“Underpinning a culture of safety are good leadership at all levels, strong governance within the service and a culture of openness and transparency”

Care Quality Commission (2017)
Chapter 7

Safety, clinical audit and clinical governance during major change

Safety is a powerful driver of improvement in any healthcare organisation.

Any change is risky and it is necessary to keep services safe while implementing change.

Good governance and audit are essential and the interface with culture cannot be underestimated.

Current situation

The main duty of all NHS service providers is to provide high quality care. Safety of people who use services is one of the main elements of quality, alongside clinical effectiveness and the experience of the people who use care. Specifically, service providers are required to avoid causing:

“... unintended or unexpected harm to people during the provision of healthcare. Patients should be treated in a safe environment and protected from avoidable harm” (NHS Improvement 2017).

Safety of people who use services is currently a pressing national concern. The level of ambition is high: the Secretary of State for Health aspires for the NHS to be the “safest, highest-quality healthcare system in the world” (Hunt, 2017).

This aspiration is reflected in a variety of current national initiatives to improve safety of people who use services. The risks are high too. The World Health Organization argues that health services today operate in such a complex, fast-moving and pressurised environment, things can frequently go wrong (WHO 2017).

Safety of those who use services is naturally a constant concern for mental health service providers and their staff. They have clinical governance systems to assure people who use services, carers, families, staff and external stakeholders that their services fulfil their duty to provide effective and safe care.

Clinical audit forms the backbone of clinical governance systems in most health service providers today. The main tasks of clinical audit procedures are to establish whether services are being reliably delivered to the required quality standard and, if not, to help improve them. Successful clinical audits collect the relevant data, analyse and understand it, and use it to inform improvement. So they are similar in principle to the structured approaches to quality improvement in Chapter 6, notably the Juran quality management model.

However, there are differences. For instance, clinical audits are often carried out by specialised teams rather than those providing services day to day who are involved in structured improvement approaches. And improvement approaches go beyond making sure services comply with set standards. They build the capability of everyone in an organisation to understand precisely how the way they do their work collectively affects quality, so together they can take actions to improve quality with no upper limit. From this perspective, improvement approaches can be viewed as complementing clinical audit procedures, and in some trusts the two are beginning to merge.

That said, introducing a systematic, devolved approach to improvement can place pressure on existing governance systems and disrupt lines of accountability. In response, trusts need to adapt their audit and quality control processes in a planned fashion over the course of a trust-wide programme to create capacity for improvement.

National initiatives for the safety of people who use services

NHS Improvement provides national leadership for the safety of people who use services across the NHS. From this organisation’s perspective, the safety of people who use services is ensured by an NHS:

• that openly and transparently identifies and acts on risks to people who use services
• that demonstrates a just culture
• where the whole system works to reduce incidents that threaten the safety of people who use services and individuals are not inappropriately blamed
• where there is openness with people who use services, carers and families when things go wrong
• where staff, people who use services, carers and families are empowered to identify where change is needed and are supported to act
• that recognises where co-ordinated and systemic action is needed to keep people who use services safe.

Specific national initiatives promoting the safety of people who use services include:

Duty of candour (2014)

This duty gives health providers a legal responsibility to “inform and apologise to the patient if there have been mistakes in their care that have led to significant harm” (NHS Litigation Authority, now NHS Resolution, 2017).

The Parliamentary and Health Service Ombudsman

(PhSO) makes final decisions on complaints that have not been resolved by the NHS in England and UK government departments, and some other UK public organisations. PhSO is independent of Government and NHS. PhSO looks into complaints where an individual believes there has been injustice or hardship because an organisation has not acted properly or fairly, or has provided a poor service and not put things right. People normally have to complain to the organisation first so it has a chance to put things right. If an individual believes there is still a dispute after an organisation has responded, they can ask PhSO to look into the complaint. PhSO share findings from its casework with Parliament to help it hold organisations that provide public services to account, and it shares these findings more widely to help others drive improvements in public services.

The findings and recommendations from PhSO investigation reports provide an opportunity for NHS trusts to become learning organisations, by drawing the lessons where things have gone wrong, as well as working towards building trust with people who use services. Such as Maintaining momentum: driving improvements in mental health care (2018).

