MASTER CLINICIAN'S GUIDE TO QUALITY AND SAFETY

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FOREWORD

At the Clinical Excellence Commission (CEC), we recognise that front line clinical staff are committed to improving outcomes for patients and their carers through an ongoing process of learning and evolution. As leaders dedicated to quality and safety within the NSW Health System, we want to work with health professionals, patients and their carers to improve the system.

The Master Clinician's Guide to Quality and Safety has been written and compiled by senior medical, nursing and patient safety professionals with the aim of assisting senior clinicians and managers to make a significant difference in fostering a culture of patient safety.

The Master Guide complements the previously released Clinician's Guide to Quality and Safety. Written in the same easy to read format, it covers such critical areas as data and measurement to drive change, mental health, patient safety, Clinical Governance Units, incident management and open disclosure. We have also included a chapter written by a junior clinician to highlight some of the issues they face and to stress the important role of senior clinicians and managers in supporting, supervising and mentoring junior clinicians in our health care system.

We at the CEC hope the Master Guide will help you by providing additional tools to not only improve the health system we work in, but to also improve patient outcomes and develop a patient safety culture as this is pivotal in providing safe and reliable care to all.

We hope that you enjoy reading the Master Guide and thank you for your leadership and commitment to quality and safety across the NSW Health System.

Carrie Marr
Chief Executive

Jonny Taitz
Clinical Director

INTRODUCTION

The Clinician's Guide to Quality and Safety was aimed at all clinicians, no matter how junior, because all clinicians have the potential to be patient safety leaders in some capacity.

This Master Clinician's Guide to Quality and Safety is for senior clinicians and managers. Why managers? Some clinicians are managers too, but some managers have no clinical involvement. Is this Master Guide really meant for them too? The answer is a firm 'yes'. High quality, safe patient care requires managers to be part of the health care team. Senior leaders have the ability to improve the quality of patient care by working alongside clinicians, ensuring that the culture of their health service is one which puts the patient firmly at the centre. Managers can help create a culture that doesn't merely react when an error occurs, but a culture which clearly says 'Safety is how we do business around here.'[1]

Patient safety is a key component of a mature health system, but it doesn't just happen because clinicians and managers decide it is a good thing. It needs a collective commitment from clinicians, managers and patients. It also needs the development of skills that are well recognised as proven ways of improving care and safety. Skills in improvement science need to be learned, practised and mastered.

Senior clinicians and managers need to know:

- How to turn an intervention into one that works
- How to build and involve an improvement team (which will often include a patient)
- The value of using incremental steps and learning from each one
- How to accurately measure whether change has occurred
- How to sustain and spread successful change
- How to learn from adverse events and perform timely, open disclosure.

We need to know and exemplify to other staff the importance of clear, honest, open communication when errors occur in patient care.

This guide will give you the theory, information and tools to be able to do these things.

Like learning any new set of skills, this will take some effort and require persistence. But it will be worth it: harm will be reduced, staff satisfaction will increase, costs will come down, your staff will start wanting to use these tools too, and, most importantly, patient care will be enhanced.

CHAPTER 1

'What matters to me' – as told by a parent

- **Patients must be at the centre of everything we do**
- **The patient and carer experience is critical**
- **Teamwork and communication between teams is highly valued by patients and carers**
- **Our patients and their families, culture, beliefs and struggles must be respected**
- **Thorough handover and discharge planning are essential but often overlooked.**

Safe: Protected from or not exposed to danger or risk; not likely to be harmed or lost.

'To our family the hospital environment is bittersweet. Like any family we are adverse to voluntarily taking or admitting our daughter to hospital, however over time there is some comfort in heading into the hospital too. There is a logic in going to hospital, a safety. It means that our child is no longer well at home and the sense of familiarity within the hospital's four walls means we can somehow rest a little easier. There are professionals around that can take over her care.

My husband will often joke that whenever he walks into hospital he can hardly keep his eyes open; he could fall asleep. On reflection we have come to realise what we once believed was just pure exhaustion is most likely an awareness that a hospital is the one and only place that you can actually truly relax, knowing that your child is in safe hands.

What works is the genuine people, who genuinely listen, genuinely care, and do not talk down to you or treat you as though you do not know your own child. A parent arriving at a hospital or undertaking an admission to hospital often means you are at the end of a long haul or your wit's end faced with no other option. Often parents will have been dealing with the situation for a long time before arriving. They may be oversensitive and most definitely exhausted (a doctor once told me lack of sleep is equivalent to blowing .08). I can speak from experience. I'm not proud of some of the things that I've probably said or done to nurses or doctors out of pure frustration. It is a cry for help when I have felt that they do not understand or that I have not been listened to. A mother can be a werewolf!

What works is having doctors who think outside the box for the betterment of the child and family. Thanks to a brave paediatrician and an emergency doctor, my daughter does not have a general anaesthetic every single time she goes in, as they have discovered a new way of using an intubation camera - otherwise she would by now have received approximately twenty general anaesthetics in two months. It is not a good result for a parent when you are told that certain things 'can't' be done even if it is in the interest of the child.

Lack of interpersonal skills and professionalism among health professionals can create negative experiences. When you are feeling vulnerable you just need someone to be nice and tolerate you. Friendly smiling nursing staff and a welcoming care setting are so important and kind, caring interactions with all staff is paramount. There is no limit to the value that can be placed on attentive and considerate health care staff that are both aware of and responsive to you and your child's needs.

An absence of empathy is enough to bring any parent to tears (and has done so). The distress is heightened when you feel that people within the hospital are not identifying with the stress and worry you are facing in relation to your child's care and consequently there is no sense of emotional support.

Feeling safe and secure is critical to a positive experience for children and their parents, as is good communication with health care staff. It causes angst when certain requests or questions are not acknowledged and attempts are not made to alleviate anxieties. Emotions run high.

Doctors, registrars or indeed any professionals that don't familiarise themselves with your child's case may fail to realise how exhausting this can be. Having to relive the history in detail over and over again, sometimes four to five times in one day, year on year can be frustrating, demoralising and stressful both for the exhausted and exasperated parents and the unfamiliar practitioner who tries to extract information from them.

What makes a difference is when you are well known to doctors/surgeons and they are made aware of your presentation to ED or other clinical areas in a timely fashion, particularly in complex or acute care settings. Often staff will tell a parent that they are not 'allowed' to contact key medical staff until they have ticked off all the previous steps. The number of times we have heard 'Oh if I had've known it was Indi we wouldn't have had to go through all that' makes the procedure seem like a colossal waste of time for all involved and a situation which could well be avoided.

Truly holistic care really matters. At times only the acute condition is looked at or treated and no attention given to our daughter's broader set of clinical needs such as existing comorbidities. This is further highlighted when health practitioners are not willing to collaborate or communicate about a case. Obviously that is not a holistic approach. As a family we ended up spending hundreds of dollars reliving events, doing the rounds to update specialists rather than the practitioners speaking to each other. There seemed to be a significant lack of processes to ensure coordination of care between services.

Eventually out of desperation we ended up travelling to the Mayo Clinic, US to find better holistic care under one roof. Practitioners came together to discuss the individual consideration of our daughter's complex case which ultimately contributed to her whole outcome.

While health professionals focus overly on the acute problem there can be a lack of consideration for patients' other health issues. This can lead to a family feeling overlooked, and as if there is a lack of respect and support due to the regularity of hospital visits. Lack of coordination of care due to seeing a different specialist for each health concern has certainly created negative experiences for us. Our family is fortunate as we have a senior paediatrician looking after our child who has the foresight to organise a holistic approach in his own time and who genuinely cares. Sadly we know this is a rarity. We also know through firsthand experience that it works. When this happens it makes a very big difference.

Experiences can be further helped or hindered by health care providers' willingness (or unwillingness) to consider or read about other specialists' recommendations and case history of your child. At one point we had a 10 week in-patient stay at a hospital. Upon discharge the follow-up psychologist wanted to do basic testing for ADHD. Why did no one raise the issue of ADHD during the 10 week stay when there was 24 hour behavioural and medical surveillance?

What matters to me and makes a difference are alerts in the system for acute patients such that staff members are aware of the personal circumstances. This can make all the difference between a positive and negative trip to the ED for our family.

The most important features in determining a positive or negative experience are the attitudes of health care professionals. In particular, nurses that provide comfort create a positive experience. It is exhausting, upsetting and frustrating when patients are not allocated nurses who are on repeat shifts. Having to explain something to yet another person on another shift for the umpteenth time is tiresome. Parents and children really appreciate familiarity and consistency of staff. They often will build a rapport and trust and know these little idiosyncrasies that make all the difference.

A good handover is crucial!

When being discharged either after a short or long term stay there need to be better procedures put in place for follow-up. Simply saying 'you need to get an appointment with your GP sometime' does not cut it in most instances.

Parents also need a night off to recuperate. Without rest you can become volatile. It is not fair on nursing staff when they are dealing with a parent working off minimal or no sleep who has not been outside the four walls of the ward or hospital. Play therapists, hospital dogs and fairy gardens can all work miracles when boredom sets in!

Information and communication are crucial to quality care. When communicating please don't refer to 'protocol', legislations or regulations. This is our child. You cannot communicate care or empathy by quoting a manual. Please talk to parents and explain in human, emotive terms.

As a parent you trust the doctors and health care professionals around you. It is really important to know that the health care providers are in control. This includes acknowledging the concerns of patients and their families; empathising with them; apologising when care goes wrong; and responding to parents' concerns with openness, trust and genuine understanding. We are human and expect that you are too.'

> **The most important features in determining a positive experience are the attitudes of health care professionals.**

CHAPTER 2

Thoughts from a junior clinician

- **Supporting junior clinicians in Quality Improvement is a core component of senior clinicians' and managers' roles**
- **Most junior clinicians do not have the skills and knowledge to perform a QI project**
- **Having a senior clinician or manager sponsor and mentor a junior clinician's QI project can often mean the difference between success and/or failure**
- **Highly reliable organisations require skilled and motivated clinicians of all levels, including junior clinicians**
- **The junior clinicians of today will be the leaders of tomorrow (and they may be caring for you!).**

'I am a senior resident at Sydney/Sydney Eye Hospital. This is my story and the beginning of my quality improvement and safety journey.

I first heard about audits and quality improvement projects as my peers discussed positive attributes sought at recruitment as a resident. For many of us, this was the first application for selection since entry into medical school. I had the impression from my peers that quality improvement was a key aspect of selection and that several residents were involved in many audits. At this stage it appeared to be an aspect of medicine which would enhance the CV and give a competitive edge for job applications/selection into training programs. Certainly, it is a common component of the selection criteria for job applications! I had very little idea of what it involved, what the processes were and what was the ultimate goal of such involvement at a junior level.

When I attended the Australian Medical Association ball, I realised the nominees and recipients of the Resident of the Year, Registrar of the Year and Supervisor of the Year awards were chosen not only for their excellent clinical skills but also their contribution to the workplace, the community and mentorship/support of their juniors and peers. This highlighted to me the responsibilities and opportunity for contribution from the early stages of one's career as a junior medical officer throughout and following training. This was also reflected in the excellent clinicians I admired during my clinical rotations as they went beyond clinical medicine to critique problems, brainstorm solutions and innovate to improve patient and staff issues.

During my experience as a junior medical officer, I had the opportunity to work as a JMO representative and participate in audits as part of the team; however I had not yet had the opportunity to understand the process of a quality improvement project and did not have the skills to design or complete one.

This year I was able to become involved in my first formal quality improvement project with our Clinical Nurse Consultant for infection control. I had approached her early in the year looking for an improvement project and she kindly included me as a junior medical officer representative for this project. I thought this was a great opportunity to be mentored and supported through a project by a clinician who works in quality and improvement every day.

The project was an innovative one using the new tool of Driver Diagrams and the team included nursing, administrative and medical representatives. It involved the review of infection control precautions at Sydney Eye Hospital, including trolleys, contents, signage and information required to inform infection control precaution decisions. The current trolley system of personal protective equipment with associated door signage had not been reviewed for over ten years and presented an excellent opportunity for improvement. There were many indications for the review. Staff had noticed that the corridor space had become cluttered with multiple infection control trolleys which posed persistent risk to patients with vision impairment or at a high falls risk. Trolleys had also become cluttered with all items of personal protective equipment and it was difficult to ascertain what was required for the type of isolation.

Detergent and hand rub dispensers had also been installed outside doors and were no longer required on the trolley. Furthermore, there have been new forms of dispensers developed which have been adopted in other hospitals, and these could potentially be used to improve the trolley system.

Under the guidance of our team leader, we had structured weekly meetings with all members, commencing with introducing the interdisciplinary team, identifying the problem and deciding on the SMART aim. We flowcharted the processes and decisions involved in assigning transmission-based precautions upon receiving a patient with multi-resistant organisms and the setup involved. We then brainstormed the problems and their causes using sticky notes, then grouped them in themes as in an affinity diagram. Problems highlighted included inadequate education and resources to guide decision making of isolation requirements and risks. We surveyed our own staff groups on whether they felt that the system should be changed to obtain a range of staff opinions and suggestions. Possible solutions were brainstormed and applied to the problem, such as wall bracket dispensing systems, education and resource folders for isolation of multi-resistant organisms.

Finally, a Driver Diagram was produced to provide a one page visual summary of the project, with complex cause and effect relationships demonstrated in a logical and understandable way. The solutions were then graded by impact and effort to highlight the simple and high impact solutions which should be prioritised. To-do lists were generated and we are now in the process of designing and implementing solutions.

This experience improved my understanding of quality improvement and has provided tools and a perspective which will shape my future practice and involvement in improvement. I think the Clinical Excellence Commission's 'Clinician's Guide to Quality and Safety' is an excellent resource for the junior clinician in guiding one through the formal processes and clarifying the rationale for each. While the earlier chapters explained the clinical relevance of quality and safety processes, chapter 5 demonstrated the key processes that I was involved in and was an excellent guide.

For a junior clinician who has yet to complete a project, the resource demystifies quality and safety and makes it relevant and accessible to all clinicians. The CEC also hosted a forum recently for junior clinicians on 'how to test and sustain quality improvement' with the inspiring guest speaker Maxine Power, which also helped consolidate the key aims and processes, as well as linking JMOs who have similar interests in contributing in this way.

I have noticed that an increasing number of junior clinicians are becoming involved in quality projects, which is a fantastic trend as there is a great deal that junior clinicians can contribute to the team and the health system. Through my quality improvement involvement journey, I have learnt that it is a highly relevant and fun process and a great opportunity for learning and development of team and leadership skills. I hope that I will continue my learning in this aspect of medicine which goes hand in hand with clinical medicine, and be able to critically appraise problems with the quality and safety perspective required to improve patient outcomes throughout my career.'

CHAPTER 3

Building highly reliable health care systems

- **Most health care systems have been reactive with a focus on learning what went wrong in the past**
- **Clinicians should agree on the minimum standards for highly performing teams and systems**
- **Senior clinicians and managers should be engaged in redesigning and transforming health care improvement**
- **An understanding of the culture of the organisation and its capability and capacity to grow is paramount**
- **We can learn as much by what goes right as by what goes wrong in the system.**

In our endeavours to improve the quality and safety of patient care, the increasing complexity of health care systems requires us to adopt a different approach.

