

When using safety data, it is important to ensure that decisions are informed by reference to agreed indicators and patient safety data and to set up robust internal processes and good governance structures.

We have identified a number of key challenges:

- **Challenge**: Treat "good news" reports with as much scrutiny and challenge as negative ones
- **Challenge**: Approaching data in new ways

Good practice example – Salford Royal NHS Foundation Trust

The Salford Royal NHS Foundation Trust has placed patient safety at the heart of their current Quality Improvement Strategy. 97.9% of patients treated at Salford Royal receive harm-free care as measured by the Safety Thermometer[72]. From the introduction of a daily 'safety huddle' in all teams including a safeguarding team, an end of life care team and an infection control team to discuss patients at risk, to innovative mobile technology use to enable quicker updates of patient records, Salford Royal has embraced a holistic and resourceful approach to improve patient safety.

The achievement of a 38% reduction in pressure ulcers from bedded units; a 52% reduction in in-patient falls; and a 44% reduction in catheter associated urinary tract infections, exemplify the comprehensive improvement of patient safety across the organisation. On-going training through Salford Royal's Clinical Quality Academy programme that aims to educate senior leaders and clinical staff in quality improvement methods has been key to implementing the Quality Improvement Strategy throughout the organisation[73].

To facilitate a more integrated approach to patient safety across the provision of hospital, community and primary care, Salford Royal introduced Datix patient safety software to centralise patient data. This change to a robust technology has played a key role in mitigating risks to secure patient safety[74]. This illustrates the importance of improving data quality that has to complement a change in culture and practice as well as the adherence to clinical audit procedures to achieve better patient safety.

The below extracts detail the views of prominent stakeholders in the area of board safety reporting:

Fleur Nieboer,

Director NHS Audit, KPMG UK

CCGs must set up good governance structures on reporting. If the correct reporting structures are not there, the organisation will not be able to commission.

Dr Linda Patterson OBE FRCP,

Clinical Vice President, Royal College of Physicians

Boards must understand and learn from data about clinical care e.g. audit and outcome data, mortality data, patient feedback and complaints or clinical incidents. This must be done in a systematic way, with non-executives having an understanding of and confidence in the process.

Charles Vincent,

Professor of Clinical Safety Research, Imperial College London

Measurement of safety

Patient safety has been high on the national and international agenda in healthcare for almost a decade. In Britain case record reviews have shown that over 10% of patients suffer an adverse event in an inpatient setting, a figure recently confirmed in 2007, and reflected in similar studies around the world. Considerable efforts have been made to improve safety and it is natural to ask whether these efforts have been well directed. Are patients any safer? The answer to this simple question is curiously elusive. While some aspects of safety are difficult to measure for technical reasons (defining preventability for instance) the more substantive problem is that, for all the energy and activity, measurement and evaluation have not been high on the agenda. We believe in fact that the lack of reliable safety and quality information is hindering safety improvement across the world (Vincent et al, BMJ 2008).

Peter Walsh

Chief Executive,
Action against Medical Accidents (AvMA)

"Early Warnings, a report on Patient Safety priorities for boards"

Board members should see their role as keeping the organisation focussed on maintaining and improving the quality of its service to patients and patient safety above all else. To do this effectively board members need to be prepared to challenge constructively when necessary to get the assurances they need that they have the information necessary to judge how the organisation is performing. They should avoid the temptation to join in self-congratulation and be on the lookout for any complacency. It is not the job of a board member to be a cheerleader for the organisation or its staff. It is perfectly possible, and indeed preferable, to assume the worst until assured otherwise but still to give credit where it is due. A good test to apply is to ask for evidence that staff and patients have been consulted and agree with the conclusions of authors of reports. In particular, board members should ask to see information about incidents, complaints and claims against the organisation in sufficient detail to be able to judge whether the issues behind the incident have been adequately considered and acted upon.

David Dalton

Chief Executive, Salford Royal FT:

"Leaders must be confident enough to expose their systems to challenge and test their systems for resilience."

Nick Atkinson

Partner, Baker Tilly Risk Advisory Services LLP:

"Traditionally, boards get a lot of report information such as incident reports, complaint reports, etc. Boards need to be cleverer about how they ask for the information in order to find where their issues are, which may be a combination of indicators together. They may need to look at a number of indicators across a service line or department. Boards have thousands of indicators to monitor, the question is how do they use the information they have to find the areas that need improving?"

