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# Safer Clinical Systems Interim Report August 2010

THE UNIVERSITY OF
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## ABBREVIATIONS

A&E     Accident & Emergency

FMEA    Failure Modes and Effects Analysis

GTT     Global Trigger Tool

H@N     Hospital at Night

HTA     Hierarchical Task Analysis

PCT     Primary Care Trust

PRIMO   Proactive Risk Monitoring tool

SBAR    Situation, Background, Assessment, Recommendation tool

SBART   Situation, Background, Assessment, Recommendation tool with Teach-back

SPI     Safer Patients Initiative


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## BACKGROUND

Safer Clinical Systems is the Health Foundation's new five year programme of work to test and demonstrate ways to improve healthcare systems and processes, to develop safer systems that improve patient safety. It builds on learning from the Safer Patients Initiative (SPI) and models of system improvement from both healthcare and other industries.

Learning from the SPI highlighted the need to take a clinical systems approach to improving safety. SPI highlighted that many hospitals struggle to implement improvement in clinical areas due to inherent problems with support mechanisms. Clinical processes and systems, rather than individuals, are often the contributors to breakdown in patient safety. The Safer Clinical Systems programme aimed to measure the reliability of clinical processes, identify defects within those processes, and identify the systems that result in those defects. Methods to improve system reliability were then to be tested and re-developed in order to reduce the risk of harm being caused to patients. Such system-level awareness should lead to improvements in other patient care pathways.

The relationship between system reliability and actual harm is challenging to identify and measure. Specific, well-defined, small-scale processes have been used in other programmes, and system reliability has been shown to have a direct causal relationship with harm (e.g. care bundle compliance in an intensive care unit can reduce the incidence of ventilator-associated pneumonia). However, it has become evident that harm can be caused by a variety of factors over time; when working in broader, more complex and dynamic systems, change in outcome can be difficult to attribute to specific improvements and difficulties are also associated with relating evidence to resulting harm.

The overall aim of Phase 1 of the Safer Clinical Systems programme was to demonstrate proof-of-concept that using a systems-based approach could contribute to improved patient safety. In Phase 1, experienced NHS teams from four locations worked together with expert advisers to co-design the Safer Clinical Systems programme.

## WHY A SYSTEMS APPROACH?

We know from the "How safe are clinical systems?" research (WISER, 2010) that processes of care are unreliable, and that there is great variation in practice between teams, services and organisations. This variation leads to differences in patient outcome and has the potential to lead to errors and increase the risk of harm. It is now widely recognised that errors and human behaviour cannot be understood in isolation, but must be considered in the context or system in which people are working; this is as true for healthcare as it is for other safety-critical industries. Clinical staff are influenced by a wide range of system factors such as: the available technology, team and staffing levels, their hours of work, the design of work areas, workplace distractions and patient factors. Wider evidence shows that this can be due to:

- A lack of agreed standardised practice, roles and responsibilities.
- Poor understanding of where errors occur and where risk lies.
- Poor appreciation of risk, errors and harm.
- A lack of systems to identify risk and harm and poor reporting systems.
- A lack of feedback loops to address errors that have occurred, and a concomitant lack of learning.
- Poor sustainability of new initiatives and changes.

- Poor teamwork and a lack of willingness to challenge the system when risks are apparent.
- The healthcare system requiring numerous handovers of patient information and responsibility for care.

Current thinking recognises the fact that adverse events or patient safety incidents are generally the result of a plethora of events or failures within the healthcare system, in which human error is usually the final element. This is demonstrated by the well-known and influential model of accident causation, Reason's Swiss-Cheese analogy. This model acknowledges that inadequacies in the systems within which people work make human error and unsafe acts more likely. The latent conditions that contribute to error include factors such as: understaffing, unclear allocation of responsibility, poor supervision, and inadequate processes for maintaining equipment.

Rather than waiting until an adverse event or harm occurs and then retrospectively identifying a root cause, an alternative approach prospectively identifies the numerous factors that might result in patient harm. The Safer Clinical Systems programme explored methods of establishing care systems within a culture able to address unsafe processes and proactively manage risk. By taking a systems approach, healthcare staff can start to define those parts of a clinical care process that might compromise safety, and then look for solutions to minimise the associated risk. Aspects of the clinical care process that compromise safety may occur at any point along the patient journey in primary or secondary care; the approach aims to highlight steps where risks are apparent and identify means of improving them. Several processes within healthcare impact on a high proportion of patient journeys e.g. medication management, infection screening, clinical testing, and information flow within and across organisational boundaries (between-ward transfer, referral from primary to secondary care). This means focusing not only on clinical care but also on the systems that support care.

Systems in this context exist to achieve particular goals, in this case to deliver clinical care. It is important to recognise that systems comprise more than individuals and their working practices; a system encompasses a set of interacting elements including people and technology, described as a 'socio-technical system'. The systems approach recognises that individuals exist and behave within a wider context: systems have boundaries with some elements perceived as within the system and some elements as outside; however, boundaries are not absolute and movement across them renders the system responsive to outside forces and wider or adjacent systems. Feedback loops between systems add additional fluidity.

A total system is, therefore, difficult to define but can be thought of as being made up of subsystems or subunits. Each subsystem is a system in its own right, and contains its own elements working and interacting with each other. Crucially, a system's behaviour should be understood as arising from the relationships across and between its parts rather than from the individual parts in isolation. In healthcare and in building safer clinical systems, it is important to recognise how the system's context influences its performance; this requires that contextual factors that affect system performance be identified.

## AIM OF THE SAFER CLINICAL SYSTEMS PROGRAMME

**The aim of the Safer Clinical Systems programme is to increase reliability in systems of care, thereby reducing the number of failures that result in harm to patient**.

Most safety improvement initiatives have been developed in response to a practical need or an actual system failure. Learning how to improve has, therefore, involved a reactive approach to correcting system

weaknesses, rather than applying new logic to the proactive design of systems for optimal safety and continuous improvement. In addition, the current approach to system performance has focused on local needs and the application of tactical tools borrowed from the manufacturing sector.

Focusing on the improvement of specific tasks and activities within a single element of the healthcare system is limited in its scope; improvements may result in better completion of the specific task but this improvement is unlikely to impact on the whole system. The modern challenge is to improve entire clinical systems to make them safer, and to stimulate processes that allow staff to learn how to improve both the system and function. As such, Safer Clinical Systems has two dimensions, improving the effectiveness of the entire system and increasing the reliability of individual elements within the system.

**The foundation of the Safer Clinical Systems approach is the combination of methods of safety management, human factors engineering and the development of improved reliable organisations, by using learning and value-focused approaches**. Generating processes that are both improved and more reliable goes beyond the achievements that can be engendered at the tactical or the tool level; it embraces the optimal design of systems with in-built resilience, and encourages situational awareness that is sensitive to underperformance and deviation. These specialist fields of knowledge rely on both scientific method and team engagement, and have been applied to various industrial (petrochemical, nuclear and aerospace) sectors. In healthcare, Safer Clinical Systems is the amalgam of these specialist knowledge bases, applied end-to-end across the process with the intention of reducing the harm associated with latent errors in clinical system design. Safer Clinical Systems goes beyond the best practices of individual clinical departments, to create a system and network of improvement activities that are grounded in the application of safety engineering and improvement.