Sign up to Safety (2014)

Launched by the Secretary of State, the Sign up to Safety campaign was devised to “bring organisations together behind a common purpose” (NHS England 2017). It involves more than 500 organisations from the NHS and other sectors.

www.ombudsman.org.uk
Freedom to speak up: whistleblowing policy for the NHS (2016)

Produced for the NHS by NHS Improvement on the recommendation of Sir Robert Francis QC, this policy supports the NHS to develop a more open culture that enables staff to raise concerns or issues relating to the care of people who use services, quality or safety. The areas covered include:

- unsafe care of those who use services
- unsafe working conditions
- inadequate induction or training for staff
- lack of, or poor, response to a reported safety incident relating to people who use services
- suspicions of fraud (which can also be reported to NHS Improvement’s local counter-fraud team)
- a bullying culture (across a team or organisation rather than individual instances of bullying).

Carter Review (2016)

Lord Carter was asked to review productivity and performance in English acute hospitals by Secretary of State Jeremy Hunt, as part of his aim to make the NHS the safest and most efficient healthcare system in the world. The review found examples of trusts that “had clearly got a stronger grip on the management of their resources than their peers”. A number of these were able to achieve “both high quality CQC ratings and [high efficiency] scores, indicating that high quality care and efficient care are not mutually exclusive” (Carter 2016, page 57). Lord Carter’s review also looked at healthcare systems abroad, including the US, Germany, Australia, Italy and France, where hospitals have a greater focus on efficiency because they have established the clear link between efficiency and care of people who use services (Department of Health 2016).

Governance in healthcare organisations

The boards of provider organisations are responsible for all aspects of leadership, direction and control of their organisations. They are expected to carry out this responsibility effectively, and demonstrate they have done so through measurable outcomes that build the confidence of people who use services, public and stakeholder confidence that their trusts are providing high quality, sustainable care.

Trusts operate in increasingly challenging environments, as recognised in the national framework for action on improvement and leadership development in NHS-funded services (NILD 2016). The challenges they face require their leaders to change how they equip and encourage people at all levels to continuously improve local health and care systems and gain pride and joy from their work.

Robust governance processes should give the leaders of organisations, those who work in and those who regulate them confidence about future capability to maintain and continuously improve the services the organisations provide. Effective governance systems give early visibility of risks that may compromise individual care, wider services or sustainable systems as well as insight into how to manage such risks.

Robust governance and effective, compassionate leadership are important drivers of improvement in quality of care. CQC has found effective leadership and clear, embedded governance systems to be key drivers of improved ratings (CQC 2017). By the same token, weak governance can have a detrimental effect on care quality (Francis 2013) and is among the main contributors to inadequate CQC ratings (CQC 2017).

Providers that have clear systems and governance enable learning and improvement from safety incidents. They encourage staff to raise concerns. They also allow staff to initiate innovation. Governance structures that enable local decision-making in this way form one of the main building blocks of an overall culture of continuous improvement (NILD 2016).

In-depth and regular reviews of leadership and governance are good practice across all industries (NHS Improvement 2017).

Current thinking

On clinical governance

The Department of Health and Social Care (previously Department of Health) describes clinical governance as:

“The system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which clinical excellence will flourish”


After the Department of Health and Social Care first used this definition in its 1999 circular, Clinical governance: quality in the new NHS, much work was done to specify the elements of a clinical governance system that could both assure quality and improve it. The results, known as the seven pillars of clinical governance, are:

- people who use services, carer and public involvement
- clinical effectiveness
- clinical audit
- risk management
- training and personal/professional development
- use of information
- staffing and staff management.

On clinical audit as a tool of governance

Clinical audits have two aims: to interrogate services to identify where they are meeting, exceeding or may have fallen below required standards; and to enable services to plan and manage improvement. They therefore include cycles of re-audit to check that planned improvements are taking place. To achieve those two aims, clinical audits and re-audits need to collect data that measure what truly matters to the delivery of high quality care and the effectiveness of care pathways.

“To ensure that there is capacity for safety improvement, audit data should be carefully interpreted, and preferably triangulated and analysed alongside other relevant data.”

David Wood, Cheshire and Wirral Partnership NHS Foundation Trust

Clinical audits should give confidence to all a trust’s stakeholders that it has ways to monitor the care of people who use services and make a positive difference by flagging shortfalls in care delivery that may compromise safety of people who use services. Clinical audit also enables comparison with national standards, which are set on the basis of what is good for care for people who use services. Audits allow such comparisons to be made openly and transparently, as well as providing information to the public.