Improving quality and engaging clinicians

NHS organisations, together with individual clinicians, are encountering increasing pressure to produce measurable quality and safety improvements. Whilst healthcare professionals undoubtedly strive to deliver the best care for patients, achieving clinical engagement in change and support amongst healthcare professionals towards quality improvement initiatives can at times be challenging. We need to accept that the place for service innovation and indeed service improvement is the clinical workplace and that it is therefore crucial to cultivate a strong culture of engagement amongst staff. Clinical teams perform best when they feel valued and supported by their leaders. It is important therefore to identify the skills and knowledge of staff and to consider what staff need from the organisation to rise to this challenge of improving quality and patient safety.

The below extracts detail the views of prominent stakeholders regarding clinical engagement:

David Dalton

Chief Executive, Salford Royal FT

"As Chief Executive of an organisation striving to provide highly reliable and safe services to its patients, I attach importance to the following: deep engagement and involvement of staff and patients to build their capability to generate ideas and test those ideas to see if a change in practice results in an expected improvement."

Amanda Green

Principal Consultant, Cognisco

"Boards should have an idea of the knowledge, understanding and confidence levels of their floor staff. Staff should know what to do when something goes wrong; how to report it, confidence to act, and confidence to push upwards and backwards when they believe it is right. Boards should be aware of the barriers that the staff may have to reporting (to whom, when, etc.)"

Paul Barach

MD, MPH, Visiting Professor, University College Cork, Ireland.

"Engaging and partnering with clinicians remains one of the biggest obstacles in addressing the growing implementation gap in providing cost effective, and quality care in NHS. Several have identified physician discontentment and lack of engaged physicians as a challenging area... Innovation is best designed by listening to those on the front lines of health-care delivery — patients and clinicians. Physician involvement is key to lead, facilitate, and participate in accelerating the adoption of new care models. There is an urgent need to build a ground up capacity to make sense of the complexity in care. There is an acute need to grasp at the bureaucratic level the importance of local clinical perceptions in making sense of the clinical workplace. Knowing the clinical workplace, attending to what clinicians value and hold dear to their hearts, and making sense of what needs to be done, are key to meaningful and sustained healthcare improvement."

Supporting staff to be safe

NHS provider organisations have a responsibility to deliver good quality training and education to staff in order to ensure the delivery of high quality and safe patient care. The Professional Standards Authority sets standards for members of NHS boards and CCG governing bodies in England[40]. Within these, it is stated that members have a duty to ensure that effective procedures are in place for whistleblowing and complaints and that members are responsible for addressing and learning from harmful behavior, misconduct or systems weakness as well as for raising any concerns identified, for example, with regards to wrongdoing or poor practice.

Effective leadership is crucial to the delivery of high-quality care and plays a critical role in ensuring patient safety. Clinical leaders must encourage and support their staff in always being truthful with patients and their families – and lead by example. Ensuring that all staff understand both why and how to adhere to the statutory duty of candour is critical to the improvement of patient safety and experience.

Dr Umesh Prabhu, Medical Director of Wrightington, Wigan and Leigh Foundation Trust, describes the importance of the duty of candour below:

Duty of Candour

"It is very important that we always tell the truth, the whole truth and nothing but the truth to our patients and their families when things go wrong and patients are harmed. We owe it to our patients not only to tell the truth but also to learn lessons.

In our Trust, the Nurse Director and I go through all complaints, litigation, Coroner's inquests and feedback, SUI and clinical incidents every week and we have clearly defined actions on all of them.

If any patient has suffered then the Chief Executive, the Medical Director and the Nurse Director meet with the family to apologise and explain what went wrong and why and what actions will be taken. If the patient is seriously harmed then we usually ask for an outside expert opinion and the family gets a copy of these reports.

These meetings are often challenging and at times emotionally draining but it is important that we do meet the family and tell them the truth. There are times where we had to meet the family two or three times.

By going through weekly complaints, litigation, Coroner's feedback, SUI and clinical incidents, I have identified seven doctors who were repeatedly rude to patients, junior doctors not being supervised, DNAR applied without informing the family and so on. I have personally met all these doctors and they have all changed and there have been no further complaints. It is all about dealing with concerns early and nipping it in the bud. Most doctors and nurses want to do a good job and are more than willing to change their behaviour if only we tell them about these at an early stage. If not then it becomes an entrenched behaviour which some doctors find difficult to change or modify. It is they who pose risk to our patients and to our Trust."