## OBJECTIVES OF THE SAFER CLINICAL SYSTEMS PROGRAMME

The objectives of the Safer Clinical System Programme are to:

i) Improve the reliability of clinical systems used in healthcare and so reduce patient harm, initially in the organisations participating in Phase 1 of the programme and over time extending the process more widely across healthcare.
ii) Develop a faculty of experts to support those in the UK who work to improve clinical systems for patient safety; this will help to build internal capacity for improvement within the NHS as a whole.
iii) Develop well-described, specified interventions to improve patient safety.
iv) Develop a UK-wide evidence base for the application of clinical systems improvement.

## METHODOLOGY

The Health Foundation's Safer Clinical Systems programme was piloted in five NHS Trusts in four locations. Each Trust chose an area where system factors were known to result in a safety issue and focused attention on understanding, measuring and improving reliability in that area. The Safer Clinical Systems interventions were developed through a co-design process involving the sites, staff from the Health Foundation and a University of Warwick based technical support team (consisting of healthcare, human factors and improvement specialists).

The programme was characterised by a prospective approach to patient safety, as distinct from the reactive approach commonly seen in NHS risk management where failings are identified retrospectively and addressed after the event. In Safer Clinical Systems, there was an explicit requirement to develop a 'safety case' for the system, through proactive understanding and risk management.

Phase 1 of Safer Clinical Systems programme was designed to prove that the approach could be used to increase reliability in care processes and reduce the number of failures that result in patient harm. An initial planning workshop in September 2008 defined the aims of the project and the outline of how it would be executed. These aspects were further developed with the sites at the initiation workshop in October 2008. The programme then ran a series of two day workshops, approximately every two months, to promote specific learning and share ideas and progress. Each site also had a human factors workshop. Projects were supported locally at each site by a coordinator from the support team, who provided expertise on improvement and safety methodologies.

In order to develop this new methodology an iterative approach was required, with ideas developed during the course of the project being fully explored. This involved a divergent-convergent approach whereby the scope of projects expanded to allow exploration and then converged to develop focussed interventions.

The impact of the projects was principally measured by assessing the reliability of the target systems. Evaluative evidence was sought that was loosely based on the elements of Realistic Evaluation, which considers: the context in which changes take place, the mechanisms or processes expected to produce change and the outcomes that can be measured. The original plan for measurement was to develop a template similar to that used in the SPI. As projects progressed the sites developed a range of measures and a template was then devised in conjunction with site B. The iterative approach to each project has meant that it was not possible to stipulate measures to be used at the onset; at several sites the planned assessment measures changed as projects developed. Each site developed a data collection system that fitted within their existing healthcare system. During the course of the programme each site also developed and maintained an ongoing Safety Improvement Case (SIC). This SIC was based on the safety case design used in other sectors and consists of a narrative, supported by data, to describe the project and how it improves reliability and therefore how it minimises risk and would be expected to reduce harm.

## SITE A

Site A initially proposed work on three high-risk areas for Phase 1 of the Safer Clinical Systems programme, comprising: transfer of clinical information, medication errors and pressure ulcers. The Acute Trust has a well-developed system for undertaking improvement work, into which they aimed to incorporate the Safer Clinical Systems programme; a deliberate decision was made to not present the Safer Clinical Systems programme as different from ongoing initiatives.

**Scoping**

Scoping of the project resulted in several changes in focus:

The initial scoping exercise, conducted in April 2009, used the Global Trigger Tool (GTT) to establish a baseline measurement of harm. The hypothesis was that medication errors would prove to be the priority area for improvement. However, GTT analysis identified the key issue for healthcare economy as being related to patient readmission; there is recognition that patients who are readmitted have a high incidence of safety incidents. As a result, it was decided that the Safer Clinical Systems programme would focus on the transfer of clinical information along the length of the patient pathway from admission to discharge, and assess any relationship with readmission. The aim of the project was formulated as being to assess the accuracy and effectiveness of communication of clinical information and handover of care across the healthcare economy; it focussed on complex care pathways in adults aged over 65 years who entered the urgent care system out-of-hours.

In August 2009 a key objective was stated to be: improving the handover and communication of care across the pathway and healthcare economy and reducing harm by 50%

**Project aim**

In November 2009 the project aim was further refined as being to reduce by 50% the actual harm from the transfer of clinical information year on year in the urgent care pathway.

The project identified specific goals of:

- Ensuring that accurate, complete and timely clinical information was conveyed, between process steps, to the appropriate team/individual.
- Improving the reliability and safe transfer of clinical information between organisations/departments.
- Adapting and integrating new tools across the system, and using them to measure and action improvements in areas of potential harm.
- Encouraging care teams to recognise the importance of patient handover to allow them to design, buy into and sustain improvement.
- Encouraging departments to learn and introduce new working practices.
- Sharing project outcomes in a workbook for use in other areas of the organisation, to indicate where they are in terms of their safety culture.

**Interventions and measurement tools used**

A range of methodologies was used as part of the Safer Clinical Systems programme at site A :

1. A standardised out-of-hours form was designed for GPs to complete when referring a patient into hospital, and has been rolled out across the out-of-hours system.
2. An audit of the completeness and timeliness of documentation conducted by ambulance services bringing patients into A&E showed this aspect of information transfer to be good.
3. The efficiency of coding blood tests performed on patients in A&E, was assessed to ensure that appropriate tests were requested and to optimise the speed of reporting.
4. The SBAR tool (situation, background, assessment, recommendation) with Teach-back (SBART) was introduced for the transfer of patients from A&E to assessment/observation wards.
5. An audit was undertaken to look at the effectiveness of selection of patients from A&E to enter the PCT-owned Community Unit. Decision trees were introduced to assist the process.
6. Paperwork used during the handover of patients from the Community Unit to the Intermediate Care Home was streamlined.
7. An audit was undertaken to find out how often GPs received updated medication information when patients were discharged from the Intermediate Care Home to home.
8. A project looked at the correspondence sent to GPs on patient discharge.

The reliability of the system was assessed in terms of patient flow through the local health economy, using several measures. Measures of project success considered: how many times patients appeared in A&E accompanied by the standard out-of-hours form; and the time elapsed between blood sampling and the results of the test being read by the clinician, which decreased from 228 minutes in October 2009 to 59 minutes in February 2010.

**Other initiatives**

A number of other ongoing projects at site A indicated a spread of the Safer Clinical Systems effects: a process of designing-in safety was applied to systems in the newly rebuilt Community Unit; the maternity unit applied an SBAR-T project to develop a new method for recording Apgar scores in newborns, this was a prime example of a rapid human factor intervention that used consensus groups to assess and manage risk and provide procedural support.

Other assessments of change conducted during the Safer Clinical Systems programme included:

- Safety environment assessment, which identified communication as a key area for improvement.
- A pilot questionnaire showing that individuals recognised changes in their individual approach to safety but less change on an organisation-wide basis.
- A PCT-wide review of documentation highlighted forms in need of updating, to capture more patient data and allow tracking of key indicators.
- The planned work on medication errors and pressure ulcers was scaled down due to the change in project emphasis but some data were collected.

The trust expressed the desire to reduce readmission rates, and has recognised that one component of improvement may be to target information flow.

**Specific emerging learning**

Emerging learning within the health economy included recognition of the importance of tools such as GTT for detecting harm and raising awareness; in addition Failure Modes and Effects Analysis (FMEA) was accepted as a new risk assessment tool.