Routine audit information may need to be augmented by additional audits concerning particular issues. For example, enquiries into Serious Incidents usually include an audit of relevant care and service parameters and other factors so that lessons can be learned from the incident and disseminated for wider improvement. Ideally, such audits should reveal any areas of vulnerability that may compromise required standards of safety. Strengthening these areas should reduce risks to safety and the chance of a similar Serious Incident recurring. Such one-off audits following Serious Incidents require a deeper level of interrogation and scrutiny than is needed for regular, routine audits.
The pros and cons of clinical audit

As a tool for measuring care quality, clinical auditing is a sound methodology but has limitations (Berk 2003). For instance, an audit may show delays in clinical responses and long waiting times for people needing to use services and this data may give rise to concern that harm will come to those unable to access timely care. However, audits do not test the statistical significance of correlations. And while there may be a correlation between poor outcomes and long waiting times, the latter may not be the only factor behind poor outcomes that needs addressing. On the other hand, it is often necessary and sensible to set standards of care on the basis that certain practices are self-evidently poor, without statistically robust evidence. It is reasonable to proceed on this basis to improve clinical care (although it may be difficult to win some arguments in this way).

Much of the literature suggests that audits tend to prioritize measures indicating high risk, high volume or high cost problems, which in turn focus attention on specific points of care processes. But focusing on compliance with a narrow set of standards and long waiting times, the latter may not be the only factor behind poor outcomes that needs addressing. On the other hand, it is often necessary and sensible to set standards of care on the basis that certain practices are self-evidently poor, without statistically robust evidence. It is reasonable to proceed on this basis to improve clinical care (although it may be difficult to win some arguments in this way).

Convergence between clinical audit and improvement approaches

The two aims of clinical audits – to identify where services are meeting, exceeding or may have fallen below required standards, and to enable services to plan and manage improvement – are similar in principle to the aims of the improvement methodologies described in Chapter 6, in particular the Juran model of quality improvement or Juran trilogy. This is a widely recognised approach for sustainably assuring, maintaining and improving quality, used by organisations in many sectors and increasingly in healthcare. According to the model, an organisation needs three processes to manage quality: quality planning, quality control, and quality improvement.

Successful improvements in service quality depend on identifying metrics that provide a true and meaningful overview of the way a service currently operates and designing into the improved service the routine collection of data that accurately reflects how well and safely it is working. The metrics, routinely collected, need to be readily understandable and meaningful to the staff who use them daily to deliver the best care possible, by identifying stress points from the data, taking effective action and improving safe practice.

The Healthcare Quality Improvement Partnership (HQIP) is the national body responsible for the National Clinical Audit and Patient Outcomes Programme in England. HQIP reflects the better understanding now among some care providers of the relationship between clinical audit and service improvement. It notes that some hospitals now structurally align their service improvement and clinical audit functions (HQIP 2016). Professor Don Berwick has also recommended that people in healthcare organisations should be trained in improvement methodology (Berwick 2013).

“Safety is a continually emerging property, and the battle for safety is never ‘won’; rather, it is always in progress.”

Don Berwick, Resident Emeritus and Senior Fellow, Institute for Healthcare Improvement

Maintaining safety through audit and quality control processes while creating capacity for improvement

Maintaining core service delivery while building the capacity for continually improving services can be a major challenge for any organisation, and especially where resources are scarce.

Standard audit processes need to be kept to ensure continued quality control alongside planning for continuous improvement. But, as noted above, work to build continuous improvement capacity starts with collecting accurate and robust baseline data showing how current pathways and processes work and measuring change against this baseline. To collect meaningful data, understanding the true value and effectiveness of each element in a pathway as well as their interdependencies is critical. Gaining this understanding involves extra work and resources.

For instance, it is important to fully understand the skills of staff and how they are deployed, when and where. This entails precise data collection and analysis, often well beyond what is routinely collected in trusts. This work has resource implications. To illustrate, if workshops are used to gain this understanding, they will take up the time of skilled staff whose first priority is to continue to deliver their core function of directly providing services. So it takes careful planning to ensure care continues to be offered without compromising safety at the same time as trusts build their improvement capacity.

‘First do no harm’ is the imperative guiding all health services. Different organisations use different approaches to understand the full impact on people who use services of their service delivery. But the main plank for all is clinical governance, which is in constant need of strengthening.