To date, most health care systems have been reactive; focusing predominantly on learning from what went wrong. These one-off serious events, called serious adverse events, have been aggregated and trended over time. While they have helped inform strategies to improve the quality and safety of health care, this historical 'project and program' approach to improvement has its limitations. Despite best intentions, system improvements have rarely been aimed at redesigning or transforming, or maximising input from front line clinicians as to how we deliver care. This reactive approach is increasingly being challenged as being inadequate as we move from an incremental to a transformative approach to health care improvement.
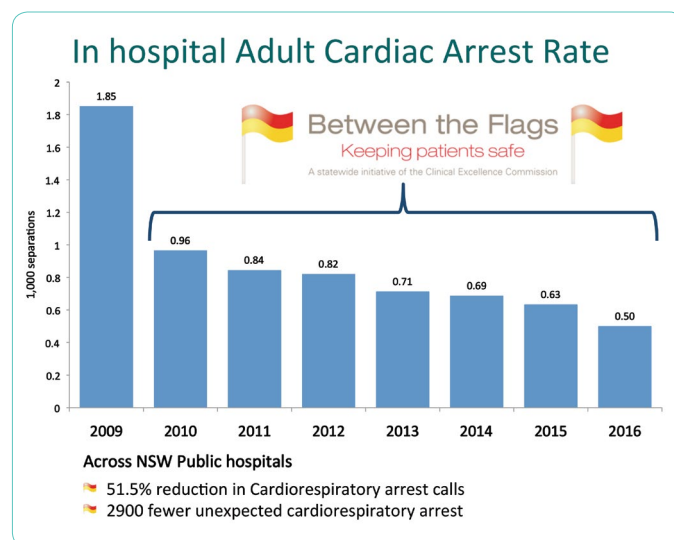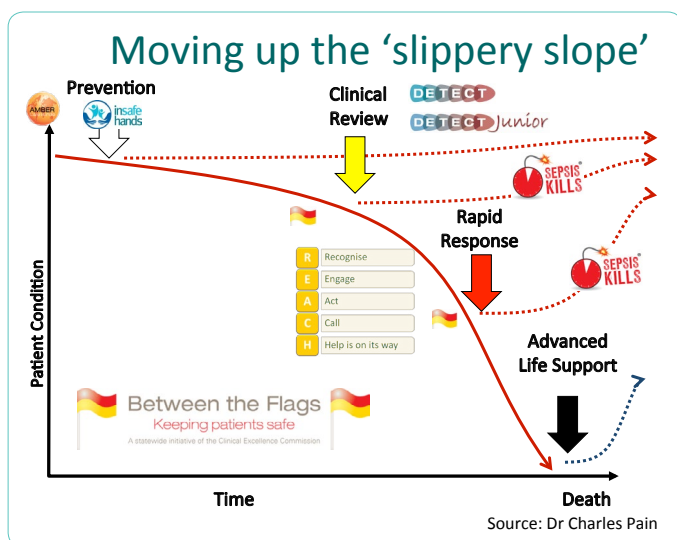
International literature is increasingly recognising this move to improving systems of care. Fundamentally, we do not wish to discount the importance of the competency of the individual clinicians who provide care; rather there is a need to shift the focus onto patients' experience and the totality of the system. This 'systems approach' considers the contribution of the sum of the various parts (structure, people, teams and processes) that contribute to the clinical outcomes.

It is no longer adequate simply to provide the best evidence-based care for a particular condition in isolation. We are now looking to provide the best evidence-based *system of care* for the patient. Much as we define the minimum standard of care for a particular condition, such as hip fracture in NSW, we now need agreement on the minimum standards for highly performing teams and systems. This will ensure the system around the care standards is continuously improving and help to build reliability and enhance our ability for real time learning so that future patients receive more reliable, more efficient and safer care.

To measure the system of care we must be clear about the various dimensions of quality and safety that we are striving to meet. The Institute of Medicine's definition of quality measures (appropriateness, access, efficiency, effectiveness and equity) as well as safety, is a good benchmark. It reminds us that it is not adequate to accept the absence of one component despite the presence of others e.g. a high degree of patient safety is compromised by poor access to care and a delay to definitive care.

A key starting point is to acknowledge that the health care system is a complex and adaptive one. This is a challenge to all managers and clinicians because if we are to move towards measuring a holistic expectation of quality and safety, the systematic approach will need to address all essential elements. Building a mature quality and safety system requires a strategic focus on people and leadership, governance, systems of care, education and evaluation. The Deteriorating Patient System Between The Flags (BTF) uses this kind of multivalent approach.

Charles Pain coined the phrase 'moving up the slippery slope'. The first diagram above shows how implementing BTF can move patients up the slippery slope. The second shows how BTF has reduced the in-hospital adult cardiac arrest rate.

Moving up the 'slippery slope'

Source: Dr Charles Pain

In hospital Adult Cardiac Arrest Rate

Across NSW Public hospitals
- 51.5% reduction in Cardiorespiratory arrest calls
- 2900 fewer unexpected cardiorespiratory arrest

At the level of the microsystem (ward or patient unit) we know that the following are important:

- **Leadership and governance** is the cornerstone for effective teamwork. Good leadership provides direction to clinicians while setting a high standard of clinical care and encompasses consideration of the needs of individual team members.

- **Team structures and dynamics** are important elements for good decision making. Situational awareness of team members, patients and the environment aids in understanding factors that may affect team performance, decision making and the delivery of safe and effective care. A shared mental model and mutual support are essential.

- **Care planning and coordination** is essential to ensure timely, effective and efficient care. This is particularly important for patients with complex health care needs.

- **Standard protocols and procedures** provide clinical teams with the resources and skills needed to provide safe and effective care continuously.

- **Patient safety and quality systems** assist in ensuring that what we are doing is working. Reflecting on clinical practice and evaluating care outcomes is an essential component in the delivery of safe effective care.

- **The patient experience** is improved when patients and their families are equal members of the health care team. It is essential that teams monitor and assess what is important to patients and whether they are meeting their needs.

- **Education, training and supervision** is fundamental to building and maintaining a sustainable workforce with appropriate skills and knowledge. Effective supervision and mentoring of all team members brings increased learning and professional development opportunities.

- **Workforce management** plays an important role in supporting high-performing teams. Processes can be designed to ensure effective teamwork is valued and sustained through recruitment practices, role descriptions, performance reviews and professional development. Standards for team behaviours should be defined and upheld through effective workforce strategies and processes.

- **Support services and equipment** include patient support assistants, cleaners, biomedical engineers and other support staff who play an important role in assisting the health care team to provide safe, effective care. Collaboration with these team members is frequently required.

- **Information management** tools including electronic journey boards and information sharing systems assist in ensuring that patient information at the point of care is current. Communication, teamwork and decision making relies on accurate patient information and communication pathways.

An understanding of the culture of the organisation and its capability and capacity to grow is paramount. This includes:

- Measuring and improving the quality of system leadership and management (ie leadership and the management team)
- Recognising the capabilities of all staff (clinical and non-clinical)
- Building team cohesiveness
- Optimising the flow of patients through redesigned systems and enhancing the quality of our individual care
- System interventions and how they can be rigorously applied including feedback loops to build a learning organisation.

Another way of thinking about the system comes from The Health Foundation (UK) model[2] which includes the following framework of five dimensions to assist in monitoring and improving safety:
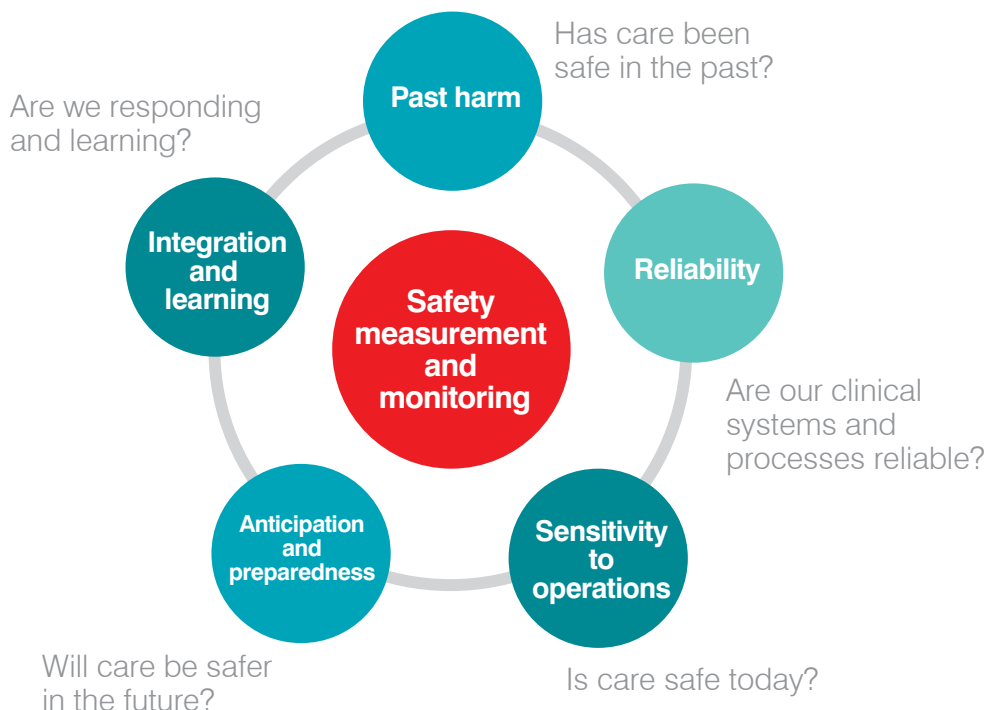
Past harm: encompasses both psychological and physical measures

Reliability: defined as 'failure-free operation over time' and applies to measures of behaviour, processes and systems

Sensitivity to operations: the information and capacity to monitor safety on an hourly or daily basis

Anticipation and preparedness: the ability to anticipate and be prepared for problems

Integration and learning: the ability to respond to and improve from safety information

If we consider this systems approach to measurement and monitoring of safety and apply it to a whole-of-system deteriorating patient safety net such as BTF, we can see how we need to know about:

- The past harms, trends and reasons for failing to detect and respond to deterioration

- The reliability (sensitivity and specificity) of our completed observations and escalation based on those observations

- The sensitivity to operations, meaning the appropriate clinical response to changes in patient clinical status and the application of ongoing clinical observations and actions taken

- Anticipation and preparedness, so that we move to predicting deterioration by using electronic algorithms which combine history, examination findings and investigation results

- Our integration and learning, so that clinicians can respond locally to information about the patient as well as lessons learnt about any weakness or failure in their local system.

The system is highly resistant to change and our improvement efforts over the past have demonstrated that our hopes and expectations of health care transformation, as opposed to incremental improvements, have not yet been realised. This drives us to consider how should we do things differently: what should be changed and what should be enhanced?[3]

This does not imply that our efforts have been wasted, nor that the approaches we have taken should be abandoned completely. Change is likely to be evolutionary rather than revolutionary.

We are gaining an appreciation of the importance of an understanding of the system and how it works before we adapt it. We can learn as much from *what goes right as what goes wrong* in the system.[4] We must trust and involve the people who work at the front lines of care because they know their part of the system and understand its strengths and vulnerabilities. They are also perfectly placed to help redesign it. However, front line staff often need support in this process because they may not be experienced system designers. They may also need support to implement their designs – hence an emphasis on coaching, advising and guiding is required.

Investment into the microsystem plays a fundamental role in transformation. The hospital is made up of many microsystems where the care is delivered by front line teams. The performance of the whole depends on the performance of its individual ward units.[5] We should therefore focus our improvement efforts at the front line of care, reorienting the rest of the system (meso and macrosystems) towards creating the conditions for high performance by improving team relationships and alignment at all levels. Spreading and sustaining change will be achieved by focusing on the performance of the microsystem, and replicating the ingredients of high performance across the whole system.

Tackling the complexity of health care is simplified if one begins at the front lines of care, trusting the commitment, integrity and innovation of the patient care teams while involving patients and supporting staff to perform to the best of their ability.

We will always need to consider individual practitioners' safety, knowledge and skills and how these are applied to clinical practice. We realise that we need to support innovation and at the same time deal with unsafe practices and culture. This requires a rigorous team focus – recognising and developing all teams, learning from our lessons and successes with (for instance) rapid response, trauma, and retrieval teams to help replicate these learnings to all other teams including non-clinical operations. High performance at the unit level is dependent on leadership, situational awareness, shared values and mental model, mutual support and teamwork. These are also the ingredients of high performance at all levels. This is where we can employ essentials of safety, such as huddles.

A whole of hospital (and whole of health care) approach is one which we need to drive. The linkages between the individuals and teams in the microsystem with the mesosystem and macrosystem are equally important. This is best illustrated by a hospital where patient care is provided by many different multidisciplinary teams and also requires inputs from external clinicians, providers or specialist services.

Short term goals and/or piecemeal change aimed at getting quick wins or driven by political or financial imperatives will derail the process and negate our strategic and longer-term focus. Quick wins are so named because they are considered relatively easy to obtain, however they can create a false reassurance of immediate improvement which is actually unsustainable.

Sustainability will be made more likely if we design solutions that win the hearts and minds of the leaders and clinicians, integrate into clinicians' everyday workflows, and have demonstrable benefits to clinical outcomes, patient safety and value for money. Consideration of all the stakeholders (patients, clinicians and management) is required.

Without sufficient understanding of the system, there is a risk that we do not obtain value for our resources, that we may lose credibility and our ability to influence, and that we may fail to secure legitimacy for our leadership, leading to a loss of followers and disengagement of front line staff. We must avoid these unintended harmful consequences. Lack of improvement sustainability also loses us credibility.[5] We have seen many who have already lost a great deal of credibility by such means.

We need to do something different if we are to transform the performance of the health care system. The lessons from the implementation of previous projects and work programs can help inform us. These programs have provided an understanding of what is needed in culture, leadership and governance from all levels. Individual clinician leaders and networks, NSW Ministry of Health, Clinical Excellence Commission, Agency for Clinical Innovation and Local Health Districts all play a role in establishing safe and reliable systems of care. We also need the hospital executives and front line clinicians and wards (microsystem) to work together in driving ongoing improvements at a local level.

Ultimately we will change the culture to one which is more proactive and predictive in order to intervene, anticipate and prevent patient harm rather than merely responding to it. As we reorient ourselves towards the front line clinicians and gain a better insight to what makes highly reliable teams, we can then aim to collectively describe the required team characteristics for effectiveness. By sharing our ideas and practical tools and skills, and co-designing new systems to build new highly functioning health care teams, we will improve health care quality and safety.

CHAPTER 4

Learning from adverse events

- **It is essential for senior clinicians and managers to understand how we learn from incidents in order to make our health system safer and more reliable**
- **We need to move the focus to real time measurement of harm**
- **By analysing all serious incidents and RCAs using a defined classification taxonomy, the CEC is able to understand whole of system harm**
- **The CEC uses a number of different formats to communicate lessons learnt. These include Biannual Clinical Incident Management data on CEC website, Patient Safety Watches, Clinical Focus Reports, Safety Alert Broadcasts, Safety Notices and Safety Alerts.**

Health professionals, managers and patients want reassurance that the health care organisation is safe and reliable. The elements and measures important to assessing and achieving safe, reliable high performance within an organisation are complex and multifactorial. Multiple measures of performance provide a more comprehensive assessment of safety and reliability.

Safe organisations systematically look for information to proactively learn and positively influence organisational learning and inform pre-emptive, continuous improvement to reduce harm and improve service. While reactive learning from incident investigation is essential, rather than relying heavily on incident investigation and subsequent recommendations to inform improvement opportunities, learning organisations integrate and analyse safety information from numerous sources across the organisation to develop safer systems, culture change, reliability and continuous learning. Such data sources include incident reports, patient safety indicators from administrative data, death reviews, coronial inquests, clinical audits, observational audits, patient and family feedback, staff feedback and culture surveys.

The NSW Health Incident Management Policy provides direction to health services regarding the management of clinical incidents and outlines the state-wide system for incident management. All staff have a responsibility to notify all incidents identified, in the NSW Health electronic Incident Management System (IMS). A clinical incident is any unplanned event which causes, or has the potential to cause, harm to a patient and includes near misses.

This section describes the methods utilised at the CEC to learn from adverse events notified in the IMS and investigated through root cause analysis (RCA) or other approved serious incident investigation methodologies outlined in the NSW Health Incident Management Policy. The CEC is responsible for the monitoring, analysing, identification and escalation of state-wide clinical risks identified though IMS. Following is a flow diagram of the process for serious incidents requiring RCA.

Incident requiring RCA occurs.

Open Disclosure process (pertaining to RCA) commences.

RCA conducted by team appointed by CE (under Privilege).

Open Disclosure process (pertaining to RCA) concludes.

RCA Report prepared.

RCA conducted by team appointed by CE (under privilege).

LHD Chief Executive endorsement of final RCA report.

RCA report provided to relevant LHD staff to implement recommendations.

RCA report provided to CEC.

RCA report provided to NSW Ministry of Health.

Implementation managed by CGU and Service directors.

CEC RCA Review Committees review and classify contributory factors.

RCA report provided to other MOH directorates, state bodies for ongoing system improvement.

Patient Safety teams conduct further analysis, IIMS reviews.

CEC Clinical Focus Reports, Incident management, reports to Minister, the public, LHDs and relevant agencies.