Initial assumptions as to the causes of safety issues were often incorrect and Safer Clinical Systems programme tools were key to identifying true areas of concern; however, during assessment it was noted that the existing datasets were often not fit for the purpose required of Safer Clinical Systems and a more qualitative approach was needed.

**Perceived challenges**

A project manager identified concerns over the time spent completing paperwork to feedback on project work, some of which may duplicate existing reporting mechanisms. The pre-existence of a large improvement programme has made it difficult to identify the specific contribution of the Safer Clinical Systems programme in site A and to have measures specific to SCS.

## SITE B

This project focussed on creating a demonstrably safe medication system by identifying and controlling relevant risks to an acceptable level, continuously monitoring performance, and creating resilience to allow the system to withstand unforeseen disturbances.

**Project aim**

The project aimed to reduce the occurrence of medication errors and omissions, with the aim of an improving prescribing reliability for emergency medical patients to 95%.

The hypothesis at the outset of the project was that medication administration would have the highest error rate, but it was found that NHS incident reporting (IR1) forms did not provide sufficient information to identify the cause of errors and progress this aspect. Scoping of the project was facilitated by the use of techniques such as process mapping and "create & detect" matrices, and identified prescribing as unreliable. Training in human factors showed that the occurrence of errors was inevitable, and that it was more important to address the safety and resilience of prescribing systems and focus on proactive risk-management. As a result, the project aim was modified to stipulate the development of a model prescribing system that was reliable, safe and resilient.

**Assessment methodologies used**

Methods used to identify problem areas included:

1. Identification of value-adding, non value-adding and mitigation steps by process mapping, hierarchical task analysis (HTA), observation and interviews.
2. Identification of the root causes of safety problems using 'create and detect' matrices.
3. Identification of contributory factors using Fishbone analysis.
4. Validation of the findings using focus groups.
5. Identification of performance-influencing factors using scenarios.
6. Prioritisation of risk using FMEA.
7. Identification of markers of resilience.

Assessment highlighted 10 common areas where systems were failing, of which three were selected for the focus of the project; these comprised: poor information flow, lack of training and procedural support and an absence of feedback concerning prescribing errors.

**Interventions and measurement tools used**
The team applied the following interventions during the course of the Safer Clinical Systems programme:

1. Pharmacist support was introduced to the post-take ward round (the first ward round following emergency admission); this resulted in very positive feedback from junior doctors and is being continued indefinitely.
2. Pharmacy induction training for junior doctors was redesigned, based on awareness of human factors training received as part of the Safer Clinical Systems programme.
3. An antibiotic crib card was introduced, targeting junior doctors, that reiterated key messages from antibiotic prescribing policy.
4. Feedback on prescribing errors made by junior doctors was implemented, to generate a feedback loop to assist learning.

Assessment of the reliability, safety and resilience of the system was primarily informed by auditing the prescribing accuracy:

- Prescribing reliability (the proportion of prescription items that did not require pharmacist intervention) increased from 79% in November 2008 to 87% by April 2010. Since then, reliability has fluctuated, emphasising the need to address sustainability.
- Monitoring of the number of patients bringing in their own medicines into hospital was introduced, with the optimal situation being for all patients to bring in their own medication. In October 2009 61% of patients brought their own medicines into hospital, which rose slightly to 64% by February 2010, and has remained around 55-60% since then.
- The number of GP faxes listing patient's drugs sent to accompany patients may have increased, with 28% of GPs providing a complete, accurate medication history for surgical admissions in November 2009 and 87% of medical admissions arriving with a full drug history in February 2010; it was not possible to directly compare surgical and medical results.
- Pharmacy induction training received very positive feedback from junior doctors in August 2009, and questionnaire will be repeated in August 2010.
- The system of providing feedback on prescribing errors received a very positive response when assessed in January 2010.

Other audits and questionnaires performed include: assessment of the number of pharmacist prescribing reconciliations made within 24 hours of patient admission and obtaining feedback on the utility of the antibiotic crib card. Training needs have been identified and action plans developed.

**Transferability**
The spread of the Safer Clinical Systems approach to the wider organisation is evidenced by: the request from the Trust Board that reporting on medication errors be presented at future Board meetings; and expression of interest in using the Proactive Risk Monitoring (PRIMO) tool by other parts of the Trust.

**Specific emerging learning**

Emerging learning with respect to site B identified that current incident reporting mechanisms fail to capture or provide information suited to learning; the Safer Clinical Systems programme showed that qualitative information can be more useful for guiding aspects of system change.

The study team perceived that the Safer Clinical Systems project reduced the risk of prescribing errors as: risks had been systematically identified and assessed; appropriate risk control measures had been introduced and tested; performance was monitored continuously; and educational programmes were used to raise awareness and enhance safety culture.

**Perceived challenges**

Difficulties were noted when undertaking the project in a unit where staff changed regularly; this created difficulties with embedding new working systems. In addition, it was felt that though junior doctors know what they should be doing the inherent organisational system sometimes prevents them from doing it.

## SITE C

This project focussed on creating a demonstrably safe system of information flow to support patient care.

**Project aim**

The original vision was to deliver a core data set, with minimal missing or incomplete information. However it became apparent that multiple sets of notes were often available for individual patients, as a result of carry-over from the old multi-trust structure and resulting from duplicate registrations in the patient administration system; clinician interviews identified two perceived main barriers to delivering a core data set as the presence of duplicate electronic patient records in the patient management system and problems with case note availability in the clinic. As a result the project aimed to:

1. Increase the availability of relevant clinical information in outpatient clinics.
2. Reduce the incidence of new duplicate records in the patient management system across the University Hospitals Division,
3. Implement ongoing monitoring to ensure that creation of new duplicate records remained at a reduced and manageable level.

**Assessment methodologies used**

Diagnosis of the issues associated with the project involved: extensive analysis of data relating to duplicate patient registrations; task and error mode analysis; literature review; stakeholder consultation and consensus development of core data bundle; analysis of local risk management information; and full human factors analysis. In addition HTA, risk assessment, failure mode analysis and Performance-Influencing Factor analysis were used to construct a 3-site risk evaluation.

**Interventions and measurement tools used**

Measurement parameters assessed the accuracy of patient registration in terms of the incidence of registration errors and duplicate entries. Over the course of the project, registration errors fell by nearly 8%, although some of this improvement was due to a re-design in maternity registrations in Q2 and not attributable to Safer Clinical Systems. The lowest number of new duplicates recorded was seen in February 2010; the proportion of correct registrations rose from 74% in April 2008, to a consistent 90%+ since October 2009; this reduction is despite the number of patient registrations per month increasing by over

1,900, and despite the number of new users increasing by 200 with the rollout of the patient management system Community module. Current work is addressing the issue of those users who register the fewest patients generating the most registration errors.

**Transferability**

Spread of the project beyond its original remit is evidenced by: the identification of merging issues between the Labs and PACS interfaces which affect the availability of investigation results; the closing of loopholes at the patient management system -PACS interface; establishment of good working relationships between Training, Operational Effectiveness and Health Records staff; and raised awareness of human factors.

Spread of the project to include participation by clerical staff has been particularly effective and has moved patient safety initiatives into the non-clinical domain; non-clinical staff participating in the human factors day were enlightened and highly motivated by recognising their role in improving patient safety.