Listening leaders

It is important that leaders of NHS organisations demonstrate strong patient-centred leadership through showing that they are giving sufficient priority to care quality and patient safety. This could involve, for example, taking the time to personally speak and listen to feedback from patients, relatives and their families as well as from staff, responding to feedback received and learning from complaints. Leaders and members must be visible in wards and departments and focus must be given to closing any existing gaps between clinicians and management.

Dr Linda Patterson

OBE FRCP Clinical Vice President, Royal College of Physicians

"It is important for board members to have front line presence and visibility, to meet front line nurses and doctors, and to have a mechanism for hearing concerns and feedback from consultants and junior doctors."

David Dalton

Chief Executive, Salford Royal FT

"High visibility of leaders throughout the trust enables them to gain situational awareness of what's happening at ward and departmental level."

Recommendations - Governing for patient safety

Improving care quality and patient safety is the focus of NHS organisations nationally. The following recommendations made in this report have been categorised under the below headings:

a) Incident reporting and management
b) Board reports and debate
c) Director induction, training and continuing development
d) Governance structures and risk expertise
e) Governance activities
f) Finance and Commissioning
g) Governance between organisations and partnerships
h) Whistleblowing
i) National recommendations

Incident reporting and management

- All NHS, private and third sector providers of health and social care services should have in place electronic incident reporting and management systems that are easily accessible for everyone in the organisation in real time.
- Organisations should be able to monitor incident reporting by having access to information on the current stages of all incidents in the incident management process. Commissioners should be able to report incidents directly to providers.
- Patients should have the means to report incidents without needing to resort to the complaints process.
- Organisations should ensure that details of an adverse event or a near miss are communicated to the referring clinician. Patient data should follow the patient and patient safety data should be shared across the local healthcare system.
- Incident reporting systems should be flexible and able to relate to other systems that control risk reduction and safety improvement mediations, such as training, continuing professional development, revalidation, credentialing and appraisals.
- Incident reporting systems should be linked, directly relating to the risk register and Board Assurance Framework.
- Organisations should use a range of appropriate incident investigation methods, not over-relying on any one approach alone. Specialist risk management staff and others (for example, clinicians) involved in incident investigation should have access to a range of training, where possible from different training providers.
- Investigation reports should be subject to systematic quality review processes.
- An independent national patient safety investigation body should be established to oversee these processes and be able to conduct major independent investigations itself when necessary.
- Investigation reports should be written in plain English and understandable by lay persons as well as risk specialists and clinicians.
- Incident reporting patterns should point the way for clinical audit programmes.
- Management should triangulate information arising from adverse event and near miss reporting with other information, such as complaints, inquests, and claims, clinical audit and care pathway variations. Clinical audit is used strategically to provide assurance on board priorities

Board reports and debate

- Boards should consider patient safety at every board meeting.
- Standard board reports should answer:

  – do we effectively and comprehensively manage those incidents that occur?
  – does our pattern of incidents and near-misses inform us of a special cause quality problem?
  – are we reducing harm to patients, and resources wasted by failure?
  – are we systematically instituting practices known to reduce harm and promote safer care?
  – do we have an open and just culture of safety?

- Boards should integrate safety, financial and activity reporting in reports.
- All cost Improvement Plans should consider possible effects on patient safety.
- Board reports should be statistically sound and explain variations in terms of whether or not these are within expected bounds.
- Boards should be receiving qualitative as well as quantitative reports on patient safety issues.
- Boards should decide on the means by which they understand the extent, nature and trajectory of harm, costs and waste caused by errors within their organisation.
- Boards should set and systematically monitor progress towards their own improvement targets for patient safety. These should be ambitious and communicated to staff, commissioners and the local community.
- Boards should understand their own exposure to risk at any given time and monitor how this changes over time.
- Boards often focus too much on individual serious incidents (SIs) and should systematically consider lower level but often more revealing patterns of adverse events and near misses.