CEC response: including Program development, further monitoring, as appropriate.
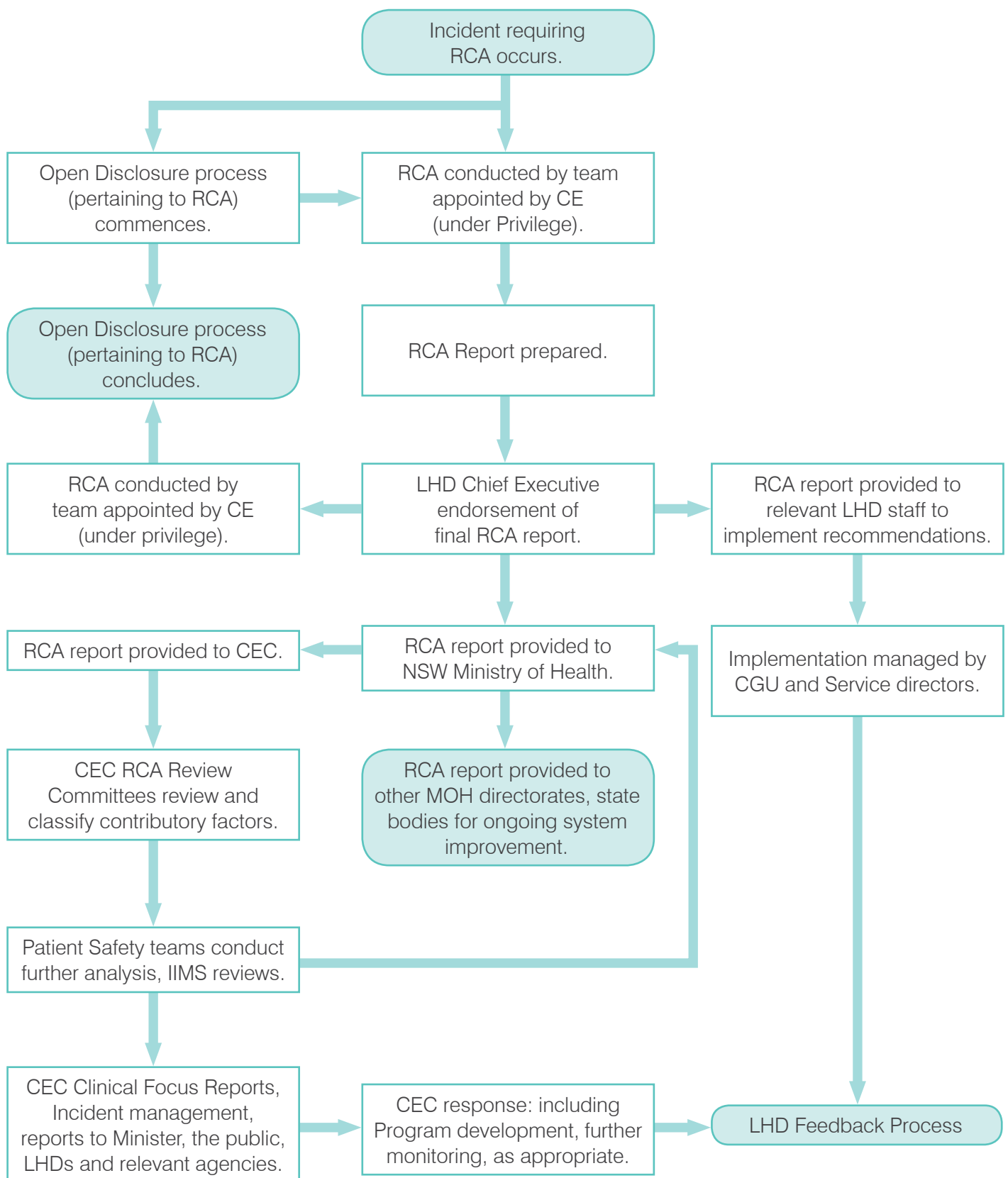
LHD Feedback Process

Figure 1 – Serious clinical incidents requiring RCA

Serious incident notification through IMS

The IMS contains all the information collected since state-wide clinical incident reporting was implemented in 2005. There are now over 170,000 clinical incidents notified each year and incident notification numbers are increasing. The increase in notifications each year is seen as an indication of increased staff awareness and recognition of incidents, and a positive reporting culture.

Incidents reported in the IMS are classified according to a list of Principal Incident Types (PITs), then further categorised against a Severity Assessment Code (SAC). The key purpose of the SAC is to determine the level of investigation and action required. There are four SAC ratings ranging from SAC1 (extreme risk) to SAC4 (low risk). Subsequent thematic analysis of clinical incident notifications enables significant issues, risks and trends relating to clinical care to be identified so staff and managers can work together to improve health care delivery systems. All SAC1 incidents and other lower SAC incidents approved by the Local Health District (LHD) Chief Executives (CE) are subject to a thorough RCA investigation or other approved serious incident investigation methodology as outlined in the NSW Health Incident Management policy. The aim of RCA or serious incident investigation is to find out what happened, identify the root causes and contributing factors that led to the incident, identify opportunities for system improvements, and develop recommendations to make health care processes, systems and services safer (Figure 1).

Early risk assessment

Early investigation of a serious incident within the first 24–72 hours of identification is an essential step in the investigation process. Establishing the immediate facts of what occurred and identification of current clinical risks to patients and staff will serve to inform senior clinicians and management of what immediate actions are required to prevent further harm to the patient, and/or mitigate the risk of recurrence.

Early investigation facilitates the preserving of physical evidence that may be lost over time. Evidence such as CCTV footage, environmental photos and isolation of equipment, medications and devices, can be later reviewed to assist in identifying contributing factors and root causes of system failures.

An experienced investigation team member engaging with staff within 72 hours of a serious incident enables the gathering of the recent recollections of the event from staff involved along with other important information that can inform the system improvements that are immediately required to prevent recurrence.

Some staff may fear that reporting an incident or providing information may result in litigation or disciplinary action. In fact gathering information from front line staff under a supportive and confidential process promotes a just culture and effective organisation learning. It also allows early opportunity to ensure support is provided to staff involved.

The provision of an interim or early investigation facilitates effective feedback to patients and families as part of the open disclosure process, and to staff as part of a transparent and supportive system improvement process. Information gained from early investigation of serious incidents can better inform formal incident escalation communications such as Reportable Incident Briefs (RIBs).

Reportable incidents and Reportable Incident Brief (RIB) process

All actual SAC1 clinical incidents and national sentinel events, as outlined in the NSW Health Incident Management policy, are *reportable incidents*. The RIB system within the IMS was designed for the reporting of these specific incidents to the NSW Ministry of Health (MoH). Within the NSW Health IMS there is a Reportable Incident Brief template/form to be completed by health service managers and sent to the CE. When the RIB is approved as complete by the CE it must then be submitted to the MoH via the RIB process.

NSW Health Incident Management policy provides comprehensive guidance regarding incident management, incidents requiring RIB, the RIB process, and serious incident investigation methodology.

A RIB is to be submitted within 24 hours of recognition of the incident. In some cases it is not possible to confirm the SAC of an incident and more information is required. The health service is required to act immediately to obtain the required information or advice so that legislated requirements are met. The NSW Health Clinical Risk Action Group (CRAG) committee is responsible for the assessment and oversight of management of serious clinical adverse events reported via RIB to the MoH. RIBs are prepared specifically for the CRAG committee. This authorised committee (under section 23 of the *Health Administration Act 1982*) analyses information derived from RIBs and associated RCAs to identify significant trends and implications for the provision of health care within NSW.

Material created for or by the CRAG committee is afforded statutory privilege and cannot be disclosed or released without approval by the Minister for Health or their authorised delegate. As RIBs are generated for the primary purpose of the CRAG, the RIB is therefore a privileged document under Section 23 of the Health Administration Act 1982 and should be maintained securely and not disclosed or used for any other purpose than for the CRAG.

The CEC collates and analyses all clinical RIBs and the associated RCA and serious incident investigation reports for the CRAG. There are approximately 500 Clinical SAC1 RIBs and related reports received each year at the MoH and subsequently reviewed by the Clinical Excellence Commission (CEC) RCA review committees. All clinical RIBs are assessed daily through a coordinated RIB huddle. Each RIB is reviewed for state-wide risks and, when required, further information is requested via the In-brief process.

Ministry of Health In-brief

Clinical RIBs are privileged documents and cannot be used for any purpose other than reporting to the CRAG. In order to obtain information that is not contained under statutory privilege, further detail regarding a serious incident or a progress update regarding an incident or issue can be requested by the MoH in the form of an In-brief. An In-brief provides more detailed information in response to specific information requested and is not afforded privilege.

Serious incident investigations

Under the provisions of Division 6C of Part 2 of the *Health Administration Act 1982*, when a reportable incident involving a relevant health services organisation is reported to the CE of the organisation, the organisation is to appoint an investigation team to conduct an RCA or other approved investigation methodology in accordance with *NSW Health Incident Management Policy*.

Clinical SAC1 investigations are privileged and require a report to be provided to the MoH within set time frames outlined in policy.

The CE has discretion to appoint an investigation team to conduct an RCA or other approved methodology for any clinical incident of a lesser severity than SAC1, if they are of the opinion that the incident may be the result of a serious systemic problem that justifies the appointment of a team. In that event, the investigation will also be afforded statutory privilege.

The health service's CE (or nominated delegate) is provided the final investigation report for endorsement of recommendations. The report is then submitted to the MoH. The MoH receives and acknowledges receipt of all clinical RCA reports.

Serious incident investigations, such as an RCA or other approved serious incident investigation methodologies as outlined in the Incident Management policy, aim primarily to identify what went wrong with the system and how to prevent recurrence. The investigation and analysis is system focused and not person focused. A systems approach to safety focuses on the latent errors within a process and system which staff work in, not the person/s who triggered the error. In the words of W Edwards Deming, 'A bad system will beat a good person every time'.

Organisations should not focus on an individual's performance. Certainly adequate training, education and professionalism are essential to the delivery of safe appropriate care. Human error will occur and more so in the highly complex organisations of health care delivery. Delivery of appropriate safe care every time is what every health care clinician and organisation should strive for. When a clinician is involved in a sequence of events that results in a serious incident they can be the first to blame themselves, yet the problem is seldom the individual's. The advanced and successful approach to error and incident management is to review and analyse the systems and processes in which staff work, to identify and rectify the failures or weaknesses within the system, and to increase reliability and safety. This approach supports all staff and patients who navigate through the increasingly technical and complex systems required for the provision of high quality patient centred health care.

NSW Health: Clinical Risk Action Group (CRAG)

As the peak clinical risk committee in NSW Health, the CRAG advises the Secretary and the Minister on means to address and reduce the occurrence of serious clinical incidents and oversee implementation of appropriate actions to minimise both the impact of their consequence and the likelihood of recurrence. The CRAG receives copies of the RCAs conducted in accordance with Division 6C of Part 2 of the *Health Administration Act 1982* (NSW Government Gazette No 115 of 18 December 2015).

Membership of the CRAG includes the chief executive (CE) of the CEC, CE of the NSW Agency for Clinical Innovation, Deputy Secretary System Purchasing and Performance, Deputy Secretary Governance/Workforce and Corporate, Director Office of Kids and Families, Chief Nursing and Midwifery Officer NSW Health, Chief Psychiatrist Mental Health and Drug and Alcohol, Local Health District/Specialty Health Network CE and Local Health District/Specialty Health Network Director of Clinical Governance (DCG).

The Chair of the CRAG is the CE of the CEC. The CEC provides the secretariat function to the CRAG committee, including the review of all submitted serious incident investigation. As part of this, the CEC has established four subcommittees and delegated functions in order to review clinical RCA reports as listed below:

- Clinical Management RCA review committee
- Children and Young Person RCA review committee
- Maternal and Perinatal RCA review committee
- Mental Health/Drug & Alcohol RCA review committee.

The secretariats of each subcommittee are members of the CEC Patient Safety Unit. Each receive RCA and serious incident reports via a secure inbox, and review and categorise them into committee folders in secure locations.

The RCA review committees meet regularly to review and classify the RCA and serious incident reports using a structured process and taxonomy. On behalf of the CRAG, the aim of the review and classification of the reports is to identify system-level themes that may have state-wide implications. In the event that serious risks or systems issues have been identified, the secretariats of each committee generate reports for the CRAG.

Reports from the four subcommittees are a regular agenda item at the CRAG monthly meetings. Following discussion at the CRAG, requests may be received for the CEC to undertake further incident analysis. This may involve the creation of reports such as: Clinical Focus Reports, Safety Alerts/Notices, Patient Safety Watches and thematic reviews.

Monthly RCA and serious incident feedback reports summarising the system issues, risks and themes obtained from the aggregated review of the investigation reports are provided to the LHD and SHN CEs and DCGs to inform system learning. Additionally, public reporting of incident management outcomes (including RCA analysis) is provided biannually on behalf of the CRAG via the CEC Clinical Incident Management report available at www.cec.health.nsw.gov.au by searching 'clinical incident management'.

NSW Health and CEC review and classification of RCA reports process – identifying the lessons learnt

Advanced understanding of how to analyse systems, human performance and their interaction is essential in developing and sustaining safe reliable learning organisations within health care. Understanding organisational and team culture and context is critical in gaining accurate information and insight into lessons learnt. A key element is clinician ownership of, and engagement with, incident information and analysis processes and subsequent actions to improve safety, reliability and efficiency of our health care systems. The following outlines the process utilised to review and classify serious incident investigation reports received at the CEC in order to aggregate and trend lessons learnt, and escalate awareness of identified state-wide risks.

The CEC RCA review committees classify each RCA report using a standard taxonomy adjusted to the committee specialty. This taxonomy has been developed over time and is adjusted to capture emerging system issues. The aim of the review and classification of the RCAs is to identify system-level themes that may have state-wide implications and prioritise communication of those risks to the CRAG.

RCA Review Committees comprise senior multidisciplinary clinicians and staff from across the state and include LHD Patient Safety Managers, health service managers, department directors, staff specialists, consultants, nursing unit managers, nursing consultants and senior allied health staff, ambulance service and CEC staff. An RCA report involving multiple specialties will be reviewed and classified by all relevant review committees to ensure appropriate senior multidisciplinary review, classification of system issues and identification of themes and emerging risks.

Themes identified through the RCA review and classifications have resulted in the development of state-wide programs, reports and tools such as Between The Flags, Sepsis Kills, Safety Alert Broadcasts, Patient Safety Watches and Clinical Focus Reports. Monitoring of system issues and emerging risks has assisted the CRAG in identifying areas requiring further assessment, support, resource and/or redesign.

The CEC RCA classification taxonomy combines the terminology used in health care with the science of classification, systems review, patient safety and human factors. It sets out categories and classifications with subsets related to the identification and classification of things that go wrong, in order to gain further understanding of the deeper reasons behind these errors.

The taxonomy focuses on communication, patient assessment and management, organisational leadership, environment and culture, and human factors. Overarching classification categories include:

- Specific services
- Clinical risk groups
- Principal incident types
- System factors contributing to the incident
- Recommendations
- Human factors contributing to the incident
- Identified patient factors that potentially increase the risk of harm.

The category of clinical risk groups classifies previously highlighted events or conditions known to be a cause of or contributor to adverse events. This helps to identify/trend conditions or events that are high risk to patient safety and which may increase the risk of an adverse event occurring. Examples include caesarean at full dilatation, failure to recognise a deteriorating patient, oxygen therapy and sepsis to name a few. The following table provides an example of the clinical risk factors used by the Clinical Management RCA review committee.