**Specific emerging learning**

Emerging learning with respect to information flow systems has demonstrated that those individuals who register the most have the lowest error rates; as a result departments where registration is limited to a few clerical staff have the lowest error rates. In addition, the project has provided insight into the scope required for interface testing.

**Perceived challenges**

The provision of regular feedback regarding the occurrence of new duplicate registrations is recognised as key to the effectiveness of the project. The concern is that without regular feedback duplicate registrations are likely to increase again.

The effectiveness of Safer Clinical Systems programme training initiatives was compromised by a high turnover of staff.

## SITE D

**Project aim**

The aims of the project were to create a demonstrably safe and reliable patient handover system within neurology to achieve safer care, and to develop a general methodology for handover of responsibility (horizontal handover) enhancing care. Handover of patient information was felt to be a major issue for at least three reasons:

1. Staff reports expressed concerns over continuity of care.
2. National Patient Safety Agency data identify failures in communication (of which handovers are a special case) as contributing to 70% of adverse events.
3. The changing organisational context of the Trust, in particular recent changes to working time legislation, have led to an increase in the number of location, staff, team and shift changes in the patient journey.

**Scoping**

The initial scope of the project (November 2008) was the handover of patients from the Medical Assessment Unit to four medical wards. However it was subsequently decided that handover to four wards would be too complex for the initial part of project. It was decided to retain a focus on the medical take and handover to

the Neurology Unit was selected, as it represents a discrete subset of acute medicine, had established clinical buy-in to the project, and was accustomed to implementing improvement initiatives. The department receives five to six new patients a day, providing a good number of new handovers for observation. Medical handovers between attending-to-attending consultants in neurology were chosen as the initial test case, as the process was seen as unstructured and having low reliability. This was seen as a test case for the wider system of medical handovers within the Trust, with a view that learning would be transferable to other clinical areas. In January 2009, the project scope was specified as focusing improving handover to the Neurology Unit for patients with suspected or diagnosed stroke admitted via the unscheduled care route.

The scope of the project was again revised in August 2009 to consider medical handover (physician-to-physician) of patients admitted to the Neurology Unit via the unscheduled care pathway.

**Assessment methodologies used**

The techniques used to assess reliability of information transfer comprised: detailed observation of nursing and medical handovers; shadowing of medical staff at all levels; documentation review; process mapping of the pathway traversed by patients; structured and semi-structured interviews; case note review; in-depth case studies; HTA of the handover process; and documentation of the current situation with system and contextual factor analysis.

Priority areas were identified as:

- Creation of core dataset specifying the content of the handover to enable reliable patient care, with stakeholder consultation guiding the requirements of the dataset.
- Criticality analysis of the dataset.
- Design of handover methodology (process).
- Measurement of the reliability of handover of the dataset.
- Measurement of the reliability of supporting tools such as the patient list.
- Application of the methodology to other horizontal handovers.
- Development of a clinical value framework to structure handover content.
- Management of performance-influencing factors during handover.
- Extension of the process to other handovers.

**Interventions and measurement tools used**

A handover support tool (aide memoire) was developed with input from stakeholders, and was introduced in October 2009. A system of a weekly e-mail was established in February 2010 to feed back data on performance to the neurology team, these detailed key learning points and run charts of key measures.

Reliability of handover was assessed in terms of the proportion of the of core dataset discussed at attending-to-attending handover. Reliability increased from 35% of core dataset being discussed in June 2009, prior to implementation of the handover support tool, to a mean of 83% being discussed in February 2010, and has remained around 80% since then. Variability in reliability initially increased, probably due to the number of individuals involved, but has since decreased possibly as a result of the regular feedback provided.

**Transferability**

It was decided that the handover methodology should be rolled out to a second specialty and the Safer Clinical Systems Delivery Group considered proposals from four specialities expressing an interest in being the second local test site (A&E, Acute Medicine, Neurosurgery and Critical Care). In April 2010 the Delivery Group decided to extend the work to the A&E Department; the Delivery Group were keen that a handover methodology be embedded in the end-to-end patient pathway, and introducing the system at the hospital entry point (A&E) should be beneficial in achieving this goal. The Safer Clinical Systems team were confident that the department showed a high degree of commitment to the methodology and had identified a multi-disciplinary team. The Group agreed to offer support to the other interested specialties either through other work programmes or on a small scale basis. Work started with A&E in August, when the Safer Clinical Systems team began process mapping, observation and risk ranking of the different handovers within the department to identify critical areas.

The Safer Clinical Systems approach to patient handover generated by the project has also been transferred to the Handover in Hospital at Night (H@N) initiative in site C. Anecdotal reports indicate that the approach has received widespread support, and is recognised as novel and directly applicable to the site C setting.

**Specific emerging learning**

The Safer Clinical Systems programme team initially received negative responses from some clinicians concerning the concept of standardisation; standardisation was seen by some as analogous to 'tick box' medicine and as compromising clinical autonomy.

Emerging learning with respect to healthcare processes identified a lack of clinical standards, without which managing the system and providing useful feedback on current working and potential improvements is difficult. The development of explicit standards within the Safer Clinical Systems project meant that there was a foundation on which teams could start to develop shared understanding as to how the handover system should work in terms of location, time, attendees, purpose and content. It was useful to focus on the clinical team's fundamental purpose from the patients' perspective and then map this to the purpose and tasks of the handover system, to identify value-adding steps.

The team focused on the tasks important during handover, rather than on how handover was conducted, indicating that the information set transferred was of greatest clinical significance. The use of a well-defined, structured dataset has resulted in a more coherent approach to communication within the department and has increased clinical engagement.

Following the implementation of weekly feedback concerning compliance with the agreed handover standards, clinical staff appeared to engage more with the project. As the attending consultant changes on a weekly basis, it proved difficult to provide feedback without it being potentially perceived as relating to individual performance; the heightened engagement may be due to weekly feedback engendering a degree of competition or pride.

Emerging learning with respect to the local setting in site D identified the importance of ensuring that all members of a team are aware of the project and its aims, despite regular staffing changes; this can be difficult in the context of a single department in a large acute hospital where numerous demands are made on clinical teams and individual projects may compete for time, attention and 'priority' status. This difficulty

is exacerbated by the problems associated with finding a time when the whole team can meet; finding novel ways of communicating with the entire team would be useful.

**Perceived challenges**

Potential challenges to the project were associated with maintaining staffing at a level that was sufficient to support the project, and the inherent competition for time and resources between Safer Clinical Systems projects and other initiatives. This was exacerbated by the local political climate and the Trust facing an unprecedented financial situation with the requirement for all staff to focus efforts on reducing and containing cost whilst maintaining the safety and quality of its services. Embedding the use of the aide memoire within the clinical team once the current project funding has ceased is likely to be difficult. Making and sustaining improvement in an unstable environment was acknowledged to be an immense challenge.