Health services taking a systematic approach to improvement on a large scale can find maintaining safety and good governance throughout the process a particular challenge. Both must be carefully planned for services to pass through the transition safely and effectively and reach a new operating model with the capacity for continuous improvement built in. The goal must be to clearly understand and track measures truly relevant to safety and quality in the old and new model, so as to understand the impact of each change and improvement. Thus the next cycle of improvement can begin.
NHS Improvement’s Patient Safety Team

The Patient Safety Team in NHS Improvement provides national leadership for safety of people who use services across all healthcare sectors and performs two key statutory duties:

- collecting information about what goes wrong in healthcare, in part by operating the National Reporting and Learning System (NRLS) and
- using that information to provide advice and guidance “for the purposes of maintaining and improving the safety of the services provided by the health service”

The NRLS receives over two million incident reports a year, principally by uploading information that frontline staff have already reported to their local risk management systems (usually Datix or Ulysses). While most incident reports concern patient safety challenges that are well recognised, such as preventing self-harm, falls and medication error, the added value of collecting these nationally is that this enables identification of new or under-recognised patient safety issues that may not be obvious at local level. If these are identified, the team works with frontline staff, people who use services, professional bodies and partner organisations to decide if action is needed. You can find more information on this here: www.improvement.nhs.uk/resources/patient-safety-review-and-response-reports/

One of the key outputs is Patient Safety Alerts. These are sent to all relevant organisations and require them to take specific actions by a set deadline in order to protect people who use services. Alerts are developed with people who use services and clinicians to ensure they recommend actions to address problems in a practical way, but they fundamentally rely on good quality clinical governance systems to ensure the required actions are implemented effectively and sustainably. More information is available here: www.improvement.nhs.uk/resources/patient-safety-alerts/

Work is also underway to replace the NRLS with a new Patient Safety Incident Management System. More information is available here: www.improvement.nhs.uk/news-alerts/development-patient-safety-incident-management-system-dpsims/

Alongside the core functions of understanding patient safety, and providing advice and guidance on safety improvement, the national Patient Safety Team also works to support increased capacity and capability for patient safety improvement work across the NHS. The Patient Safety Collaboratives Programme delivered through the 15 Academic Health Science Networks, was established to support organisations to work together on their safety challenges, including in Mental Health care. More information is available here: www.improvement.nhs.uk/resources/patient-safety-collaboratives/

The team also support the development and implementation of patient safety policy. This includes setting out when and how organisations need to undertake full investigations of incidents, through the Serious Incident framework. This also covers work to prevent and respond to Never Events. Allied to these, the team is also supporting the healthcare system to improve how it responds to and learns from the care provided to people who die. More information on the Learning from Deaths programme is available here: www.improvement.nhs.uk/resources/learning-deaths-nhs/

Summary

This chapter shows that a structured approach to improvement supported by an open and just culture can make safer ways of working part of an organisation’s DNA. It recognises that organisations also need robust and transparent governance to keep services safe during major change.
References


NHS Litigation Authority (2017) www.resolution.nhs.uk/ [accessed December 2017]


Using the DASA tool to assess the risk of violence among psychiatric inpatients

Case study 43 - Safety, audit and continuous monitoring

Mersey Care NHS Foundation Trust

What was the problem?

Aggression and violence are common occurrences in inpatient settings for people with mental health problems, and resolving aggressive incidents a key task for staff. The trust wanted to help staff predict the likelihood of aggressive incidents so they could try to prevent them.

What was the solution?

Training staff in the psychiatric intensive care unit to use DASA-IV (Dynamic Appraisal of Situation Aggression – inpatient version), a structured risk assessment tool. It consists of a seven-item scale against which inpatients are rated daily. Those who score highly may require increased attention over the next 24 hours to reduce the potential for a serious violent incident. Research shows DASA predicts incidents of violence better than senior clinicians.

DASA scores are included in daily nursing handovers, enabling staff to plan interventions and strategies for the day and offer inpatients support when their scores are high. Staff can identify patterns and themes around behaviour and risk, which allows more effective planning and support. DASA is now used on five high secure wards, on medium and low secure wards and in general acute psychiatric wards. Recently staff have used it on an older person’s ward and psychiatric intensive care unit.

What were the challenges?