Director induction, training and continuing development

- All directors should receive awareness training to help them properly understand patient safety and risk in a healthcare context.
- Director training should include the epidemiology of patient safety, the scale and costs of adverse events, factors that influence organisational safety, organisational culture and effective patient safety mediations, understanding statistical process control and other quality management methodologies and leadership of patient safety.
- All board members should understand and be able to explain the significance of patient safety, national and local systems for safety and risk and their own organisation's safety improvement approach.
- There should be greater clarification as to what the governance (as opposed to management) role in patient safety is.
- All boards should routinely receive information about serious service failures in other organisations which may affect their own services, the approach of regulators or other significant compliance issues.
- Board members should understand the range of investigation methods used in their own organisations.
- Board members involved in any form of incident investigation or review should have access to training, especially when leading quasi-legal investigations or proceedings

Governance structures and risk expertise

- All organisations should have governance systems and structures that enable the board to be properly assured on safety and risk issues. These should be periodically tested using walkthrough or scenario exercises.
- Patient safety reporting should be linked systematically to the risk register and Board Assurance Framework.
- The risk register and Board Assurance Framework should recognise risks at the interface with partners and suppliers, that can also cause reputational risk.
- In all organisations there should be a multi-disciplinary management group systematically reviewing incidents, near-misses, complaints and other indications of process failures and interpreting these for trends, special causes and patterns to routinely advise the board.
- The Walker Report[75] raised the debate around whether boards should have a risk committee. Further thinking needs to be done on whether healthcare organisations should have a risk committee alongside the audit committee to better understand the risks and control of risk within the organisation. One Foundation Trust Chairman described the audit committee as focusing on the past and present and the risk committee as looking into the future.
- Boards should agree and publish their risk appetite for each of their strategic objectives.

Governance activities

- The board's own annual review should consider the treatment of safety issues.
- The audit committee should assure the board that the organisation's patient safety system is reliable and fit for purpose.
- The Chair's annual appraisal of all directors should include assurance that directors fully understand their role in patient safety and that all directors actively contribute to safety and risk issues.

Finance and commissioning

- Patient safety should be used as one means by which organisations understand waste within their systems and processes.
- Both commissioners and providers should have plans in place to understand the global value of those episodes of care associated with an adverse event. Any partnership or contract needs to deal explicitly with responsibility and liability and be reviewed as part of the contract.
- Patient care episodes associated with an adverse event should automatically be included in the monthly challenge list and fed into CQUIN discussions between commissioners and providers.
- Contracts should encourage the sharing of information about patient safety, and specify responsibilities and liabilities.
- Patient safety data should be shared between providers and commissioners with the aim of improving safety. Commissioners should use this data responsibly and avoid penalising providers exhibiting a transparent and open approach to patient safety.

Governance Between Organisations (GBO)[76] and partnerships

- All boards should have a means of understanding and engaging with risks and safety issues at the boundaries of care and at handover points.
- Any partnership arrangements should have in place a pre-agreed system for incident reporting and risk management and review.
- The governing bodies on all partner arrangements should have access to information on reported incidents and near misses.
- Boards cannot outsource reputational risk. Partnership arrangements should routinely include prospective plans for reporting, managing, investigating, reviewing, resolving and taking action on serious untoward incidents.
- Recording systems must ensure that the referrers and external (e.g. joint or specialist) commissioners of patients receive feedback on adverse events affecting the patients referred.

Whistleblowing

- Organisations should have methods and processes for whistleblowing in place that staff can trust.
- Organisations should have clear channels of reporting concerns and opportunities not to share these with their line manager.
- Whistleblowing arrangements should be organised so that staff can report incidents without revealing who they are.
- All boards should identify a Senior Independent Director (SID) who should have a role in local whistleblowing arrangements.

National recommendations

- Recognising that responsibility rests with the boards of healthcare organisations, there should nonetheless be a national body focusing on patient safety.
- This body should have the ability to receive whistleblowing concerns and have the power to investigate individual issues. It should also set standards, ensure adequate training, learning from the NRLS, and help organisations with investigation.