## GENERAL LEARNING CONCERNING THE SAFER CLINICAL SYSTEMS APPROACH

### METHODOLOGICAL LEARNING

Reviewing the Safer Clinical Systems project development processes identified several key learning points that may influence future methodologies. The University of Warwick support team concludes that:

- In Phase 1 participants were involved in developing new approaches and tools, which necessitated continual modification of the projects. This iterative 'trial-and-error' approach to the early stages of the specific projects facilitated adult learning. However it led to frustrations concerning the speed of project progression and difficulties for support staff trying to move the project forward without a clear direction. It would be optimal to identify which elements of the iterative approach should be maintained to ensure learning by exploration and identify those that can be superseded based on the different requirements in Phase 2.
- The new areas of Safer Clinical Systems (such as human factors, leadership and safety engineering approaches) should be front-loaded into a concentrated learning period in Phase 2.
- The differing nature of the Safer Clinical Systems projects meant that implementation of a unified data collection system was not appropriate. Future projects should continue to use local data collection systems, unless projects become more closely aligned.
- The use of Safety Improvement Cases facilitated broader assessment of project success, by allowing narrative reporting of aspects of the systems approach that would not be detected by quantitative measures.
- Learning was often more valued when conducted in small groups or on site.
- The use of a zoom-in-zoom-out approach, where the project's implications and impact were assessed across all levels of the organisation, increased understanding. Use of this approach at an earlier stage may have promoted wider learning.
- The use of mitigation maps and the acknowledgement of safety barriers were seen as value-adding steps.
- Sites often had existing safety improvement initiatives in place and imposing a set process for the Safer Clinical Systems programme may have created tensions at the sites.

A number of common themes of emerging learning were raised by the Safer Clinical Systems programme teams at the different sites:

**The Safer Clinical Systems ethos**

- The Safer Clinical Systems programme facilitates widespread understanding of how system weaknesses can increase the risk associated with human factors. Appreciation of such associations enables individuals to view errors differently and focus efforts on identifying factors that contributed to the error rather than the error itself.
- Simple interventions can have a big impact; however, the simplicity of an intervention does not necessarily mean that implementation is easy or that they will be sustainable.
- The Safer Clinical Systems process aims proactively to identify and manage latent points of failure in a system. Such proactive risk management methods are more powerful than reactive methods, and the resulting processes are transferable between settings and situations.
- The Safer Clinical Systems approach can enhance existing methodologies and individual learning. However, key skills such as human factor analysis and situational awareness take time to develop and observation (a key assessment tool) is time consuming.
- The Safer Clinical Systems programme should not be viewed as a time restricted project but should be used to embed resilient and reliable systems that promote timely, high-quality patient care and safety. Achieving real improvements in safety culture and standards takes time and continuing work.

**Engendering a safety culture**

- Having motivated staff at all organisational level, is crucial when developing safe systems. Managerial support and involvement is important for the success and implementation of change. As Safer Clinical Systems support staff have no management authority for the clinical team or system being improved, change was bought about through facilitative leadership. From the outset this involved co-designing the purpose, aims, scope and potential solutions with stakeholders. This will hopefully ensure that the improvements made are sustainable.
- Collecting and analysing quantitative and qualitative data proved time and resource intensive. However, the clinical teams greatly valued having timely data to feed back on process and system performance. Provision of such data promoted active participation in the projects.
- Safer Clinical Systems learning was often generic and applicable to a wide range of safety projects; this facilitates knowledge transfer both horizontally across teams and projects and vertically within the hierarchy of the organisation.
- Developing cross-organisational working practices takes time, resources and effort but is invaluable; building relationships supports integrated working across boundaries and beyond the initial project scope. Developing a culture of transparency and sharing of information across teams, services and organisations is essential for the success of the Safer Clinical Systems approach.

**Training and education**

- Educational interventions should be concentrated in the early stages of a project.
- Detailed, thorough training regarding the human factors associated with risk would be beneficial.

- Training to promote team working was highly appreciated and should be made available to as wide an audience as possible within each site.
- Site awareness training would support wider adoption and transferability of the Safer Clinical Systems principles. The involvement of executives and key influencers in training would help facilitate adoption at the site.
- Learning about the applicability of Safer Clinical System tools should be conducted within projects.
- Different groups within teams have different training requirements and provision should not take a one-size-fits-all approach.

**Measuring safety**

- It is difficult to show a causal link between reliability and harm. Limitations are associated with using numerical indices to demonstrate safety as: a low number of incidents does not necessarily reflect good safety culture; and the number of incidents seen cannot be used to estimate the likelihood of an incident occurring in the future. There is a need to develop an argument to address whether an improved safety culture leads to genuine and recognisable safety improvements.
- The lack of evidence to confirm that improving the reliability of a system actually reduces harm or saves money puts pressure on improvement teams when working in a financially pressured climate.
- Safety Improvement cases allow the portrayal of more complex arguments than simple data, allow discussion of risk minimisation and harm reduction and also allow the uncertainty of causal relationships to be explained.

## CONTEXTUAL LEARNING

The exploratory nature of Phase 1 of the Safer Clinical Systems programme provoked discussion around defining and understanding what a system is, and on subsequently recognising how an improved system relates to measurable patient harm. The link between improved systems and patient harm proved a difficult concept for many involved in the Safer Clinical Systems programme. Whether an improved safety culture leads to improved safety is difficult to prove, requiring that an improvement from a baseline measurement of safety indicators follows an intervention. In most situations quantitative data are lacking and demonstration of safety improvements generally relies on qualitative evidence and an intuitive conviction that the process must achieve benefits. In addition in the wider organisational context, the beneficial effects of a specific intervention may be masked by those ensuing from other safety initiatives.

The more usual problem-based approaches to improving safety typically focus on harm (and measuring harm) and the identification of a direct causal relationship between a specific action and an event. However, the resulting point improvements within the system are often either unsustainable due to other influences, or shift the problem to another part of the system. A key learning outcome from Phase 1 was that system-level working is undoubtedly the required approach but is complex and challenging, both in its implementation and in the presentation of its impact.

Undertaking a safety project within a larger programme, such as Safer Clinical Systems, will inevitably be considered within the context of a particular organisation at a specific time. The problems, pressures and priorities of the organisation will shape how they perceive Safer Clinical Systems projects as matching strategic goals. A local Safer Clinical Systems team will need to take this into account to align their goals with those of the organisation. Experience at the Phase 1 sites suggests that there are four critical elements to this process, involving:

1. Board commitment.
2. Engagement of senior clinicians and understanding of the working culture.
3. Leadership for change and innovation.
4. Linking with existing and emerging  local and national priorities

In order to be successful in each of these elements, a prerequisite is for the Safer Clinical Systems team to have internal clarity of focus concerning the objectives and changes needed to achieve goals; in Phase 1 this sense of clarity gradually strengthened for the individual pilot sites as work continued. There is considerable value in focusing effort to build in clarity earlier so that other aspects of managing the project can be tackled effectively.

## BOARD COMMITMENT

System level change can be far-reaching and involve many participants. It is therefore vital that the Board is committed and backs the change. The current NHS focus on patient safety means that it is relatively straightforward to obtain Board sign-up to safety projects; however this can be at a superficial level and the Board may not fully appreciate what is involved in projects such as Safer Clinical Systems. It is key that any Safer Clinical Systems team engages with and educates its Board to ensure that they understand:

1. The nature of systems-based change and how this differs from projects targeting a specific issue in requiring change in many aspects of the system. Most NHS Boards like projects that deliver results, impact and visibility in a short timeframe. The nature and timescale of system change needs to be fully appreciated by Board members to ensure their continued commitment across the duration of the project and beyond.
2. That systems-based change is proactive, in that it seeks to eliminate an identified risk in the system that is a precursor to actual harm. Boards are often more used to a reactive approach that establishes procedures to counter an identified and measured harm. The Safer Clinical System approach seeks to establish systems that minimise risk, rather than dealing with rare safety incidents. For this reason, education needs to counteract the pervasive acceptance within many Trusts of error as 'situation normal'.
3. That Safer Clinical Systems initiatives are more substantive than usual improvement methodologies. Improvements resulting from more reliable and safer systems should be seen as a component within the overall process of organisational change.