RISK GROUPS
Events or conditions that were a direct cause or contribution to the outcome of the incident

- Acute abdominal pain, inc. AAA - Acute coronary syndrome (ACS) - Aggression - Airway management - Allergy/ADR/anaphylaxis - Aspiration/choke - BTF charts/altered criteria - Confusion/Delirium - Deep vein thrombosis (DVT) - Dementia - Deteriorating patient – failure to recognise - Deteriorating patient – delay/failure to escalate - Deteriorating patient – inappropriate/delayed response to escalation - Deteriorating patient – issues with rapid response - Diagnostic error - Embolism – air - Embolism – fat - Embolism – pulmonary (PE) - eMR - Fluid management - Interpreter service not used - Locum/agency/casual staff - Look alike/sound alike	- Medication – all other - Medication – infusions/PCA/epidural - Medication – reconciliation - Oxygen therapy - Pain Management - Paramedic handover not passed on to treating teams - Patient absconded – ward/other - Patient absconded/did not wait – ED - Perforation during procedure (bowel/pneumothorax) - Post-fall management - Post-surgical/procedural care - Pregnancy impacted on care (pregnant patient) - Sepsis - Thromboprophylaxis - Trauma management **LOCATION** - Cardiac catheter laboratory - ED – representation - Imaging/Interventional Radiology - Out of hours presentation/admission - Small health facilities

The taxonomy also provides a list of system, human and patient factors that may contribute to an incident occurring. The next Table provides an example of some of these factors and the associated subsets that further identify system issues contributing to adverse events. Problems with access to services due to outlier or bed or service availability, problem with assessment of falls risk or physical health, and problem with care planning because high risk not considered or patient receiving wrong level of care are some examples. Further analysis of the problem and classifying why that problem/system factor occurred provides more detailed understanding of the system issue and more accurate identification of solutions. RCA varies in quality for each report. Sharing the taxonomy will assist RCA investigation teams in identifying system issues and using a common language within the report to assist state-wide aggregation and monitoring of their investigation findings to inform state-wide solutions.

RCA CLASSIFICATION TAXONOMY

SYSTEM FACTORS

Access	■ To service/bed ■ Outlier (patient location) ■ To diagnostics (imaging/pathology) ■ To external provider
Assessment	■ Cognitive/MH status ■ ED triage ■ Falls Risk ■ For approved leave ■ Harm to others risk ■ Patient/carer concerns not considered ■ Physical health ■ Pressure injury risk ■ Self harm/suicide risk
Care planning	■ Care continuity ■ Care coordination ■ Child protection ■ Discharge planning ■ End of life ■ High risk not considered ■ Inadequate care plan ■ Over-reliance on telephone contact ■ Patient expected to initiate own follow-up ■ Patient/carer not involved in care planning ■ Reliance on family/carer for support ■ Wrong level of care
Communication	■ Documentation inadequate ■ Inadequate information or education to patient/family/carer ■ Informed consent not obtained
Environment	■ Access to means to self harm ■ Activity ■ Culture ■ Physical surrounds
Equipment	■ Failed ■ Not available ■ Not used when indicated ■ Not working/not maintained ■ Suitability for purpose ■ Usability
Investigations	■ Not requested ■ Delayed ■ Inappropriate ■ Results not actioned ■ Results not reviewed

Observations & Monitoring	■ Physical/physiological observations inadequate ■ Significance not recognised/responded
Policy & Guidelines	■ None ■ Not available ■ Not implemented – by a staff member ■ Not implemented – by organisation ■ Not in line with NSW Health policy or EBP ■ Not known ■ Routine violation ■ Unclear/unworkable
Supervision	■ Delegation ■ Escalation ■ Support inadequate
Teamwork	■ Roles unclear or inappropriate ■ No identified lead clinician ■ Teamwork not evident
Transfer	■ From higher level care after hours ■ Inappropriate transfer of unsuitable patient
Workforce	■ Availability senior staff ■ Credentialing/scope of practice ■ Orientation/induction inadequate ■ Rostering/staff member ■ Skill mix ■ Training/education inadequate

RCA reports are used locally by the CE to inform clinicians and managers of what went wrong and what needs to be done to prevent recurrence. The lessons learnt from individual facilities and services are aggregated within the local heath districts, and further aggregation at a state-wide level provides a powerful message of what the patient safety risks are and the importance of sharing those lessons across the system, ie 'if it could happen in one facility, it could happen somewhere else'. Proactive learning prevents patient harm.

After the RCA reports have been reviewed by the CEC RCA review committees, the classifications are entered into a database/spreadsheet for identification and trending of identified system issues. The top system factors consistently identified in the RCA reviews include problems with care planning, communication and policy and guidelines.

Reporting the lessons learnt

Leaders and clinicians need multiple sources of data/information to understand context, safety and quality issues, and opportunities for improvement. For example, given the wide variation between services and facilities, accurate comparisons cannot be made based on IMS notification numbers alone. Caution is advised if using IMS reporting counts or rates as the single source of benchmarking data for a project or program, as many variables can influence incident reporting. Lower rates of reporting are not a reliable indicator of safer care. Further qualitative, rather than quantitative, interpretation of the data is therefore recommended. Supplementing voluntary reporting with formal assessments of harm rates provides valuable information and context, and promotes a culture of quality improvement. Triangulation of patient safety information from multi-disciplinary review of serious incident investigations, mortality and morbidity reviews, coroner reports, and health information (HIE) data provides combined information to inform gaps in care delivery and opportunities for system improvement and redesign.

Providing feedback of the lessons learnt from incident reporting to clinicians, managers, patients and the public is an essential step in system learning and improving reliability, effectiveness, appropriateness and safer patient care. Some examples of CEC feedback on lessons learnt to inform and improve NSW health care systems include the following:

Clinical focus reports
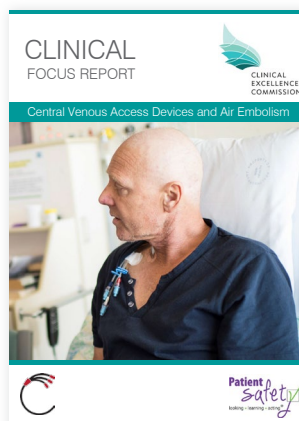
Clinical focus reports are prepared in response to system issues identified from IMS data, incident investigations, RCA report reviews, and collaboration with clinical experts and specialty reference groups. They may be initiated by the RCA Review Committee, the CRAG and/or the CEC patient safety directorate in response to emerging risks and themes identified. Clinical focus reports are provided to all LHD/SHN CEs and DCGs to distribute to all facility managers, directors of medical services, directors of nursing or allied health, senior management and department managers and, most importantly, to the clinicians at point of care within the LHD. All clinical focus reports are placed on the CEC website.

This system feedback aims to inform, raise awareness, and assist system wide improvement to mitigate harm and improve patient safety. The reports are generated in response to lessons learnt from incident notifications and investigation reports created by clinicians working within the system. They provide a source of system feedback to share learnings and best practice, thereby supporting a model of continuous organisational learning.

Example: air embolism is a preventable patient safety event. The CEC Patient Safety team and the CEC RCA review committee identified that incidents of air embolism occurred in patients with Central Venous Access Device (CVAD) in situ or on removal of the CVAD. Collaboration with the ACI and specialty reference groups was undertaken to further analyse the incident notifications and seek multidisciplinary clinical specialty advice. There were a number of common factors found which contributed to an increased risk of air embolism. A clinical focus report subsequently created by the CEC and ACI, 'Central Venous Access Devices and Air Embolism', highlighted common patient, clinical practice and system factors which contribute to CVAD related air embolism. This report along with other clinical focus reports can be found on the CEC website at www.cec. health.nsw.gov.au by searching 'clinical focus reports'.

Biannual Clinical Incident Management Report

As a lead agency for quality and safety improvement in the NSW public health system, the CEC is the delegated custodian of the state-wide data held within the IMS and has a key role in analysing and reporting on the information it provides. The patient safety team within the CEC regularly reviews the IMS and RCA reports to identify contributing factors, system issue trends and themes that can inform patient safety and quality improvement.

The CEC published its first web-based Clinical Incident Management Report in 2013, outlining biannual data summaries from January 2010 to December 2012. Each report provides state aggregated information on the number, principle types and severity of clinical incidents notified and some analysis of consumer complaints. These publicly available reports are on the CEC website.

Information is also provided on how to interpret the incident data and information. The greatest benefit of the IMS notification is contained in the narrative written by the notifier and manager. The narrative is seen as the voice of the clinician providing the care and working directly within the system. It is not recommended to use the IMS notification counts alone as a benchmark and these should not be considered an accurate measure.

The biannual Clinical Management Report can be located on www.cec.health.nsw.gov.au by searching 'clinical incident management'.

Patient Safety Watch

The CEC reviews report SAC1 and SAC2 IMS notifications twice a week. Additional searches are also undertaken on request and patient safety information is received from other sources, including clinical specialty groups, regarding potential and emerging risks. Risks are also identified from reviews undertaken by the CEC RCA review committees. These safety data form the basis of Patient Safety Watches which are released to the system to highlight an emerging trend or issue.

Safety Alert Broadcasts

Safety Alert Broadcast (SAB) notifications provide a systematic three-tiered approach to the distribution, prioritisation and management of patient safety information. This includes a standardised system for monitoring the implementation of required actions by Local Health Districts/Specialty Health Networks (LHDs/SHNs). The SAB notifications use the following colour coding to indicate the level of urgency:

• Safety Alert (Red)

The aim of the **Safety Alert** is to quickly disseminate information to LHDs/SHNs about a safety matter needing **immediate attention and action**. The Safety Alert specifies **mandatory** action/s to be taken by health services and the time frames in which such should occur, and assigns responsibility for action. LHDs/SHNs are required to acknowledge receipt within a defined time frame (usually two working days) and ensure:

- ☐ Completion of required action/s within designated time frame
- ☐ Local policies and guidelines are updated to include new information if required
- ☐ Required responses are submitted to the CEC at cec-quality@health.nsw.gov.au within the designated time frame.

• Safety Notice (Amber)

The aim of the **Safety Notice** is to inform LHDs/SHNs about potential quality and safety issues requiring **risk assessment at the local level** so as to determine appropriate action/s regarding any identified problems.

LHD/SHNs or services are required to:

- ☐ Consider the relevance of the information in the Safety Notices
- ☐ Review relevant policies and procedures in place to address the issues
- ☐ Identify required action/s and implement.

• Safety Information (Green)

The aim of the **Safety Information** is to disseminate quality and safety information to health services to ensure lessons learnt from state-wide, national and international sources are shared across the NSW Health System in an active manner. LHDs/SHNs or services are required to:

- ☐ Consider relevance of the information to the LHDs/SHNs
- ☐ Identify any action/s and implement (if any).

CHAPTER 5

Investigations and reviews

- **An investigation is a process of gathering facts about a matter and should be independent**
- **Investigations are a core component of clinical governance and not just a human resources concern**
- **It is important to have established terms of reference and a defined methodology**
- **Procedural fairness should be maintained at all times**
- **The decision maker is responsible for the final decisions and should be separate from the investigation team**
- **A key output of the investigation is the development of recommendations and a proposed timeline for their implementation.**

This chapter is a brief introduction to how investigations or reviews (called investigations in this chapter) should be conducted. It does not deal with the assessment of the matter resulting in the investigation, nor any action required by the health service to protect patient safety and well-being. Furthermore, the selection of the investigator/team is not addressed herein.

An investigation is defined as a process of gathering information to determine the facts about a matter regarding which the decision maker (see below) is then able to resolve a course of appropriate action.

Investigations come in all different sizes and complexities. They may range from a simple review of a minor matter to a large investigation with a team of experts gathering evidence from a variety of sources. Investigations may also range from the review of a simple service to investigation of a complaint or concern about a clinician. All investigations should be conducted with integrity, in search of the truth and in a timely manner.

Within NSW Health there are a range of policy directives that assist staff in undertaking investigations. The main policy directives are:

- *Incident Management Policy*
- *Management of a Complaint or Concern Against a Clinician Policy Directive and Guideline*
- *Look-Back Policy*
- *Misconduct Policy*.

In addition, the Ombudsman NSW has a very helpful fact sheet on *Investigation of complaints*. Their misconduct policy is broader and also has useful information about the assessment of the issue raising concerns, the conduct of an investigation and possible outcomes from an investigation.[6]

Terms of reference

Prior to undertaking an investigation it is important to determine its specific purpose and scope. For larger investigations, these are set out in the Terms of Reference. Even if formal terms of reference have not been developed, it is important that the investigators are clear about what they are trying to achieve and the bounds of their investigation. It is also important to ensure that prior to commencement, appropriate expert advice on the terms of reference and the clinical context of the investigation is sought.

The terms of reference should include the specific purpose of the investigation; the scope or bounds of the investigation so that it is clear what it does and doesn't cover; the composition of the investigation team, including relevant experts; the time frame of the investigation; and when necessary, the methodology to be used.

Any perceived or real conflicts of interest need to be declared to the person commissioning the investigation (Chief Executive, Director of Clinical Governance) prior to commencement. It is the responsibility of the commissioner of the investigation to manage perceived or real conflicts of interest in order that they will not impact its findings.

At times there may be other investigations taking place including police, disciplinary proceedings or other aspects. In such situations it is important that the investigation coordinates with these others as far as is possible without jeopardising the integrity of any of the investigations. At times the police may request that the health service delay its investigation until they have completed theirs so as not to contaminate witnesses. While this may be convenient for the police, it may not absolve the health service from undertaking a timely investigation. If there are concerns of this nature, legal advice should be sought.

Sources of evidence

There are a number of sources of evidence that can inform the investigation, depending on its type. They may include a review of medical records (both paper copies and electronic); witnesses to events, either through witness statements or interviews; other documents such as emails and reports; and answers to specific questions posed by the investigation team. The team needs to identify early in the investigation the possible sources of evidence and how they will be obtained. On some occasions it may be important to secure physical evidence so that it may not be tampered with. This may include the medical records so that retrospective entries are not made.

In assessing the evidence, it is important to determine beforehand what the standard of care is in a particular situation. Relevant content experts should be able to advise on the standard of care to be applied in the investigation. Not only is it important to determine the standard of care but also how that standard is to be measured in the investigation. The specification of the standard of care should be as objective as possible. For example, the NSW Health Code of Conduct specifies the behaviour expected of staff of NSW Health.

For investigations undertaken by health services, the standard required is based on the 'balance of probabilities'. It is only in criminal cases where the standard of evidence is required to be 'beyond reasonable doubt'. Since health services will not be undertaking criminal cases, the 'balance of probabilities' is the accepted level of evidence required to form an opinion about the information gathered (see also the Briginshaw Principle on page 25).

Conduct of an investigation

If not already included in the Terms of Reference, a methodology for conducting the information gathering should be determined and documented prior to commencement.

All investigations should be independent investigations. Furthermore, they should be *perceived* as being independent for the parties involved in the proceedings. The investigators need to address any perceived conflicts of interest (e.g. a previous relationship with one of the parties to the matter) and decisions made as to their relevance and how they will be managed.

The interviewing of witnesses can be challenging. It is important to identify in advance the questions to be asked. However, at times it may be necessary to depart from these during the interview to explore a new finding. Interviewees should be given due notice (i.e. of more than 48 hours) prior to the interview and be able to bring a support person along. At least two investigators should conduct the interview to avoid a situation where the interviewer and the interviewee have different interpretations of what occurred.

Making a record of interview can be problematic. While it is good to have an audio recording, these are often difficult and time-consuming to transcribe, and the result can be hard to analyse. An alternative approach is to take short notes during the interview. It is good practice to have the interviewee confirm the record's accuracy – this helps to avoid future conflicts about what was said, as it is not uncommon for multiple parties to have differing recollections.

Investigations often review many documents and these can be difficult to manage. It is important to have a good filing system so that the investigation team may return to key documents when required. The team should not underestimate how long it takes to review documents, particularly medical records. Adequate resources and time need to be allocated.

In most situations, health services are not able to compel a person to attend an interview or answer questions. A refusal of a party to cooperate with the investigation should be documented in the report with a comment about how this lack of evidence has influenced the investigation. The evidence could be central to the substantive issues being investigated and therefore problematic for the findings or it may concern a minor aspect of the investigation and therefore not affect them.

If the investigation involves a respondent to the complaint or concern, it is important to provide them with details of the allegations. However, it is often not appropriate to provide the respondent with the complaint in full, as the complainant may be subject to possible repercussions from the respondent. Therefore the respondent is provided with a summary of the substantial allegations against them.

Procedural fairness

It is important for the investigation team to ensure procedural fairness as it is not uncommon for accurate investigations to be undone because procedural fairness was not followed.

It is therefore important for any respondent to be made aware of all relevant allegations against them and the investigation's findings, and have an opportunity to respond to these within an appropriate time frame. The period of time for the respondent to reply to the allegations should be sufficient for them to make an appropriate response but not unduly delay the investigation.

Output of the investigation

Normally the investigation will result in a report to the person that has commissioned the investigation. This will include the terms of reference, methodology, sources of evidence, findings and, if requested at the initiation of the investigation, any recommendations to the decision maker. The report may be relatively short or it may be quite extensive for more involved and complex investigations. In the latter case, an executive summary should also be included. The report should also include recommendations from the investigation and a proposed timeline for their implementation.