Appendix 1

Key patient safety reports

- Berwick review into patient safety
  https://www.gov.uk/government/publications/berwick-review-into-patient-safety

- Mid Staffordshire NHS Foundation Trust Public Inquiry (Francis Report)
  http://www.midstaffspublicinquiry.com/report

- Early warning seven step quality framework from High Care for All
  http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_085828.pdf

- Quality in the new health system - Maintaining and Improving Quality from April 2013
  https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213304/Final-NQB-report-v4-160113.pdf

- Complaints Handling in NHS Trusts signed up to the CARE campaign. (Patients Assoc)
  http://www.patients-association.com/Portals/0/Complaint handling in NHS Trusts signed up to the CARE campaign_Jan_2013.pdf-

- Complaints and Raising Concerns (Health Committee report, 2015) http://www.publications.parliament.uk/pa/cm201415/cmselect/cmhealth/350/35002.htm

- Getting to grips with human factors – strategic actions for safer care (Clinical Human Factors Group)
  http://chfg.org/articles-films-guides/guidance-documents/a-new-human-factors-resource-for-boards-from-the-chfg

- Review into the quality of care and treatment provided by 14 hospital trusts in England (Keogh review)
  http://www.nhs.uk/NHSEngland/bruce-keogh-review/Documents/outcomes/keogh-review-final-report.pdf

- External Inquiry into the adverse incident that occurred at Queen's Medical Centre, Nottingham (Toft report)
  http://www.who.int/patientsafety/news/Queens Medical Centre report (Toft).pdf

- Investigating clinical incidents in the NHS (Public Administration Select Committee, March 2015)
  http://www.publications.parliament.uk/pa/cm201415/cmselect/cmpubadm/886/886.pdf

Reference

1. GGI (2010) "What Every Healthcare Board Needs to Understand About Patient Safety" http://www.good-governance.org.uk/what-every-healthcare-board-needs-to-understand-about-patient-safety/
2. Nightingale, Florence (1974) [First published 1859]. "Introduction by Joan Quixley". In …. Notes on Nursing: What it is and what it is not. Glasgow & London: Blackie & Son Ltd. ISBN 0-216-89974-5
3. Vincent, C. (2010) 'Patient Safety 2nd edition' BMJ Books Wiley Blackwell
4. Kohn, L., Corrigan, J. and Donaldson, M. (editors) (1999), 'To Err Is Human: Building a Safer Health System', Institute of Medicine
5. Weick, K. and Sutcliffe, K. (2001) 'Managing the Unexpected: Assuring High Performance in an Age of Complexity'
6. Nightingale, F. (1863) 'Notes on Hospitals (3rd edition)'
7. Imperial College London, Centre for Patient Safety and Service Quality (CPSSQ), https://www1.imperial.ac.uk/cpssq/about_cpssq/ (last accessed 16.11.15)
8. Vincent C. (2010)Patient Safety, 2nd edn. Oxford: Wiley Blackwell;
9. Smith, R. (1998) 'All changed, changed utterly: British medicine will be transformed by the Bristol case', BMJ 316:1917
10. Scally, G. and Donaldson, L. J. (1998) 'Clinical governance and the drive for quality improvement in the new NHS in England' BMJ 61-65
11. NHSLA Factsheet 2: financial information (2015): http://www.nhsla.com/currentactivity/Documents/NHS%20LA%20Factsheet%202%20-%20financial%20information%20-%202014-15.pdf
12. NRLS Quarterly Data Summaries (September 2015) http://www.nrls.npsa.nhs.uk/resources/collections/quarterly-data-summaries/
13. Best, M. and Neuhauser, D. (2004) Ignaz Semmelweis and the birth of infection control Qual Saf Health Care; 13:233-234
14. Hartley, N. (2013) 'Transparency and Honesty: A Whistleblower's Story'
15. Department of Health (2013) 'A Promise to Learn- a Commitment to Act' https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf
16. Professor Sir Bruce Keogh (2013) 'Review into the quality of care and treatment at 14 hospital trusts in England'
17. Department of Health (February 2015) Culture Change in the NHS: Applying the lessons of the Francis Inquiries
18. My NHS: Data for better services, https://www.nhs.uk/service-search/performance/search (last accessed 16.11.15)
19. Health Foundation (based on 99 responses to a survey led by the Health Foundation, Monitor and the NHS Trust Development Authority in 2014), http://www.health.org.uk/node/130
20. Berwick D. (2013) A Promise to Learn – a Commitment to Act. Improving the Safety of Patients in England https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf
21. Francis, R. (February 2015) Freedom to speak up: An independent review into creating an open and honest reporting culture in the NHS
22. Kirkup, B. (March 2015) The Report of the Morecambe Bay Investigation, https://www.gov.uk/government/publications/morecambe-bay-investigation-report
23. NHS England, Patients safety collaboratives, https://www.england.nhs.uk/patientsafety/collaboratives/ (last accessed 19.11.15)
24. Cook RI, Render M & Woods DD (2000) 'Gaps in continuity of care and patient safety', British Medical Journal 320: 791-94
25. Department of Health (June 2015), Government announces Monitor and Trust Development Authority move to single leadership to deliver increased support to hospitals, https://www.gov.uk/government/news/government-announces-monitor-and-trust-development-authority-move-to-single-leadership-to-deliver-increased-support-to-hospitals