As part of the educative process it is important to have a clear idea of what the Safer Clinical Systems team requires of Board members. The Board can become a significant source of influence but needs to understand the task and the team's expectations of it.

Phase I of the Safer Clinical Systems programme specifically targeted the medical director for executive engagement. In retrospect the failure to engage other executives, may have blocked or slowed progress and spread. The consensus view from Phase I was that a broad level of awareness of the initiative by executive directors and close involvement of an executive lead would be beneficial.

## CLINICIAN ENGAGMENT AND UNDERSTANDING THE WORK CULTURE

A Safer Clinical Systems programme will impact upon most if not all personnel working in the targeted clinical area. Many (potentially senior) clinicians may be asked to make radical changes to their working practices and service delivery. As such, it is vital that clinicians engage with the Safer Clinical Systems project from the outset. Clarity of purpose is vital at this stage, as it is counter-productive to seek clinician engagement if the objectives are unclear and the required changes not identified.

Metrics exist to assess the level of clinical engagement overall and many organisations now use them to prospectively characterise the existing culture within their work setting. The working culture of different professional groups may vary, and it is important to understand their values and drivers to enable acceptance of a new way of working by a critical mass of personnel.

As the Safer Clinical Systems approach develops it is important to identify champions (especially clinical), who can present the case for an intervention and influence the behaviour of others. A particular challenge with the Safer Clinical Systems programme is that all team members and many of their organisation need to engage to effect whole-system change; an isolated champion or small team may not always be able to achieve results.

## LEADERSHIP FOR CHANGE AND INNOVATION

Implementing change is always challenging, as it typically asks people to work differently and be comfortable with the unfamiliar; overcoming resistance to change is integral to the Safer Clinical Systems approach. Effective leadership is vital to facilitating the changes required by Safer Clinical Systems projects, as it provides direction and focus to create cohesive effective teams and influences staff in other areas who may be indirectly affected by the process of change. The Safer Clinical Systems team needs to ensure that it understands the leadership requirements of a particular project and is equipped to fulfil it.

## OTHER EVIDENCE OF WHETHER SAFER CLINICAL SYSTEMS PROJECTS IMPACTED ON THE SAFETY APPROACH

The Safer Clinical Systems programme received overwhelming support from the sites, which recognised the impact projects had on their approach to safety. Safer Clinical Systems projects integrated with existing safety initiatives to varying degrees; site A fully integrated their project within the existing Improving Care System; site B developed a new programme that built on previous improvements within pharmacy.

A short questionnaire to sites showed that they believed that the Safer Clinical Systems programme had a major impact on the way they worked both as individuals and to a lesser but significant degree as an organisation. The questionnaire addressed a range of domains including: trust and respect of colleagues,

priority of and commitment to safety, willingness to take risks to test ideas, and the likelihood of evaluation of adverse incidents.

Interviews undertaken in April 2010 demonstrated that the Safer Clinical Systems programme had a significant impact on the way clinical teams and their organisations approached safety, with sites reporting changes in culture and behaviour. In some cases the change seemed to extend beyond the core clinical team e.g. in site D clinicians used the handover core dataset to improve presentations and referrals; in site C administrative staff became engaged in the patient safety agenda; in site B a range of pharmacy staff became aware of safety and risk factors, and medication interruptions and IT issues became recognised as safety factors rather than work irritations. Eighteen of 20 interviewees agreed or strongly agreed that patient safety had integrated better into their working practices. Other positive effects were perceived as an improved safety culture, organisational learning, and clinical engagement with safety. Project participants agreed that the Safer Clinical Systems initiative introduced them to new aspects of safety, at a new level of complexity. It was recognised that improving safety is not simple and should not be over-simplified if sustainable change is to influence safety at the organisational level; the Safer Clinical Systems approach should not be sold as an easy fix, but should be promoted based on the benefits of its wider organisational implications.

## LINKS WITH OTHER SAFETY INITIATIVES

Patient safety has become a national priority and the Safer Clinical Systems programme is only one of a number of initiatives.

In England the Patient Safety First campaign is being rolled out and consists of a large number of very focussed interventions. Other initiatives have led to the implementation of care bundle approaches or specific interventions, and have been identified as characteristic of safety-conscious organisations. These approaches are similar to the SPI, which has the added advantage of considering leadership and human factors. In Scotland, the SPI is being rolled out across all Health Boards as the Scottish Patient Safety Programme.

The NHS Institute's Safer Care Programme (including the Leading Improvement in Patient Safety component) is undertaking training in human factors and reliability, and implementing a greater focus on leadership; however there is less emphasis on broader safety awareness, project-based learning and use of various tools and interventions.

In site D, safety initiatives are now part of a Strategic Health Authority programme of safety linked to the national Patient Safety First campaign, delivered in partnership with the Institute for Health Improvement and part-funded by The Health Foundation. A test of the applicability of the Safer Clinical Systems approach may be to see if it can act to support the wide range of projects being implemented in the site.

Work to date has allowed Safer Clinical Systems sites to undertake a safety improvement project and learn about the systems approach to patient safety. This has facilitated proof-of-concept of the Safer Clinical Systems approach and identified components key to the programme. Some components are undergoing continued testing at the end of Phase 1. Work in Phase 2 will aim to further to refine key concepts and approaches, and evaluate and develop them further to achieve widespread applicability.

Phase 1 might be characterised, both in focus of activity and learning outcomes, as:

- Developing a trial-and-error approach to the use of diagnostic tools, which has helped to describe and understand system processes. Though time is required for this type of experimentation, a more structured approach using a reduced, consolidated and structured set of prescribed diagnostic tools is required for Phase 2.
- Promoting recognition of the relationship between system-level work and risk as an intermediary to harm. This has resulted in an important advance in thinking, by increasing appreciation of the inherent existence of risk in an operational system that could lead to harm. As a consequence the optimal approach to safety management is proactively to seek and identify risk and then build more reliable systems to reduce or eliminate it, to prevent harm occurring in the longer term. The growing appreciation of this position could be considered as an incremental change in safety culture.
- A consequence of the time required for exploratory aspects of Phase 1, was that less time and attention could be given to implementing interventions. The nature of the defining and diagnosing processes has meant that sites have not always known until well into the project what they need to do to re-frame their systems. Phase 2 will focus on demonstrating change as interventions will take time to implement and test.

Phase 2 would need to build on these key learnings from Phase 1, ensuring that new sites understand the overall vision of improving patient safety at organisational level. Sites will need to be fully aware of the critical assumptions of SCS, namely:

- That safety cannot be achieved when unreliable systems exist.
- That risk is inherently greater in unreliable systems.
- That proactively identifying and managing risk by improving (and measuring) the reliability of the system is necessary.
- That the link between system change and specific forms of patient harm is likely to be indirect and will take time to demonstrate.

The objectives of Phase 2 of the Safer Clinical Systems programme involve promoting understanding and acceptance of these key assumptions and using them in an operational context to drive system change and engender a safety culture.