Decision maker

Normally the investigation team does not make the decision as to what will happen as a result of the investigation. In most circumstances it is important that the decision maker is separate to the investigation team.

It is the role of the decision maker to determine what actions will arise from the investigation. In undertaking any such action, the decision maker will need to ensure that procedural fairness is again maintained. This will normally include providing the respondent with a copy of the report and the proposed actions so that they can respond. At this point the Briginshaw principle[2] is important to take into account. This principle indicates that the level of satisfaction with the evidence in the investigation report considered by the decision maker must be commensurate with the gravity of the consequences flowing from the particular findings. This means that where the actions proposed are more serious (e.g. termination) then the decision maker needs to be satisfied that the findings support such actions.

Conclusion

This brief chapter only touches on the key issues in conducting investigations and readers are referred to the policies and Ombudsman's fact sheet cited earlier.

CHAPTER 6

Open disclosure

- **Open disclosure is required whenever a patient has been harmed**
- **Senior clinicians and executives should foster a culture that supports timely and full open disclosure**
- **There are five essential elements of open disclosure**
- **Being open and honest is the basis for the relationship of trust between patients, their health care providers and the facilities in which they are treated**
- **Formal open disclosure requires planning and should be led by the senior clinician responsible for the patient's care.**

Open disclosure is defined in the *Australian Open Disclosure Framework* as:

'an open discussion or series of discussions with a patient and/or their support person(s) about a patient safety incident which could have resulted, or did result in harm to that patient while they were receiving health care.'

Open disclosure is required whenever a patient has been harmed, whether that harm is a result of an unplanned or unintended event or circumstance, or an outcome of an illness or its treatment that has not met the patient's or the clinician's expectation for improvement or cure.

A disclosure discussion is also generally required when a 'no harm' incident has been identified, and may be required for 'near miss' incidents if there is an ongoing safety risk to the patient and the patient would benefit from knowing.

Open disclosure can:

- Increase trust between patients and health care providers when information is exchanged and an apology is received
- Assist patients to become more active partners in their care
- Improve patient safety through greater understanding of how things go wrong
- Improve patient safety through learning how to prevent things going wrong.

Patient safety incidents may be classified as follows:

A harmful incident:

A patient safety incident that resulted in harm to a patient, including harm resulting when a patient did not receive his/her planned or expected treatment. The term 'harmful incident' covers what used to be known as an 'adverse event' and/or a 'sentinel event.'

A no harm incident:

A patient safety incident occurs but does not result in patient harm – eg a blood transfusion being given to the wrong patient but the patient was unharmed because the blood was compatible.

A near miss:

A patient safety incident that did not cause harm but had the potential to do so – for example a unit of blood being connected to the wrong patient's intravenous line, but the error being detected before the transfusion starts.

The NSW Health Open Disclosure Policy sets out the minimum requirements for implementing open disclosure following a patient safety incident within NSW Health services. The policy outlines the two stages of the open disclosure process – clinician disclosure and formal open disclosure. Effective open disclosure requires that health care facilities provide for staff and patients a just, fair and safe culture which values patient-based care, focuses on continuous learning and improving quality and patient safety, and discourages speculation and attribution of blame.

Immediate action: supporting the patient and the clinician

Any person working in any capacity within NSW Health, including contractors, students and volunteers, who identifies that a patient safety incident has occurred has a duty to take action. The initial response to a patient safety incident may be by the person who identified the incident or a responsible person who was notified and involves:

- Ensuring personal safety
- Providing immediate and appropriate clinical care to the patient and safeguarding against further harm
- Notifying relevant people – eg the unit/department manager, senior treating clinician and the patient and/or their support person(s)
- Providing support for health care staff if required
- Assessing the incident for severity of harm and the level of open disclosure response required.

The next steps

Once immediate support has been provided for the patient, their support person(s) and health care staff involved in the incident, the next steps are:

1. Gathering basic information about the incident from clinicians and other health care staff involved while the details are still fresh (ensuring confidentiality is maintained)

2. Gathering basic information about the incident from the patient and their support person(s), if able, while the details are still fresh (ensuring confidentiality is maintained)

3. The initial open disclosure conversation – clinician disclosure.

The NSW Health Incident Management Policy outlines the steps for notifying and recording a patient safety incident. Reporting, investigating and analysing the causes of such incidents should begin as soon as possible. Staff members are required to record all patient safety incidents in the patient's health record and the IMS.

The five essential elements of open disclosure are:

- An apology
- A factual explanation of what happened
- An opportunity for the patient to relate his or her experience
- A discussion of the potential consequences
- An explanation of the steps being taken to manage the event and prevent recurrence.

In addition, effective open disclosure also includes:

- Acknowledging to the patient and/or their support person(s) when things go wrong
- Listening and responding appropriately when the patient and/or their support person(s) relate their experiences, concerns and feelings
- Giving the patient and/or their support person(s) the opportunity to ask questions and get answers
- Providing support for patients and their support person(s) and health care staff to cope with the physical and psychological consequences of what happened.

Being open and honest is the basis for the relationship of trust between patients, their health care providers and the facilities in which they are treated

Clinician disclosure is an informal process involving:

- **Meeting with the patient** and/or their support person(s) once the patient is removed from any harmful situation and has received treatment and support for the harm that may have occurred
- **Acknowledging the patient safety incident** to the patient and/or their support person(s)
- **Explaining** all known facts relevant to the incident, to provide context for the apology
- **Apologising** for the occurrence of the event
- **Actively seeking input and feedback** from and **listening** to the patient and/or their support person(s)
- Consulting with the patient and/or their support person(s) on **a plan for ongoing care** if required, including the possible need for formal open disclosure
- Providing contact names and phone numbers of people in the health service who are available to address concerns and complaints, including psychological and social support contacts.

During these discussions, it is important not to speculate, attribute blame to yourself or others, criticise individuals or imply legal liability. If you don't know the cause of the patient safety incident, say so, and explain what is being done to investigate the cause(s) of the incident.

For patient safety incidents where the patient has suffered anything more than minor harm, the senior treating clinician or manager should be engaged as promptly as possible and participate in clinician disclosure, unless the patient and/or their support person(s) request otherwise. A serious patient safety incident represents a major threat to the patient's sense of control and trust in the health care team. It is essential that the initial communication be with a person with whom the patient has a trusting relationship, and that it conveys care, concern and respect for the patient.

Formal open disclosure is a structured process which follows on from clinician disclosure as soon as is practicable. It provides a format that facilitates effective and timely communications between the patient and/or their support person(s), clinicians, senior clinical leaders and the organisation.

To enable this process, a multidisciplinary open disclosure team is activated before meeting with the patient and/or their support person. A senior clinician or manager who is trained as an open disclosure advisor guides this team through preparation, delivery and debriefing of the formal open disclosure discussion with the patient and/or their support person.

Formal open disclosure may be required for any patient safety incident, as determined by the Director of Clinical Governance (DCG), and/or the appropriate senior manager (eg the facility, operations or health service manager), and the patient and/or their support person(s).

Signaling the need for formal open disclosure

There are several signals that formal open disclosure may be required, including:

- If the patient and/or their support person(s) indicate to health care staff that their concerns have not been resolved, either on follow up by the clinician or manager, or through local complaints
- Type of adverse event where the DCG and/or the facility/operations/service manager determines that the response should be escalated to formal open disclosure

Formal open disclosure may be required for any clinical incident, regardless of the Severity Assessment Code (SAC).

Preparation for a formal open disclosure discussion

The key actions to prepare for a formal open disclosure discussion include:

- Notifying all relevant people about the patient safety incident and the requirement for formal open disclosure
- Documenting commencement of formal open disclosure
- Considering legal and insurance issues for the organisation and clinicians
- Appointing the open disclosure coordinator
- Liaising with the patient and/or their support person to offer and arrange the formal open disclosure discussion
- Contacting an open disclosure advisor to provide support to the team
- Identifying a senior staff member experienced in open disclosure to lead the formal open disclosure discussion
- Establishing the open disclosure team, with the assistance of the open disclosure coordinator
- Meeting of the open disclosure team to prepare for a formal open disclosure discussion with a patient and/or their support person.

The open disclosure advisor is a senior staff member specially trained in advanced empathic communication skills, who is available to support formal open disclosure in a health facility or service and whose role is to provide impartial, unbiased and informed advice and guidance.

The senior clinician responsible for the patient's care should be the person to lead the formal open disclosure discussion with the patient and/or their support person(s). This could be the patient's medical consultant, nurse or midwifery practitioner or nurse/midwife consultant or a senior allied health representative, depending on the nature of the incident. It is important to consider the wishes of the patient and/or their support person(s) about who will be leading this discussion. The patient may prefer the person they trust to lead the discussion and facilitate the contributions of the other staff.

The role of the open disclosure team is to support and oversee formal open disclosure for a patient safety incident. Not all team members will be required to attend the discussion with the patient and/or their support person(s). The composition of the team should be appropriate for the size and structure of the health care facility and include multidisciplinary representation suitable for the type of incident. Members are responsible for meeting to prepare for a formal open disclosure discussion with the patient and/or their support person. The roles and responsibilities of the open disclosure coordinator, open disclosure advisor and senior staff member leading the open disclosure discussion may overlap in smaller facilities or services.

The open disclosure coordinator will be able to advise on the composition of the team for each open disclosure discussion, taking into account the patient's preferences. Patients generally prefer to speak with a senior clinician who has been involved in their care. Wherever possible, appropriate arrangements should be negotiated with the clinicians and the family. Families often prefer to have the discussion at their home or at a neutral location and this option should be offered to them.

The open disclosure advisor should meet with the health care staff involved in the formal open disclosure discussion as soon as possible afterwards. The purpose of this meeting is to review the discussion outcomes, which are then reported back to the open disclosure team and included with any documentation from the planning discussion.

Responses to any offers made to the patient and/or their support person(s) are recorded, along with any outstanding issues to be resolved, undertakings given that need to be followed through, and recommendations to the team about further management of the patient safety incident.

The review discussion also provides an opportunity for clinicians to debrief with the open disclosure advisor, to identify any unresolved or new areas of concern for the clinicians as a result of the discussion, and to discuss how ongoing support for the clinicians (if required) will be delivered by the health service.

When any investigations or reviews of the patient safety incident have been completed, information should be provided to the patient and/or their support person(s) in the form most acceptable to them. Ideally this should occur at a face to face discussion. This is especially important when a copy of the Root Cause Analysis (RCA) report is to be provided, to ensure that the often impersonal and clinical nature of the report can be explained, to enable discussion of the content and to allow for questions to be asked. Information provided should include:

- Details of the patient safety incident such as the sequence of clinical and other relevant facts
- Details of the concerns or complaints raised by the patient and/or their support person(s)
- An apology (in similar terms to verbal apologies already made) for the harm suffered and shortcomings in the delivery of care
- A summary of the factors that contributed to the patient safety incident
- Information on what has been done and will be done to avoid recurrence of the incident type, and how these improvements will be monitored.

Whenever a report is to be provided to the patient and/or their support person(s) in addition to a RCA report, or when an RCA has not been required, care should be taken to ensure that the language and communication style are appropriate to the patient and/or their support person(s).

The patient and/or their support person(s) may ask that provision of the final investigation report is deferred. In such cases they must be provided with the name and contact details of a liaison person at the health care facility and informed that they may request to receive the final report at any time.

Continuity of care

The patient and/or their support person(s) should be clearly informed about and involved in planning for ongoing clinical management. This may include arrangements for rehabilitation and transition of care to their general practitioner or a community care provider.

Reassurance should be provided to the patient and/or their support person(s) that they will continue to be treated according to their clinical needs, even if they are in dispute with the health care team. They should also be informed that they have the right to continue their treatment with another health care provider if they prefer.

Monitoring systems improvements

The CGU and/or the manager responsible for insurable risk should monitor and record the implementation of any changes recommended as a result of a review or investigation into the patient safety incident, and the effectiveness of those measures in preventing a recurrence.

Where possible, the patient and/or their support person(s) should be offered an update on implementation and effectiveness of any changes to practice that have been made as a result of the patient safety incident, within an agreed time frame.

STARS® TOOL FOR CLINICIAN DISCLOSURE

S — Sorry: AAA
- **Acknowledge** what happened, explain known facts
- **Apologise** for the incident **"I'm sorry that this has happened"**
- **Acknowledge the consequences** for the patient.

T — Tell me about it: ask the patient and/or their support person to tell their story about what happened. Listen and respond appropriately.

A — Answer questions: honestly, without speculation or blame.

R — Response: Explain what happens next
- **the plan for future care** including a person to contact
- **follow up**
- **lessons learned** - how the incident will be investigated and managed to prevent recurrence.

S — Summarise: key points of the discussion and the next steps.

For more detailed information please refer to the Clinician Disclosure section of the CEC Open Disclosure Handbook
www.cec.health.nsw.gov.au/programs/open-disclosure

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Examples of suitable words to use:

Sorry: Acknowledge, Apologise, Acknowledge

Acknowledge what happened:

'Mrs Smith, the staff have let me know that you didn't receive your insulin when it was due this morning.'

Apologise:

'I am sorry that this has happened.'

Acknowledge the impact of the patient safety incident:

'We will need to check your blood sugar more often today. I agree that things didn't go to plan. I can see that you are upset. I am really sorry.'

Tell me about it

'To find out exactly what happened, I'd like to understand what you saw or experienced. This may help us to understand how this could have happened and how to prevent things like it happening in future.'

Answer Questions

'You may have some questions that you need answered – you can ask questions at any time. What would you like to know?'

Response/Plan for care

'The problem was recognised quickly and we are now back on schedule with your insulin injections. With your permission, we will continue your treatment as planned. If you feel or notice anything unusual please let us know. We don't expect that you will need to stay here any longer than originally planned.'

Summarise

'We still need to find out how this happened, and we will let you know as soon as possible what we find out. I will be here today until 5pm. If you have any questions or concerns, please contact me or the nurse in charge. Please feel free to ask the staff as well if there is anything you need or want to discuss. Is there anyone that you would like us to contact for you? From your admission notes I can see you have nominated [name of nominee].'

For more detailed information please refer to the *CEC Open Disclosure Handbook* (search under 'CEC Open Disclosure Handbook' at www.cec.health.nsw.gov.au).

CHAPTER 7

Essentials for a high functioning Clinical Governance Unit

Developing a focus on patient safety and reliability

How we got here - ten years on

- **Clinical Governance Units (CGU) were set up as part of the NSW Patient Safety and Clinical Quality Program**
- **It is important to encourage a culture that ensures there is both a system and clinician responsibility for safety and quality**
- **CGUs can comprise patient safety, patient experience, consumer engagement, quality, policy, data analytics, change and innovation**
- **Despite significant improvements in patient safety, there is still room for improvement**
- **To reach full potential, CGUs need to engage and partner with senior clinicians, managers and the whole organisation with quality and safety as shared goals.**

In 2005 the New South Wales Government launched the Patient Safety and Clinical Quality Program.[8] This was a response to the Camden/Campbelltown inquiry (Bret Walker SC Report) into a cover up of serious adverse events, as well as other high profile public inquiries which revealed health systems as unsafe. These included an inquiry at Bristol, UK which identified a significant mortality rate for children undergoing cardiac surgery compared to peer hospitals, a review of King Edward Memorial Hospital in Perth, WA which found obstetric mortality and morbidity there was significantly higher than at other centres, and the Royal Melbourne Hospital inquiry into allegations of misconduct in the intensive care unit.

The NSW Patient Safety and Clinical Quality Program had five key components:

- The systematic management of incidents and risks to identify appropriate remedial action and systemic reforms
- The Incident Management System (IMS) to facilitate the timely notification of incidents, track investigation and analysis of health care incidents and enable incident reporting
- The establishment of CGUs to implement the NSW Patient Safety and Clinical Quality Program
- A Clinical Excellence Commission
- A Quality Systems Assessment (which has been superseded by an Organisational Safety and Improvement matrix).