26. NHS Commissioning Board (2013) 'Serious incident framework'
27. National Reporting and Learning System, http://www.nrls.nhs.uk/ (last accessed 24th May 2015)
28. House of Commons Public Administration Select Committee (2015) 'Investigating clinical incidents in the NHS' http://www.publications.parliament.uk/pa/cm201415/cmselect/cmpubadm/886/886.pdf (last accessed 24th May 2015)
29. Department of Health (24th August 2015 – 31st October 2015), Independent Patient Safety Investigation Service Expert Advisory Group – Call for Evidence
30. European Patients Forum, www.eu-patient.eu (last accessed 24th May 2015)
31. Williamson, J. and Durkin, M. (2014) 'Patient safety collaboratives: Innovating to tackle the leading causes of harm to patients' (http://www.kingsfund.org.uk/sites/files/kf/media/janet-williamson-patient-safety-collaboratives-mar14.pdf (last accessed 24th May 2015)
32. Social Media Pioneers, http://www.hsj.co.uk/Journals/2014/05/28/p/d/x/Social-Media-Pioneers-supplement.pdf (last accessed 24th May 2015)
33. http://www.medicalprotection.org/uk/your-practice-september-2012/patient-safety-and-social-media (last accessed 24th May 2015)
34. NHS Litigation Authority, Archives, Standards and Assessments, http://www.nhsla.com/Safety/Pages/HelpfulTools.aspx (last accessed November 2015)
35. NHS LA, Safety and Learning : Part 1 Board meeting March 2014
36. NHS Litigation Authority, Improving patient and staff safety, http://www.nhsla.com/safety/pages/home.aspx (last accessed November 2015
37. NHS England (March 2015), Revised Serious Incident Framework: Supporting learning to prevent reoccurrence
38. NHS Outcomes Framework 2013-2014 https://www.gov.uk/government/.../nhs-outcomes-framework (last accessed 24th May 2015)
39. NHS Improving Quality, http://www.nhsiq.nhs.uk (last accessed 20.11.15)
40. Professional Standards Authority (November 2012) Standards for members of NHS boards and Clinical Commissioning Group governing bodies in England, http://www.professionalstandards.org.uk/docs/psa-library/november-2012---standards-for-board-members.pdf?sfvrsn=0
41. Whistleblowing for employees (last updated July 2015) https://www.gov.uk/whistleblowing/overview (last accessed 24th May 2015)
42. Hunt, MP, R. (2014). Sign Up To Safety- The path to saving 6,000 lives. Speech, Virginia Mason Hospital
43. Royles, D. (2014) 'We need a new language around whistleblowing' Health Service Journal, http://www.hsj.co.uk/comment/we-need-a-new-language-around-whistleblowing/5069175.article#.VXYKq2RViko (last accessed 6th June 2015)
44. Department of Health (July 2015), Learning not blaming: The government response to the Freedom to Speak Up consultation, the Public Administration Select Committee's report Investigating clinical incidents in the NHS and Dr Bill Kirkup's report on failings in care at Morecambe Bay
45. Patients First (June 2013) Submssion to the Whistleblowing Commission http://www.chfg.org/wp-content/uploads/2013/07/Whistleblowing_Commission_submission__Final_-2.pdf
46. Patients First (2014) 'The freedom to speak up review. Sir Robert Francis QC – Submission by Patients First'
47. Department for Health (2013) 'Report of the Mid Staffordshire NHS Foundation Trust public inquiry'
48. HSCIC, Summary Hospital-level Mortality Indicator (SHMI) – Deaths associated with hospitalization (April 2014-March 2015) http://www.hscic.gov.uk/searchcatalogue?productid=19144&q=title%3a%22Summary+Hospital-level+Mortality+Indicator+(SHMI)%22&sort=Relevance&size=10&page=1#top
49. Monitor (2015) 'Well-led framework for governance reviews: guidance for NHS foundation trusts'
50. NHS Confederation (2014) 'How Monitor, CQC and the NHS TDA will work to assess how well led organisations are'. http://www.nhsconfed.org/resources/2014/06/working-together-to-develop-an-aligned-framework-for-judging-well-led-organisations (last accessed 6th May 2015)
51. Monitor (2015) 'Risk assessment framework'
52. Monitor, Care Quality Commission and NHS Trust Development Authority (2014) 'How Monitor, the Care Quality Commission and the NHS Trust Development Authority will work together to assess how well led organisations are'. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/312990/Well-led_