A novel feature of the Safer Clinical Systems approach is that it aims to identify risk as well as harm, a complex undertaking that is difficult to quantify. Local priorities and external pressures can compromise this goal and tend to promote an approach that reacts to harm. The causal link between harm, reliability and risk may be difficult to establish and the impact of environmental and cultural factors may not be obvious. To

counteract these potentially counterproductive pressures, the advantages of identifying risk needs to be emphasised in terms of prevention of a broader range of harm than targeted by traditional approaches.

Systems theory advocates that feedback encourages the development of adaptive and emergent processes. The use of feedback loops to raise awareness of errors and encourage learning has been shown to be important in both in previous projects and during Phase 1 of the Safer Clinical Systems programme. The dynamic nature of risk and the need for continuous measurement and feedback should be integrated into the design of future Safer Clinical Systems projects.

## LOCAL AND NATIONAL INFLUENCES

In order to optimise Safer Clinical Systems projects and the programme as a whole, safety improvement teams needs to understand local and national drivers that can affect their working. Force field analysis is a technique used to explore potential barriers and enablers to implementation, sustainability and spread of a piece of work. When undertaken by the Safer Clinical Systems teams force field analysis was seen as beneficial, and it was suggested that the methodology should be undertaken at an early stage and repeated throughout the programme to ensure that a project was supporting and responding to local priorities.

A continuing challenge identified during Phase 1, was the differing perspectives of individuals as to the relative importance of the project and programme. To achieve wider benefits, the Safer Clinical Systems approach advocates that learning need to occur in various directions:

- Vertically to the management team and influential senior individuals.
- Vertically and horizontally to the broader group of individuals whose work is influenced by the project.
- Horizontally to teams undertaking other safety improvement projects.
- Centrifugally by means of social and professional networks.

Some sites had wider awareness of the benefits of the Safer Clinical Systems approach, and embedded their project within existing work systems or used zoom-in-zoom-out methodologies to assess implications and impact at all organisational levels.

## TIME SCHEDULES

Phase one of the Safer Clinical Systems programme did not adhere to its original timetable. This is not unusual for a project that uses a new approach and aims to show proof-of-concept, as the challenges and areas of exploration cannot be predefined. In retrospect the programme could have developed and progressed more quickly, had it been more restrictive in its remit and methodology and the objectives more tangible. If a project is too diffuse the goals may prove unachievable or progress more slowly than expected; if too specific and focussed the benefits the Safer Clinical Systems programme has over other campaigns may be lost.

However experience did show that some Safer Clinical Systems components benefit from time, such as:

1. Building the appropriate team and allowing the development of trust and mutual respect.
2. Thorough diagnosis of project goals and approaches.
3. Relationship building, particularly across organisational barriers.
4. Learning new techniques, tools and approaches and overcoming inherent suspicion of them.

5. Developing an open culture that allows free discussion of issues.
6. Working with data that is not geared to the needs of a safety improvement programme.
7. Integrating safety improvement projects into existing improvement, governance and other internal structures.
8. Engaging a wide body of staff.
9. Building staff confidence to encourage them to influence organisational safety.

Learning from Phase 1 suggests there should be clear goals regarding the broader system issues and how far they extend. The progression required to move from micro-system projects to whole system change may have been too great for Phase 1, and careful consideration needs to be given to future developments to ensure projects are manageable but remain challenging and rewarding.

## THE EVOLVING APPROACH TO SAFER CLINICAL SYSTEMS

Most safety improvement programmes for healthcare have been developed by focusing on specific safety issues and have involved using defined interventions such as care bundles. The Safer Clinical Systems programme was developed to take a new approach. It has combined learning from improvement science and safety engineering and applied these to patient safety. Many improvement approaches are now being used in healthcare, including lean thinking and six sigma. Techniques originally used in manufacturing have been adopted by healthcare, although this has initially resulted in a bias for adopting the tools and techniques rather the philosophy behind them. For example, lean thinking focuses on approaches to maximise customer value while minimising waste, and develops this as a way of working to improve quality and efficiency. In other sectors (such as the petrochemical industry) safety engineering has developed into a science of testing and system evaluation to minimise risk and thereby reduce harm; where significant risk is present in a system, a formalised, prospective approach to safety is taken. The Safer Clinical Systems programme has begun to combine the approaches of improvement and prospective safety management, and to apply them to the healthcare setting. The overall aim is to reduce risk and harm to patients by proactively improving system reliability.

The Safer Clinical Systems programme adopted an evolving approach to its component projects, which specified that:

1. Any problem needs to be carefully diagnosed and the level of associated risk or harm should be quantified before deciding on actions.
2. Whenever possible the system should be stabilised and variation reduced before undertaking risk management initiatives.
3. Risk should be proactively identified.
4. Once risk is controlled then resilience should be developed, to ensure that the system can cope with new and recognised threats.
5. Trust strategy, definition of priorities and use of a suitable approach are important components of system change.
6. Leadership, staff engagement and effective project management are important components of system change.

The methodology for Phase 2 of the Safer Clinical Systems programme will include: defining and describing the overall system of interest and the specific focus of study; and describing the vision/approach to building safer systems.

## DEFINING AND DESCRIBING THE SYSTEM

The first aspect of defining and describing the system to be studied in Phase 2 involves identifying and specifying (with evidence) the focus (and boundaries).

Based on learning from Phase 1, work with sites will apply a systematic approach to improving the safety and reliability of certain agreed processes and systems that support clinical care. These have been chosen based on evidence from Phase 1 that shows them to: be of great interest to the NHS, often be unreliable, contain inherent risk and system defects/failures, and potentially contribute to patient harm.

The two agreed options for sites will be to create **in a sustainable way**:

- Safe, reliable prescribing in patient pathways.
- Safe and reliable transfer of clinical information along patient pathways.

These systems have been selected as they are relevant to a wide variety of patient pathways and are recognised as high-risk areas in terms of patient safety. As they are relevant to numerous patient settings, they will facilitate assessment of the transferability and generalisability of the interventions, tools and processes that are developed.

Secondly, how this bounded process fits within the organisation and the wider healthcare system needs to be defined. Transfer of the process to a range of different clinical settings will facilitate exploration of how it adapts and what factors influence performance. The influence exerted by system factors may necessitate system-wide review and change. This aspect of the project in particular will advance understanding of the role of leadership and the development of a safety culture.

## DEFINING THE APPROACH TO BUILDING A SAFER SYSTEM

The overall long-term vision of the Safer Clinical Systems programme is to promote the acceptance of an emerging definition of a safe clinical system as *'a clinical system that delivers value to the patient, is **demonstrably free from unacceptable levels of risk** and has the resilience to withstand normal variations and fluctuations .'* The overall approach to building a safer system recognises the ultimate goal of achieving resilience to unexpected challenges.

Phase 2 of the Safer Clinical Systems programme aims to take teams through the first few steps in this journey of assessing/diagnosing, testing and implementing solutions.

Various tools and techniques were used at the sites during the course of the Safer Clinical Systems programme. Some were traditional improvement tools already in use at the sites; others were new to the teams and were usually practices from the safety engineering world. This resulted in the development of a core toolkit that can be used within the Safer Clinical Systems programme to increase understanding.