The NSW Patient Safety and Clinical Quality Program is underpinned by 'just culture' guiding principles. James Reason has described a 'just culture' as an environment in which people are encouraged to provide essential safety-related information, but are also clear about where the line must be drawn between acceptable and unacceptable behaviour. There is an expectation that when an adverse event occurs, individuals will be treated fairly and not held accountable for system failings over which they have no control.[9]

Key 'just culture' principles can be summarised as follows:

1. **Openness about failures** – errors are reported and acknowledged without fear of inappropriate blame, and patients and their families are told what went wrong and why

2. **Emphasis on learning** – the system is oriented towards learning from mistakes and extensively employs improvement methods

3. **Obligation to act** – the obligation to take action to remedy problems is clearly accepted and allocation of this responsibility is unambiguous and explicit

4. **Accountability** – the limits of individual accountability are clear so individuals understand when they may be held accountable for their actions

5. **Just culture** – individuals are treated fairly and are not blamed for the failures of the system

6. **Appropriate prioritisation of action** – action to address problems is prioritised according to available resources and directed to those areas where the greatest improvements are possible

7. **Teamwork** – teamwork is recognised as the best defence against system failures and is explicitly encouraged and fostered within a culture of trust and mutual respect.

Looking forward

The Australian Safety and Quality Framework for Health Care [10] specifies three core principles which contribute to safe and high quality health care – namely that it should be :

- Consumer centred
- Driven by information
- Organised for safety.

Clinical governance is a framework in which the governing body, managers, clinicians and staff share responsibility and accountability for the quality of care, continuously work to reduce and minimise risks, foster an environment of excellence, and safeguard the maintenance of high standards.

It has been over ten years since the establishment of CGUs across NSW. Despite the huge efforts made towards improving safety, there is still much room for improvement. Industries with a perceived higher risk, such as the aviation and nuclear sectors, have a much better safety record than health care. There is a 1 in 1,000,000 chance of a traveller being harmed or killed while in an aircraft, while estimates show that in developed countries as many as 1 in 10 patients are harmed while receiving hospital care. This harm can be caused by a range of errors or adverse events.[11]

While the inception of CGUs was timely and appropriate, our current challenge is to ensure a shift from the historical focus on better compliance, towards continuous improvement. In order to progress the important work of improving patient safety and experience and our own reliability, our approach needs to focus on collaboration and capacity building. Certain factors and conditions need to be in place for this shift from compliance to improvement to occur throughout the organisation.

A highly effective CGU will steer the organisation into a culture of transformational change by creating a systematic culture of continuous improvement for both staff and patients.[12] The CGU is not only a resource for executives, facilities and district organisations, it is also there to support and encourage clinicians in making improvements in day to day work, thereby improving quality of care and patient safety.

It is important to note that reliable organisations have strong clinical leadership. While policies and protocols are a vital cornerstone of clinical standards, it is clinicians who have to implement them. Therefore it is imperative that they are involved in an ongoing dialogue from the very beginning. It is important to recognise what clinicians view as quality – they are interested in time (not wasting it) and patient outcomes. Tapping into these two interests can provide a platform for an organisation wide approach to quality.

A CGU might have to change the opinion of clinicians based on previous experiences. It is important to encourage a culture that ensures there is both a system and clinician responsibility for quality. Managers should share responsibility for patient outcomes to encourage a systems view. It is important to share information, stories and data with clinicians. In short, the organisation should have a culture of learning. According to Peter Senge [13] a learning organisation is *'…where people continually expand their capacity to create the results they truly desire, where new and expansive patterns of thinking are nurtured, where collective aspiration is set free, and where people are continually learning to see the whole together'*.

To engage clinicians there needs to be learning at work, alongside organisational learning. A learning climate needs to be fostered and learning structures created. Creating a culture of learning involves critical reflection upon goals, beliefs, values, conceptual frameworks and strategies, and a CGU can drive this.[14] Leadership across the organisation plays a vital role in quality: leaders need to create an inspiring vision of what the organisation should look like and share this with patients and clinicians through a participatory process.

The six dimensions of quality

The Clinical Governance Framework is underpinned by an internationally accepted framework for defining health care quality within six dimensions: [15]

- **Effective**, delivering health care that adheres to an evidence base and results in improved health outcomes for individuals and communities, based on need
- **Efficient**, delivering health care in a manner which maximises resource use and avoids waste
- **Accessible**, delivering health care that is timely, geographically reasonable, and in a setting where skills and resources are appropriate to medical need
- **Patient centred**, delivering health care which takes into account the preferences and aspirations of individual service users and the cultures of their communities
- **Equitable**, delivering health care which does not vary in quality because of personal characteristics such as gender, race, ethnicity, geographical location or socioeconomic status
- **Safe**, delivering health care which is reliable and minimises risks and harm to service users.

The strategic focus of a CGU should be based on these six dimensions of quality.

Designing the infrastructure

As much of the work in Clinical Governance involves engaging clinicians, it is imperative that the staff match the various tasks that are required.[16] A highly effective CGU will harmonise the needs of the organisation with its staffing structure and resources.

The structure of the CGU may comprise patient safety, patient experience and consumer engagement, quality, policy, data analytics and change and innovation.

Patient safety functions

Patient safety is defined as *'…a discipline in the health care sector that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery. Patient safety is also an attribute of health care systems; it minimises the incidence and impact of, and maximises recovery from, adverse events'*.[17]

Patient safety has been the cornerstone of the CGU's efforts in creating a fair and transparent culture where near misses and adverse events are reported.
All staff in the organisation should have an understanding of how near miss and adverse event reporting can improve the organisational response to patient safety.[18]

Patient safety seeks high reliability under conditions of risk.[19] While illness presents the first condition of risk in health care, patient safety advocates continuous cycles of learning, reporting of adverse events or near misses, dissemination of lessons learnt, and the establishment of cultures that are trusted not to cast unfair blame.

The key elements include

- Ensuring relevant staff are trained to undertake appropriate investigations that will identify the underlying causes of adverse events and near misses
- Providing feedback on any actions taken as a result of reported near misses and adverse events
- Collecting and analysing information on adverse events
- Publishing de-identified adverse event and near miss reports
- Providing education programs for all staff on adverse event reporting systems
- Promoting an environment where staff feel comfortable and confident to report incidents
- Providing education for board members or advisory committees on quality improvement initiatives
- Redesigning systems and processes and adapting staff training or clinical practice to minimise errors.

Data should be used for improvement rather than to make a judgement or identify a failure to meet the benchmark. While measuring outcomes is a focus of a CGU, it is important to also tell the patient stories associated with the data, as this can clarify the significance of the outcomes by framing them within a meaningful, person centred perspective.

Open disclosure

The CGU should have a designated open disclosure coordinator who understands the principle of supporting the full disclosure of information to patients, carers and families after an adverse event. While open disclosure was discussed in detail in Chapter 6, here we can succinctly define it as *'an open discussion or series of discussions with a patient and/or their support person(s) about a patient safety incident which could have resulted, or did result in harm to that patient while they were receiving health care.'* [20]

Incident management, open disclosure and quality improvement are all interrelated components of a system which supports and promotes the delivery of open, honest and safe patient-based care.

Patient experience and consumer engagement function

In contrast to the traditional focus on complaint management, the goal today is to drive the organisation towards greater engagement with patients and their families, with consumer engagement teams striving to deliver a more dynamic patient experience. A further focus for the patient experience and consumer engagement team is on providing support to families who are carers.

**Patient and family centred care** has these characteristics:[21]

- People are treated with dignity and respect
- Health care providers communicate and share complete and unbiased information with patients and families in ways that are affirming and useful
- Patients and family members build on their strengths through participation in experiences that enhance control and independence
- Collaboration among patients, family members, and providers occurs in policy and program development and professional education, as well as in the delivery of care.

Quality functions

Quality improvement and innovation enhances patient experience. The CGU is committed to placing quality at the heart of everything the organisation does. The Quality Team leads the organisation, utilising education and implementation of Model For Improvement methodology [22] which emphasises innovation and rapid fire testing to aid in developing a clear aim for improvement and a measurement plan. [23]

The Quality Team is usually responsible for leading the accreditation process. Accreditation is not a one-off but a continuous quality improvement process requiring stakeholder engagement throughout the whole organisation. The Quality Team has a significant role in promoting and supporting organisation wide quality improvement, and the CGU should have a clearly articulated strategic plan to enable staff and consumer involvement. [24]

Executive participation and leadership in accreditation is essential.

> **In God we trust; all others bring data.**
>
> W.E. DEMING [25]
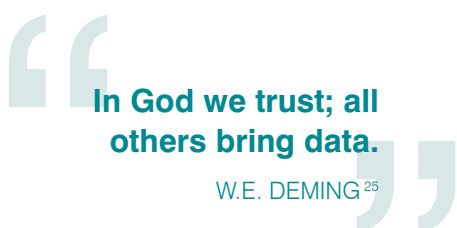
Change, innovation and clinical redesign

The CGU plays a critical role in working with patients, carers and clinicians to innovate and redesign clinical care, thereby providing increased capability in the health system as well as enhanced health care outcomes for patients.

Working in partnership

It is essential for a high functioning CGU to work in partnership internally and, most importantly, across the organisation. As mentioned previously, too often CGUs are seen as compliance-focused and not prepared to work hand in hand with clinicians. Clinicians have the front line experience and are able to quickly advise what will and won't work. This, along with partnership with consumers, is vital in understanding context and culture so as to be able to implement change and increase patient safety and reliability.

The key characteristics of working in a partnership are: [26]

- Actively work together for a shared and common purpose
- Show mutual respect and trust
- Communicate with each other in clear and open ways
- Respect each other's insights, priorities, goals, ideas, differences and experiences

- Value each other's knowledge, strengths and expertise and bring these together in complementary ways
- Jointly agree on the aims and outcomes of the Helping Process and share responsibility for fulfilment of the tasks involved
- Negotiate decisions and resolve disagreements and conflicts as they arise.

High impact leadership behaviours

A dynamic and enthusiastic manager will set the course for the CGU to achieve great things. The Institute for Healthcare Improvement (IHI) [27] outlines five high impact leadership behaviours to enhance the unit's work and achievements:

1. **Person centeredness:** be consistently person centred in word and deed
2. **Front line engagement:** be a regular, authentic presence at the front line and a visible champion of improvement
3. **Relentless focus:** remain focused on the vision and strategy
4. **Transparency:** require transparency about results, progress, aims and defects
5. **Without boundaries:** encourage and practice systems thinking and collaboration across boundaries.

Conclusion

The essentials of a high functioning CGU are multifaceted. The roles of compliance and quality improvement need to be balanced in order to progress the important work of innovation, safety and reliability. Having a leader who inspires and staff with the right qualities and skills to progress the work is as important as the structure. As the CGU needs to engage with clinicians, a partnership approach which acknowledges complementary expertise is essential. Finally, a strong team who work together will achieve much more, so promoting teamwork is essential.

CHAPTER 8

Developing a real time understanding of safe care

- **We are rarely able to assess patients in real time and in most hospitals we are playing catch up**
- **Health care is complex and most harm is unintentional**
- **Situational Awareness can be developed with the understanding that in clinical teams every team member's views are of equal importance**
- **The huddle is the core intervention to develop Situational Awareness**
- **The huddle facilitates proactive identification of risk prior to deterioration or delays in the patient journey.**

Introduction

A constant challenge for health care providers is to know what is actually happening to their patients. Usually the way we assess patients is by considering and assessing what happened in the past, then making a clinical decision. We are rarely able to assess patients in real time and in most hospitals or clinics we are often playing catch up. In this chapter we will propose that, by modifying the way we work, and by adding methods honed in the military and other sectors, we will be able to manage our clinical workload more effectively and make a real difference to the patients under our care.

Developing a culture of safety

Safety in health care is what we are all about. 'First, do no harm' is the foundation of all medical care. One cannot be person centred if one's care is unsafe, so we need to take the safety of the patients we treat into account in all that we do. Unlike the airline industry, we do not overtly state that safety is our business – we often assume it will just happen through our clinical judgement and actions. Unfortunately, over the past 30 years health care has become more complex and difficult and safety cannot be assumed to be a given. In addition, we have begun to understand the factors that we need to take into account to ensure we do no harm. Most harm, though unintentional, is a consequence of how we work and how we deliver care. The concept of reliable care is the foundation of patient safety, as it includes the concepts of human factors, teamwork and quality and can be extended to include resilience of care where one constantly learns from one's actions.

Reliable care can be defined as getting it right the first time, every time, no matter who is treating the patient. We achieve 100 per cent reliability about 80 per cent of the time. Imagine if other industries routinely operated at that level of efficiency, e.g. your car only starting three or four days out of five, the aircraft you fly in not

being operational every one in five flights etc. The culture of safety and quality aims to achieve a health care system in which we are constantly aiming for 100 per cent reliability – very different from the current paradigm in which we only achieve 80 per cent.

To achieve high reliability we need to redesign our services, introduce standardisation and more effective use of resources, and develop real time situation awareness. We will then achieve deeper understanding of what it takes to be safe. This chapter will concentrate on situation awareness and offer some ways to achieve it.

What is situation awareness?

The concept of situation awareness is derived originally from the military and has since been adapted for any complex work environment. A definition by Endsley [28] states situation awareness provides 'the primary basis for subsequent decision making and performance in the operation of complex, dynamic systems'. At the lowest level the operator needs to perceive relevant information (in the environment, system, self, etc.), then integrate the data in conjunction with task goals and, at the highest level, predict events and system states based on this understanding.

This means one needs to gather information from multiple sources, integrate it and then come to a shared understanding of what is actually happening. Examples where this applies include in the cockpit of an aircraft, in team sport, in the military and in many other complex adaptive systems. In health care we rarely achieve the state of complete situation awareness as most of our work is done within professional silos. It is only where there is true multi-professional teamwork that situation awareness may be prevalent; however, that is not the common way of working and we still have silos in many of our clinical areas, such as between professionals and between teams.

How can one develop situation awareness?

Situation awareness can be developed through the understanding that in a clinical team everyone's views are of equal importance. This implies that there must be a degree of respect for all team members. Hierarchy, while present, should be used to facilitate the flow of information and a good team leader will generate situation awareness by encouraging discussion in an environment of equality and value. Teams need to work on the culture they have and a safety culture tool such as the MAPSaF [29] can be used to assist them in developing a culture of safety.

The huddle as a method to develop situation awareness

The huddle is the core intervention to develop situation awareness. It aims to change the approach to patient care from one of reaction (what has happened) to anticipation (what may happen). This is a major shift in the way we think about care and it assumes that most clinical conditions can be anticipated. It is proactive and allows for the mutual sharing of information in a structured way. The huddle does not replace the ward round – rather it is an addition to the working of the hospital ward or the clinic.

Huddles can take place in any setting. The underlying premise for the huddle in health care is that everyone around the patient has information that could add value. This includes the patient and their family members, doctors and nurses of all grades, administrative and support staff, students and allied professionals who may have a different view of how the patient is doing. Everyone's voice needs to be heard.

The huddle is structured and lasts no more than ten minutes. [30] Standardised scripts are useful and training is required in order to change the way people normally present clinical findings. The huddle facilitates proactive identification of risk ahead of deterioration or delays in the patient journey. Unit-based huddles can be held on a regular basis, starting at the bedside with the nurse, doctor and patient, then moving to a ward huddle two to three times a day. Each huddle provides increased collective understanding and shared insight into the condition of patients and can lead to anticipation of what may happen.

Huddles can also be held on a division or hospital-wide basis to allow hospital managers and leaders to be made situationally aware of what is happening in the organisation.

Real time analysis of harm

Besides enabling a real time analysis of what may happen in the clinical area, the huddle allows one to apply methodology to the safety of the clinical area. [31] The following questions should be asked at the start or end of each huddle:

- **How reliable are we today?** Are our clinical systems and processes reliable and will we do what we say we will do?
- **Are we sensitive to today's operations?** Is the care we are delivering today safe? (This is where one applies human factors theory and asks about the tasks, the equipment, the staff, the culture and environment, and, finally, the patients)
- **Are we anticipating and preparing?** Will the care we deliver be safe in the future; are any patients at risk of deterioration or harm, or delays in treatment?
- **Are we reviewing and learning from current and past operations?** Are we responding to what we have done and improving wherever possible?

What are the next steps?