Implementing a new risk assessment tool when staff are already extremely busy is difficult: nurses’ attitudes, time and money for training were issues to resolve. The tool had to be easy to use and produce tangible results. Two clinicians developed a bespoke training module for nurses that was trialled on wards and modified to make implementation easier. Training, which lasts about an hour, takes place during handover periods, when two shifts are on site. The trust swapped paper for an electronic version of DASA to make inputting and collecting data easier. Ensuring nursing discussions included DASA was a significant challenge, overcome by embedding DASA scores in handover notes. Staff in general acute psychiatric services had limited time to complete the documentation, but after discussions about DASA’s value they have begun to use it.

What were the results?

During the trial phase on three high dependency wards at Ashworth Hospital, overall incidents fell by 7%, use of restraints fell 44% and staff sickness rates also fell (see Figure 24). These reductions have been sustained since. Twelve wards in the trust now use DASA.

What were the learning points?

• Because staff are short of time, any tool must be capable of quick implementation and significantly improve care quality.

• Nurses need support during implementation; having a named person to contact, such as a project manager, can help.

• Risk assessment tools that are quick to score and represent data visually are far easier to implement.

• Having a dedicated team that drives safety, and senior clinicians keen to reduce violence and risk, are key.

Next steps

The trust plans to develop an electronic application for every ward that uses DASA, taking account of the different electronic records of people who use services used in the trust. Wards will then be able to represent data and trends graphically, making it easier for staff to understand the impact of interventions.

Want to know more?

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Case study 44 - Safety, audit and continuous monitoring

Implementing a safety management system

Cheshire and Wirral Partnership NHS Foundation Trust

What was the aim?

The trust’s incidents, complaints and inquests feedback suggested it was assuring care processes rather than the reliability of its clinical pathways. It wanted to shift its culture from one of compliance to continuous quality improvement.

What was the solution?

Introducing a safety management system, which continuously analyses team, service and organisational quality and risk data. The improvement team-level safety of those who use services is central to this. They are based on the Health Foundation’s model described in ‘The measurement and monitoring of safety’, which evaluates the safety of people who use services across five dimensions. These reviews largely replace the traditional local clinical audit programme.

What were the results?

More than 30 reviews have been completed. Staff value the process more than clinical audit. Corporate teams can better support clinical teams through ‘enabling plans’, which have replaced traditional RAG-rated action plans.

What were the learning points?

Staff value the emphasis on best practice and areas requiring improvement, which has helped with engagement.

Next steps

The trust’s healthcare quality improvement team is developing the role of ‘patient safety leaders’ as quality improvement champions in each team that has been reviewed.

Want to know more?

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Case study 45 - Safety, audit and continuous monitoring

Using a speech and language therapy team to enable good communication standards

Cheshire and Wirral Partnership NHS Foundation Trust

What was the aim?

Most people with learning difficulties have some speech, language and communication difficulties. The trust wanted to ensure it met the Royal College of Speech and Language Therapists’ five standards for communicating with people who have learning disabilities and/or autism when they are inpatients at a specialist hospital or in a residential setting:

- There is good information that tells you how best to communicate with someone.
- People are helped to be involved in making decisions about their care and support.
- Others are good at supporting someone with their communication.
- People have lots of chances to communicate.

People are helped to understand and communicate about their health.

What was the solution?

Speech and language therapists conducted audits of communication practice at two of the trust’s units to recommend improvements.

What were the results?

The audits showed high levels of compliance with the five standards, but highlighted the need to continuously oversee their implementation. This will be one of the main roles of a new speech and language therapist post for inpatient units in east Cheshire.

Examples of how the trust ensured consistency in applying the standards include:

- Making sure any new information about a person using the service’s communication is shared in their paper file and electronic care record. This is shared in the ‘communication book’ in the nurse base and verbally, so staff know the information is available.
- Using alternative methods of communication, such as staff on observations having access to a British Sign Language book of signs; signs on walls and other visual resources. Staff also use photographs to help people who use services understand what will happen next – for example, at appointments.
- Client-specific training days, attended by the multidisciplinary team (including the speech and language therapist), part of which involves going through the person using the service’s communication needs and how to support them. Families are also invited to the training day to offer their perspective.
- People who use services are encouraged to comment on topics such as food, the environment and activities at meetings about their care. A ‘participation development officer’ carries out ‘patient stories’ to get people’s feedback about the service. Where people who use services are unable to do this verbally, they are observed on the unit to capture their story if it is in their best interests to take part.

Next steps

Providing communication training for staff emerged as a key theme in the audit. The trust is discussing how to improve this as part of training needs analyses.

Want to know more?

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