A **process map** is a logical step-by-step representation of business activities showing key inputs and outputs. The **process map** is a basic tool for any improvement project and was used widely to understand high level issues. Process mapping was made more sophisticated by developments within the Safer Clinical Systems programme: **Create and Detect maps** enabled clear representation and exploration of the source of risk or harm. **Swim Lane maps** allowed staff to directly relate their work to safety issues and to identify safety defences. They also encouraged engagement and continued interest in the progress of individual projects; Mitigation and correction steps were introduced in recognition that a process occasionally goes off track and that it is important to have a rescue pathway, and has led to the development of **Mitigation maps.**

**Structured observation** was widely used by sites as part of ongoing improvement work but its importance was emphasised by the Safer Clinical Systems programme. The Safer Clinical Systems programme developed the observation tool by emphasising that observers need to be trained to recognise parameters relevant to feedback processes. In addition, the need to observe the system environment and the approach to process was relatively new. The main issues with observation were the time needed and the difficulty in maintaining the high level of input needed for monitoring. The Safer Clinical Systems programme also made widespread use of **interviews** and **focus groups** both to establish the diagnosis and to validate findings and approaches; these proved key to maintaining clinical engagement and motivation.

**Hierarchical Task Analysis** (HTA) was a new technique for all sites that was widely used. HTA enables a goal to be broken down into the subtasks required to achieve the goal; it serves as a basis for detailed risk analysis and ranking, and for failure mode analysis and predictive human error analysis. HTA was used to demonstrate where and why processes fail and where risk mitigation strategies or systems need to be introduced.

**Failure Mode and Effects Analysis** (FMEA) is a process for the systematic identification of major vulnerabilities within a system. It provides a quantitative risk evaluation that can be used to prioritise threats. FMEA was new to sites but was widely used and well received; users reported that it facilitated both identification of major issues and their prioritisation.

**Fishbone analysis** is used to identify and list the scale and scope of issues and problem areas, and was used as part of Safety Improvement Cases to display the numerous issues relating to the system under study; Fishbone diagrams help to present the complex and varied factors that affect systems. Fishbone analysis enabled teams to understand performance influencing factors (including teamwork, resource, clinical engagement and leadership) that link the clinical micro-system to wider organisational systems. During Phase 1, Fishbone analysis was usually implemented in the diagnostic phase but it may have been useful to continuously revisit it to understand the changing picture.

**Proactive Risk Monitoring** (PRIMO) is a new tool that is still under development; it promotes organisational learning based on feedback concerning basic risk factors that is elicited at regular intervals. PRIMO aimed to

proactively understand risks to safety and effectiveness. PRIMO ensured staff engagement with the process of proactive risk identification.

Various methods were used to **assess safety culture** and environmental background: the Manchester Patient Safety Framework (MaPSaF) is a tool used to help NHS organisations and healthcare teams assess their progress in developing a safety culture. MaPSaF was found to promote discussion but use was time consuming and the tool does not derive a measure that facilitate comparison; the Agency for Healthcare Research and Quality (AHRQ) questionnaire is used to assess organisational safety culture and was perceived as allowing monitoring but needed more coordination of the results; the Texas Safety Attitudes Questionnaire was found to assess individual perspectives and collate them into an overarching view.

**Force Field Analysis** is a technique used to explore potential barriers and enablers of implementation, sustainability and spread of a piece of work. Early use of the technique and regular updates may help maintain focus and prioritise successful interventions.

**Safety Improvement Cases** were introduced as a tool, to structure reporting and clarify interventions and purpose. They facilitated a more narrative reporting style, so that success could be assessed in terms of non-measurable parameters. The discipline of completing and updating Safety Improvement Cases proved challenging but was important for maintaining project structure. Safety Improvement Cases facilitated a more balanced approach to defining problems and demonstrating improvement.

Mechanisms to support reliability were introduced, these included: simple checklists and the development of **SBAR-T** where the standard SBAR process had a "teach back" added to ensure a focus for receipt of information and transmission of correct information (confirmed as an issue by WISER).

It was clear that a defined set of tools should not be prescriptively applied to the Safer Clinical Systems programme. Evidence from Phase 1 indicated that the effectiveness of the process requires an understanding of what works best, for whom, and under what circumstances. Varying contexts and cultures should to be recognised and addressed according to their unique setting. The toolkit provides a selection of instruments that can be used for many purposes; the set described comprised some basic tools that sites may wish to use in the future. The Safer Clinical Systems programme facilitated the introduction of tools to site teams and the development new tools that help to understand a system and diagnose where errors or the risk of harm can occur.

## FACULTY DEVELOPMENT

Key learning to support faculty development was gained during Phase 1:

- Individuals within the Phase 1 sites considered themselves suited to supporting various Faculty roles, and many were keen to peer-assist new sites.
- Few Safer Clinical Systems programme participants were enthusiastic to take on a topic expert role.
- An in-depth knowledge of the evolving approach needed for the Safer Clinical Systems programme is considered obligatory for all involved in the faculty, to ensure that unique features of the approach are not lost.
- Phase 1 sites could have made more use of the expertise in the faculty but there was also a desire for the support of external experts.

The Faculty will include external experts, who would be individuals involved in related initiatives with knowledge that would support the Safer Clinical Systems faculty; they may not be aware of key features of the Safer Clinical Systems programme in which case they would need training to support their faculty role.

The plan for the faculty is to develop expertise from within the Phase 1 sites, to provide support to participants in Phase 2. This involvement could take the form of an individual with specific topic expertise, a generalist with knowledge of the wider Safer Clinical Systems programme, or a mentor for sites in their specific project. To date, faculty support has focused on increasing the knowledge of the team and their understanding of the evolving Safer Clinical Systems approach.

Evidence from Phase 1 indicates that training should not be provided on a generic basis but in response to specific needs. The level of expertise in existing sites is thought to be sufficient to meet the current needs of the projects and the overall programme. Potential future training needs, to build additional expertise in a Phase 2 faculty, will be considered.

## SUMMARY

A concluding statement from the WISER report (2010) specified that 'the contributing factors (to improved safety) suggest that a systems focus is required to improve the reliability of healthcare processes and patient safety'. Most safety improvement programmes have been developed around specific safety issues and involved closely defined interventions. The Safer Clinical Systems programme was developed to take a new approach that learns from improvement science and safety engineering aspects of risk management; where significant risk is identified in a system a formalised, prospective approach to safety is taken. The Safer Clinical Systems programme has begun to combine the approaches of improvement and prospective safety management and apply them to healthcare, to reduce harm and risk to patients by proactively improving system reliability. Phase one of the programme has also developed new tools, as well as the over arching new approach

Phase 1 of the Safer Clinical Systems programme targeted healthcare systems believed to be vulnerable to the occurrence of safety issues. The systems of interest were assessed using a range of tools, to identify key areas of safety risk, asses reliability, and design focussed interventions to reduce the level of risk by improving the reliability. The project took an iterative approach to allow exploration of diverse issues in the context of both the system and the organisational environment. Assessment of the impact of the project on the system under study primarily aimed to confirm reliability. Phase 1 has demonstrated proof-of-concept for the approach, having shown preliminary evidence of the capacity to improve reliability in systems for: aspects of patient flow within the hospital environment, patient information transfer, patient handover between different care settings, and medication prescribing within the hospital environment, Phase 1 has also involved the generation of a considerable body of learning applicable to the broader Safer Clinical Systems programme; this learning will be used to guide progression of the programme into Phase 2, particularly in terms of refining methodological and measurement processes and the wider goal of engendering a sustainable safety culture at the organisational level.