Trainee clinicians can start to apply this theory in their own practice and try to assist in the development of structures at the microsystem level. Clinical leaders are key to the development of this new way of thinking. The theory of high reliability and human factors can be focused into a simple intervention that lasts for ten minutes every six hours. Early research has demonstrated that this does make a difference to the culture of safety and provides another way to protect the patients we treat. [32]

CHAPTER 9

Quality and safety in mental health

- **Severe mental illness has a unique and challenging impact on individuals, families and the wider community**
- **There is a tendency for mental health services to be regarded as silos within the general health system**
- **Further effort is required to achieve full integration of safety as core business throughout mental health services**
- **Physical health outcomes for people suffering a severe mental illness are extremely poor**
- **Specific additional safety improvement goals within mental health can be achieved within the existing clinical governance and patient safety frameworks. Important areas of focus should include reduction in the use of restraint, self-harm and suicide, medication error, absconding from care, non-adherence to treatment and reduction of violence and aggression toward others.**

Introduction

This chapter describes current and emerging practices and strategies for improving patient safety in mental health services. As these are an integral part of the larger health service, the broad term strategies and processes for ensuring patient safety in that larger system equally apply within mental health services. Given the variable level of integration of mental health services within the wider health service (including levels of integration and participation in quality and safety initiatives), this chapter seeks to address a wide and diverse audience. It includes components of a patient safety and quality framework (structures, programs and tools) which apply equally in a mental health and general health environment, and programs and tools specific to mental health services.

There are some exemplars of 'best practice' mental health patient safety, both locally and internationally. However, variable participation by staff and managers at all levels of the organisation means that continuing effort is required to achieve full integration of safety as core business throughout mental health services.

A number of factors contribute to this patchy engagement with patient safety and these are best understood if one considers a brief history of how mental health care has been delivered. There are some unique and challenging features of severe mental illness (SMI) and its impact on individuals, families and the wider community.

This chapter provides a brief overview of these factors, then describes how the tools of clinical governance and patient safety are utilised in mental health services, and some of the individual and system issues which are regularly identified in patient safety reports for mental health services.

A history of recent mental health reform

Until as recently as the mid-20th century, mental health services were almost invariably seen as separate from general health services (reflecting and perpetuating the mind-body dichotomy) and indeed were situated separately, and this isolation contributed in part to a culture of care which we would now consider paternalistic or authoritarian. There were few, if any, evidence-based treatment modalities available, and the model of care was largely one of containment and 'asylum' from the wider world. Given the prolonged relapsing course of many mental illnesses, many patients spent long periods of time in these institutions (often years).

With the advent of some effective medications to treat psychotic illness and depression came a push for 'de-institutionalisation', with the intent that people could spend a relatively short period of time in hospital, then live in the community with continuing medical review and medication treatment. This contributed to the downsizing and closure of the large stand alone institutions and the development of 'general hospital psychiatry' units which saw the beginning of 'mainstreaming' of mental health and general health services. This coincided with significant development in the understanding of major mental illnesses, rapid progress in biomedical research and treatment, and the growth of integrated community-based and acute hospital-based mental health services.

However, in spite of the mainstreaming and colocation of mental health and general health services, there has been a tendency in many places for mental health services to continue to operate and be seen as silos within the general health system. Such silos have at times impeded patient access to necessary services and other supports, and limited effective collaboration between mental health and other parts of the health system with particular regard to timely sharing of information and other resources. All this has served to perpetuate the view that mental health services and the patients they serve are separate and different from 'general health'. This is a form of stigma, but stigmatising

attitudes and behaviours can occur just as easily within the health system as they can in the broader community. The barriers to sharing of information and free access to services (including corporate and clinical services) within health systems have contributed in some places to inadequate mental health service participation in patient safety programs, which in turn contributes to poor patient outcomes.

Current mental health reform context

There has been a significant and ongoing mental health reform in NSW and Australia, as evidenced by the National Mental Health Strategy and Plan which dates back to 1990. Current mental health reform objectives which impact significantly on patient safety and quality improvement include the Commonwealth plan to fund portions of mental health service delivery through Primary Health Networks – a desire to increase the integration of mental health services across all tiers of government and across public, private and community-managed organisations. There is a national Suicide Prevention Framework piloted in NSW by the Black Dog Institute, an ongoing strong desire to improve meaningful consumer engagement and participation at all levels of service delivery and governance, and an important aspect of public participation is the continuing adoption and development of a recovery model. It is not the goal of this chapter to describe such initiatives in detail; however it is important to understand that key tenets of the recovery model are that the consumer must participate in decisions about their care, and that recovery to live a meaningful and engaged life is more important than a single-minded focus on symptoms and risk.

The importance of true consumer participation is a key factor in mental health service reform. It is also important to ensure that consumers are always offered appropriate evidence-based care for which outcomes are measured and that services strive to eliminate unwarranted clinical variation. The equitable access for all consumers to evidence-based care packages, and the elimination of unwarranted clinical variation, are key components of a patient safety program in mental health, as they are to any health service.

Some relevant clinical features and consequences of serious mental illness

It is important to understand that, for a number of people experiencing serious mental illness, the long term course of their illness leads to recovery. But for many of those that we continue to see within our health services the trajectory is one of recovery followed by relapse, and in some cases enduring disability and comorbidity (such as poor physical health and substance use). The consequences of a chronic relapsing illness course, particularly one which most often has its onset in late adolescence and early adulthood, include disrupted education, career and relationship development, so that people suffering mental illness are often also very socially and economically disadvantaged and isolated. It is therefore important that mental health services work closely with other agencies including Education and Training, and Housing and Employment and ensure that these disadvantages are addressed as part of the treatment plan – failure to do so may adversely impact on the individual's vulnerability to illness relapse and deterioration.

The consequences of a significant mental illness often contribute to social disadvantage and disengagement, including disengagement from mainstream health services. This is a significant concern because physical health outcomes for people suffering a severe mental illness are extremely poor – it is estimated that the life expectancy of someone experiencing significant mental illness is **15–20 years less than a person without a mental illness.** Much of the difference in life expectancy is caused by poor general health, including cardio-respiratory and endocrine disease, obesity and lifestyle-related physical health problems. There is a significantly higher rate of smoking, alcohol abuse and illicit drug misuse among people with severe mental illness, further contributing to poor overall outcomes.

There is no doubt that social exclusion and stigma affect the ability of mental health patients to access support and care, including general health care. There are also aspects to the experience of a mental illness itself which contribute to difficulties with engagement, adherence to treatment and communication, because mental illness per se often affects social interaction and communication skills. It is therefore very important that there is careful assessment of social capability for those with SMI, and, where needed, care coordination between the various physical mental health and social support services.

Mental health patient safety progress

Many of the issues that contribute to patient harm in general health (falls, medication errors, unrecognised deterioration, DVT, sepsis) are equally relevant in mental health services. There are also additional areas of focus that must be considered in any mental health patient safety program. These include the reduction in restrictive or coercive practices (use of restraint and seclusion, use of involuntary treatment orders), reduction in instances of self-harm and suicide, reduction in instances of aggression or violence towards others, non-adherence to treatment, and absconding from care.

Specific additional safety improvement goals within mental health services can be achieved within the existing frameworks of clinical governance and patient safety that are in place in many service environments, but will require additional specific and targeted projects as do many other patient safety initiatives (e.g. sepsis reduction, Between The Flags).

Issues in safety and harm reduction in mental health

There are a number of recurring themes that arise in the literature relating to patient safety in mental health services. They are not significantly dissimilar to themes that occur in other parts of our health services. Some of the system issues which regularly emerge from reviews and investigations include difficulties in managing care that is fragmented between specialities and different parts of the health and social services system. This includes poor care coordination, poor communication of information (including lack of timely communication), and poor coordination of care for those with comorbidities (e.g. mental health and drug and alcohol comorbidity).

Within mental health services there are particularly vulnerable populations, including but not limited to aboriginal persons, members of the LGBTI (Lesbian, Gay, Bisexual, Transgender, Intersex) community, the very old and very young, and those from a non-English-speaking background. Poor management (including poor coordination of management) of physical health comorbidity is, sadly, not uncommon, as is inadequate detection and response to physical deterioration in mental health settings.

Some of the individual care issues that arise include unsophisticated risk assessment (particularly risk of harm to self or others) and insufficient engagement of multidisciplinary and/or senior clinician supervision at critical junctions in the patient journey. Diagnostic delay (particularly of physical or substance misuse comorbidity in persons with an established mental illness), excessive use of restrictive care practices, medication errors, and unwarranted clinical variation all contribute to poor outcomes. Pharmacological variation, including poly-pharmacy, excessive or inadequate doses, access to other treatments such as ECT (Electro Convulsive Therapy), and deviation in evidence-based or accepted treatment guidelines also play a significant role.

All of the issues raised above can be addressed through the traditional tools of quality improvement such as incident investigation, complaints management, audit and benchmarking.

These rely on a robust and clearly communicated clinical governance framework in which every clinician and manager has a role to play. It is essential that everyone understands their role in patient safety, is familiar with the goals of the patient safety program for their service, and can speak knowledgeably about these and how further improvements might be made.

Reduction in harm and improvement in quality for our mental health services requires that mental health services are fully integrated with other parts of health, and that there is a shared and integrated clinical governance and patient safety framework. There will be many safety projects in common across all of health, and some which are specifically aimed towards mental health patients, regardless of location (e.g. emergency department or the general medical/endocrine ward). The measure of success of a patient safety program including mental health will depend on how well it operates across all parts of the health system, and the extent to which patient safety is at the core of the organisational vision, with strong ongoing commitment at the leadership level and participation throughout all levels of the organisation.

CHAPTER 10

Advanced measurement framework

- **Senior Clinicians and Managers must encourage rigorous analysis of data in their teams**
- **Understanding variation is the most important aspect of any effort to improve patient safety and understanding common cause and special cause variation is fundamental**
- **Too often changes are recommended based on variation when the data is not well understood. Many changes based on variation in a stable system may only increase variation**
- **The use of process control methodology is vital to the effective monitoring and management of much of our work, including clinical activity and non-clinical metrics such as financial data.**

How reliable are you at delivering safe quality evidence-based care to patients every time in a complex health care system?

In 2003, Elizabeth McGlynn reported on the quality of health care delivered to adult patients in the US.[33] She noted that of the 6712 medical records of participants reviewed, only 53.7 per cent of patients received 'scientifically indicated care'. 46.3 per cent of participants did not receive the recommended care (95 per cent confidence interval (CI) 45.8 to 46.8 per cent) while 11.3 per cent received care that was not recommended and potentially harmful (95 per cent CI 10.2 to 12.4 per cent). In 2012, Runciman et al[34] reviewed 1154 adult Australians' episodes of care and reported that only 57 per cent (95 per cent CI 54-60 per cent) of the 35,573 eligible health care encounters received appropriate care, and advised the need for national agreement on clinical standards and better structuring of medical records to facilitate the delivery of more appropriate care.

What is the definition of 'reliable care'?

- The extent to which an experiment, test or measuring procedure yields the same result on repeated trials
- Consistently good in quality or performance: able to be trusted
- A health care system that ensures every patient consistently receives evidence-based, effective care every time he or she needs it.

Traditional or 'classical' clinical research focuses on evidence-based medicine (EBM). Its aim is to acquire new knowledge through scientific experimentation including blinded testing, the elimination of bias, and the use of an appropriately large sample size in a large single study classically testing one hypothesis.

Improvement science, in contrast, focuses on the multiple processes required to deliver EBM. The core characteristics are that the testing is observed rather than blinded; the bias is implicitly stable, not eliminated; the data collected is sufficient to allow many sequential tests; and rather than a fixed hypothesis, the process or processes being reviewed are, by definition, adaptable to change.

The data measurement and analysis skills required of clinicians in improvement science are very different to the suite of statistical tests used when engaging in classical scientific medical research. Indeed, the ability to deliver EBM as a strong and effective clinical leader requires an understanding of what WE Deming refers to as Profound Knowledge,[35] of which there are four core components:

- Appreciation of a system
- Theory of knowledge
- Psychology
- Understanding variation.

What *insights* might be obtained by looking through the Lens of Profound Knowledge?

Appreciation for a System

- Interdependence
- Dynamic
- Interactions
- System must have an aim
- Whole is greater than the sum of the parts.

Psychology

- Interaction between people
- Intrinsic motivation
- Beliefs, assumptions
- Will to change.

Theory of Knowledge

- Learning from theory, experience
- Operational definitions
- Expert prediction
- PDSA for learning and improvement.

Understanding Variation

- Variation is to be expected
- Common or special causes
- Potential mistakes
- Knowledge of baseline.

> **'APPRECIATION OF A SYSTEM'**
>
> **If each part of a system, considered separately, is made to operate as efficiently as possible, then the system as a whole will not operate as effectively as possible.**
>
> ACKOFF, 1981

The fundamentals of data measurement for reliable sustained improvement are based on four data processes:

- Measurement definition
- Data collection
- Data analysis
- Data interpretation.

Measurement definition

Defining the problem and deciding upon/defining the aim is the starting point for all quality improvement work but is typically an area that is poorly executed. It is critical to get it right from the outset. If the objectives are not explicitly clear, or if people have varying perceptions of the problem or the agreed aim, the quality of the measurement definition is likely to be compromised.

A key element in creating measurement definitions in improvement science is the imperative to both articulate and document repeatability and reproducibility of all definitions. This includes the problem; the aim; and the series of process, outcome and balancing measures as identified by all team members and key stakeholders from the outset. This is an essential first step before using the Model For Improvement tool.

Repeatability relies upon the creator of the definition to not only understand it but to be able to repeat it verbally and document it, word for word, every time to all team members. It is critical that this can then be reproduced by up to five other people on the improvement team, applying the same principle of verbal and documented feedback every time.

1 Decide aim

2 Choose measures

3 Define measures

4 Collect data

7 Repeat steps 4 – 6

6 Review measures

5 Analyse & present
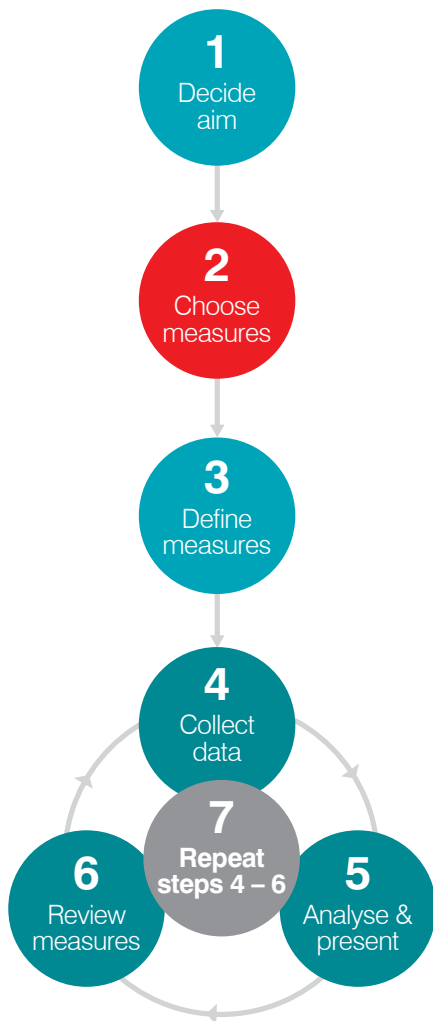
Source: Seven Steps to Measurement, Measurement for Improvement, NHS Institute for Innovation and Improvement 2011

What to measure and why?

There are three types of measures:

Outcome measures:

- Refer to the 'voice of the customer or user'
- Define how the system is performing
- Broadly speaking describe what the result is.

Process measures:

- Refer to the 'voice of the workings of the system'
- Serve to answer process questions ie are the parts and/or steps in the system performing as planned?

Balancing measures:

- Look at the system from different directions and/or dimensions
- Reflect on what happened to the system as we improved the outcome and process measures (e.g. unanticipated consequences, other factors influencing outcome)
- Can be both positive and negative
- Are classically appreciated when up and downstream system impacts are considered.

WHAT TO MEASURE?			
Patient experience and outcomes	**Safety and reliability**	**Efficiency and value**	**Leadership and high performing teams**
Patient satisfaction survey	Clinical incidents	Turnaround time	Staff survey
% patients complication free in recovery	Readmissions	% theatre utilisation	Training and development
Pain score	Exceptions from time out checklist	Cancellations	Staff turnover
Average time patient starved	% correct equipment to hand	Delays (Late starts and finishes)	Staff absence

Data collection

Once the types of measures to achieve the aim have been decided, critical questions to ask are as follows:

- Where is the data going to come from?
- When will the data be taken?
- Who will take the data?
- How will the data be collected? e.g. consider turning the data into a different unit (hours into days).