framework_statement_of_intent_1_.pdf (last accessed 6th May 2015)
53. NHS Trust Development Authority (2014) 'Integrated Planning Checklist 2014/15: Quality'. http://www.ntda.nhs.uk/wp-content/uploads/2013/12/PLANNING-Quality-37-Supporting-a-Well-Led-Organisation.pdf (last accessed 16th May 2015)
54. NHS England (November 2014), Next steps towards primary care co-commissioning
55. NHS England and NHS Clinical Commissioners (November 2014), Next steps towards primary care co-commissioning https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2014/11/nxt-steps-pc-cocomms.pdf
56. Lacobucci, G (November 2015), General practice commissioning: in whose interests? http://www.bmj.com/content/351/bmj.h6000
57. NHS England (December 2014), Managing conflicts of Interest: statutory guidance for CCGs
58. NHS Five Year Forward View (October 2014) https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf
59. NHS England, New care models –Vanguard sites https://www.england.nhs.uk/ourwork/futurenhs/new-care-models/ (last accessed November 2015)
60. NHS England, Enhancing the quality of life for people living with long term conditions –The House of Care https://www.england.nhs.uk/house-of-care/ (last accessed November 2015)
61. National Patient Safety Congress in May (2012) www.patientsafetycongress.co.uk (last accessed 6th June 2015)
62. Marx, David (2009) Whack–a–Mole: the price we pay for expecting perfection By Your Side Studios, Texas
63. Lucien Leape Institute (2013) Through the Eyes of the Workforce: Creating Joy, Meaning, and Safer Health Care National Patient Safety Foundation
64. 'Handoffs and Patient Safety (2014) Grasping the Story and Painting a Full Picture', Western Journal of Nursing Research http://wjn.sagepub.com/content/early/2014/06/19/0193945914539052.full (last accessed 6th June 2015)
65. GGI (2014) 'Board Assurance Prompt – quality schemes in healthcare providers for better commissioning' http://www.good-governance.org.uk/board-assurance-prompt-quality-schemes-in-healthcare-providers-for-better-commissioning/ (last accessed 6th June 2015)
66. Department of Health (2008) High quality care for all: NHS next stage review final report
67. GGI Good Governance Handbook in collaboration with HQIP (January 2015)
68. The Nolan Principles: The Seven Principles of Public Life https://www.gov.uk/government/publications/the-7-principles-of-public-life
69. Monitor (March 2015), Survey of NHS foundation trust governors 2014/15
70. National Reporting and Learning System, Report a patient safety incident, http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/
71. NHS England (September 23 2015), Health and high quality care for all, now and for future generations https://www.england.nhs.uk/2015/09/23/patient-safety-reporting/
72. Salford Royal NHS Foundation Trust (2014) 'Quality Accounts 2013-2014' http://www.srft.nhs.uk/media-centre/publications/annual-reports-and-reviews/?assetdet104846=33004
73. Salford Royal NHS Foundation Trust (2013) Annual Report & Annual Accounts 2012-2013' http://www.srft.nhs.uk/media-centre/publications/annual-reports-and-reviews/?assetdet104846=23331
74. Salford Royal NHS Foundation Trust sets new standards in patient safety using Datix, http://www.datix.co.uk/news-and-events/news/salford-royal-nhs-foundation-trust-sets-new-standards-in-patient-safety-using-datix/
75. Sir David Walker, Walker Review of Corporate Governance of UK Banking Industry, HM Treasury 2009
76. Governance Between Organisations (GBO) A debate paper launched at NHS Confederation Conference 2008 and published by IHM

www.good-governance.org.uk