Driver Diagram

(see Chapter 11 for a more detailed description)

The 'Driver Diagram' is a significant improvement tool that allows you to describe the SMART (Specific, Measureable, Achievable, Realistic, Timed) aim with associated primary-themed categories. Each primary driver is classically associated with several secondary drivers that are matched to that theme. The overarching principle is that all secondary drivers listed must be measurable. They, unlike primary drivers, are classical process measures. Primary drivers, as with the aim, are more often than not outcome measures. For each secondary driver there needs to be an associated series of six questions: Who? What? Where? When? Why? How? In essence these describe the key activities of each PDSA (Plan, Do, Study, Act) cycle.

The Driver Diagram differs from the Cause and Effect Fishbone (Ishikawa) diagram [36] in that while the latter allows one to focus on the problem(s), the Driver Diagram focuses on the aim. One can frequently create a Driver Diagram by focusing on the six sources of input variation (and therefore the source of the problem/s) i.e. people, methods, machines, materials, environment and measurements, to populate the primary and secondary drivers.

This is useful when the problem is clear but the potential solutions are less so!

Diagram representing the linkage between the Driver Diagram and PDSA

Learning occurs with each iteration
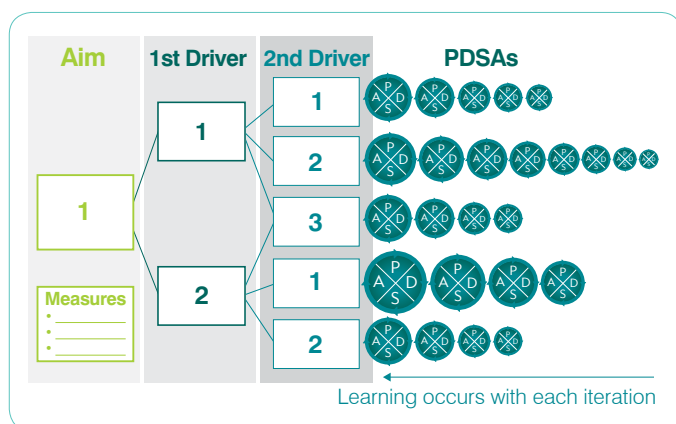
The diagram depicts two important features of most PDSA cycles:

1. A key understanding is the decreasing size/adjustments required in each PDSA cycle as one progresses to a reproducible, sustainable and reliable process design
2. It typically will take 4–5 PDSAs before a final reliable state is achieved, although sometimes many more.

The who, what, where, when and how of PDSA

The difficulty of undertaking a sequence of PDSA cycles should not be underestimated. It requires a disciplined and patient approach to ensure that a series of precise definitions and measurements are applied consistently and reliably to each testing cycle every time. This ensures integrity of data collection, appropriate interpretation and subsequent application for the next PDSA, until such time as the data is reflecting a robust sustainable process improvement which can be reliably reproduced at least 95 per cent of the time.

How-to guide to testing a hypothesis using PDSA with the 1, 3, 5 methodology:

- **Version 1:** Find a friend. Test. Amend to Version 2 instantly with feedback.
- **Version 2:** Find another friend. Test. Amend to Version 3 instantly.
- **Version 3:** Test on Patient 1. Ward 1 with 3 Clinicians (don't need to be your friends!). Amend to Version 4
- **Version 4:** Test on 3 Patients. 1 Ward 1–3 Clinicians. Amend to Version 5.
- **Version 5:** Test on 5 patients. 1 Ward 5 clinicians.

Notes re above:

- Do not move from Ward 1 until 5 clinicians have applied the PDSA cycle on 5 patients such that no further changes are required ie the process is now likely to be reliable and not operator or patient dependent.
- Only when the process is reliably reproducible 95 per cent of the time on Ward 1 should you spread the testing to two further wards (2 and 3). This step can require immense patience and discipline, particularly if the key timeline of rapid daily testing and amendment is not or cannot be followed.
- It is not unreasonable to be able to move onto Wards 2 and 3 within 1–2 weeks with a clinical process improvement that has a significant number of patients affected by the suboptimal process. This requires all of the facets of strong leadership and well-identified key stakeholders who share the aim and the will to sustain improvement.
- Real time continuous data collection and measurement is critical to demonstrate whether the change that has been made is an improvement or not.

PLAN DO STUDY ACT – RECORD OF ACTIVITY

AIM Describe your first (or next) test of change. What are we trying to accomplish? Cycle number: 1	BY WHOM?	WHEN?	WHERE?

P

PLAN List the tasks needed to set up this test of change. How will we do it?	BY WHOM?	WHEN?	WHERE?

Predict what will happen when the test is carried out. What do you think will happen?	Measures to determine if prediction succeeds.

D

DO
Describe what happened when you ran the test.

S

STUDY
Describe the measured results and how they compared to the prediction.

A

ACT
Describe what modifications to the plan will be made for next cycle.

Data analysis and interpretation processes

In order to help people in health care improve the systems and processes with which they work on a daily basis, the following additional key analytical tools are used to help identify causes of process variation, determine the stability of the process being measured, predict process outcomes, and predict and plan for the future through cycles of PDSA plans:

- Run charts
- Statistical Process Charts (SPC)
- Pareto chart *
- Cause and Effect Diagram *
- Flow charts *

These have been previously discussed in the Clinician's Guide to Quality and Safety

Before embarking on Improvement work it is critical to understand the word variation.

> **We live in a world filled with variation – and yet there is very little recognition or understanding of variation.**
>
> WILLIAM SCHERKENBACH, 1991

Run charts
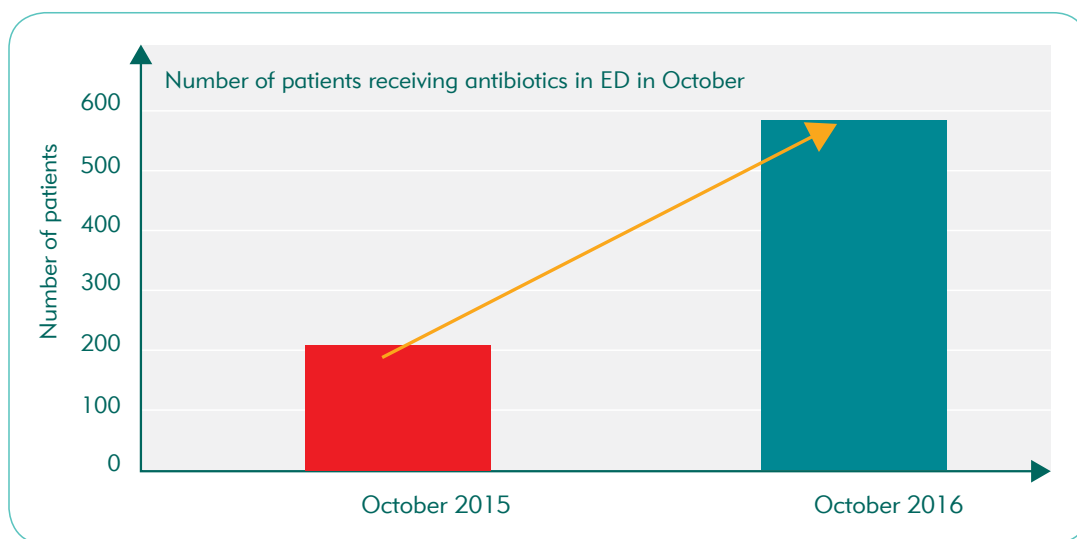
The same data can be displayed as follows:
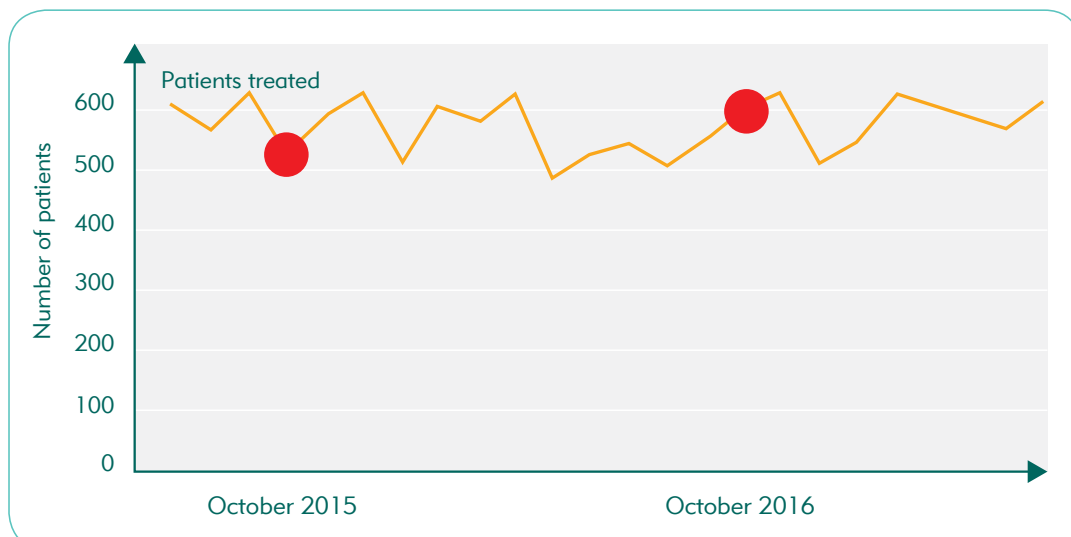
What does this data tell us?

Given two **different** numbers, one will **always** be bigger than the other!

What action is appropriate?

Somethng important

0

This month   Last month
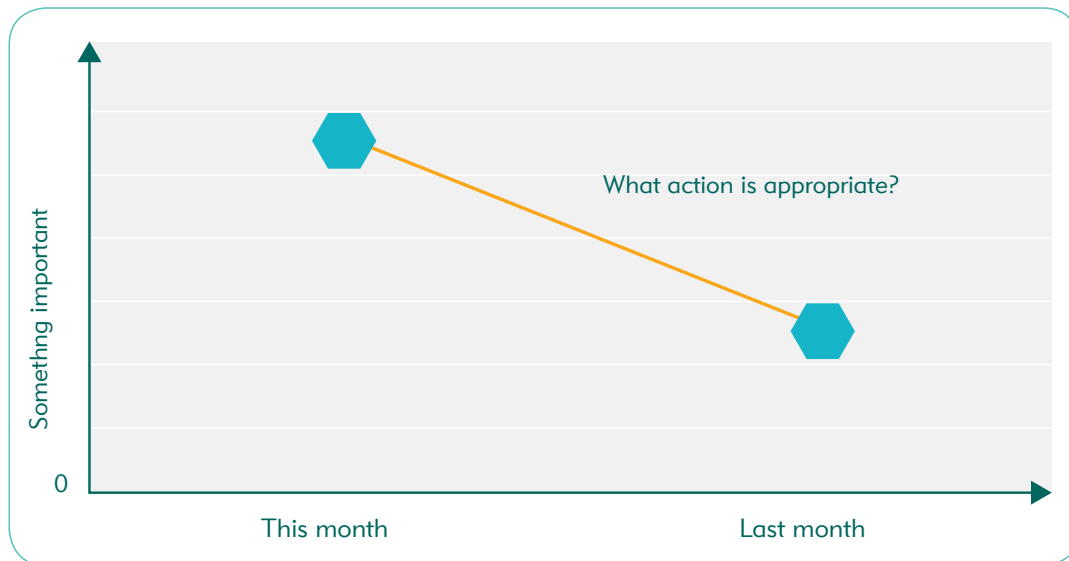
The Myth of Trends

The myth of trends – are these trends real or natural variation?
Is the time period long enough to make a judgment on the data?

If we don't understand the variation that lives in our data the
following happens:

- Deny the data as it doesn't fit with our view of it
- See trends where there are none (myth of trends)
- Explain the natural variation that exists in the process as a
  special event and respond accordingly
- Blame and give credit to people for things over which they
  have no control
- Interfere with the process that produced the data.
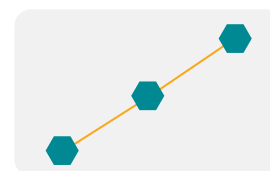
Upward trend?
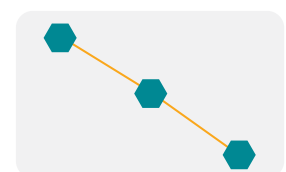
Downward trend?
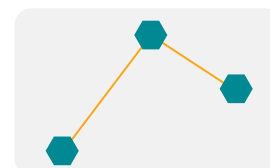
Downturn? Setback?
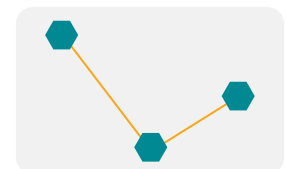
Turnaround? Rebound?
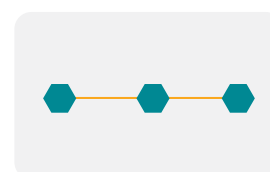
Static? Flatline?

A run chart is the most simple process chart. It is a line graph of data plotted over time. The plotted data can be variables (measurements) or attributes (counts).

Elements of a Run Chart
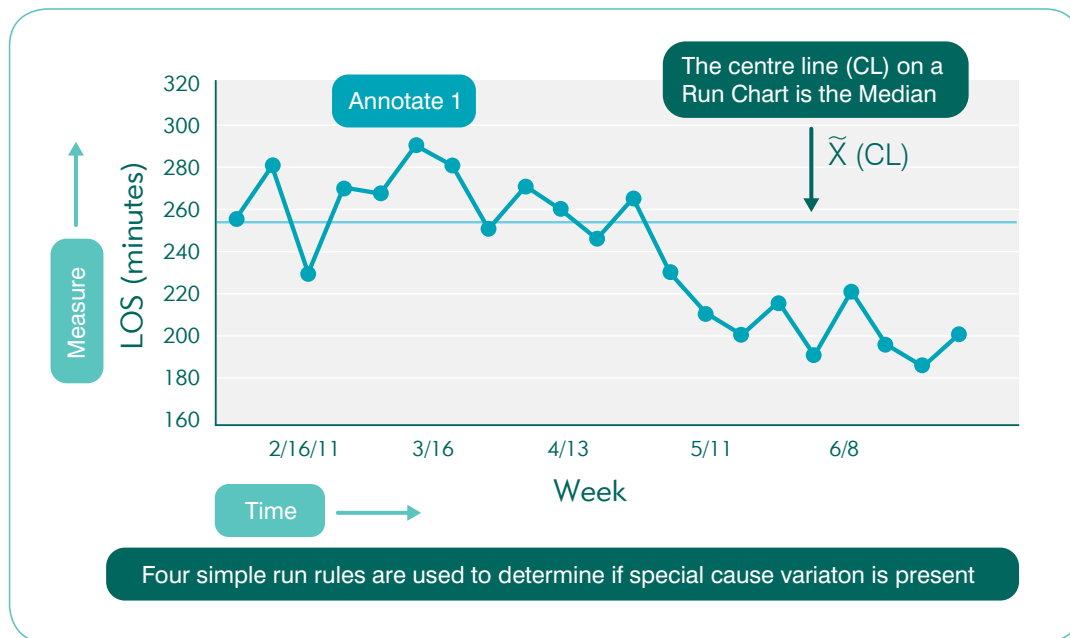
- The purpose of a run chart is to look at how the system behaves over time
- It is used to detect trends or patterns in data over a nominated period
- It is therefore critical that the data is recorded in the order that it was produced and collected
- Its classical use is when you are gathering baseline data at the beginning of an improvement project. It is the basis of a control chart
- The normal statistical baseline data requirement is usually at least 25 data points.

> **Data should always be presented in such a way that preserves the evidence in the data…**
>
> WALTER SHEWHART, 2011

How to Make a Run Chart

1. Identify the question you woud like to answer using Run Chart
2. Develop the horizontal scale (x-axis)
3. Develop the vertical scale (y-axis)
4. Plot the data points
5. Label the graph
6. Calculate and place a median centre line on the chart
7. Add any additional information which will communicate a more complete picture to the intended audience (including annotations on change efforts).

Source: Murray and Provost, pg 3–4

Statistical Process Charts

A run chart is converted into a Statistical Process Chart (SPC) when a sufficient amount of data has been collected to allow statistical analysis and calculation of Upper Control Limits (UCL) and Lower Control Limits (LCL). The median is typically used rather than the mean when you are unsure whether the data is normally distributed.

By definition an SPC is a control chart of a process. It was invented by Walter Shewhart who refers to it as 'a system of cause'.

Definition of a process

A series of linked steps, often but not necessarily sequential, designed to:

- Cause some set of outcomes to occur
- Transform inputs into outputs
- Generate useful information
- Add value.
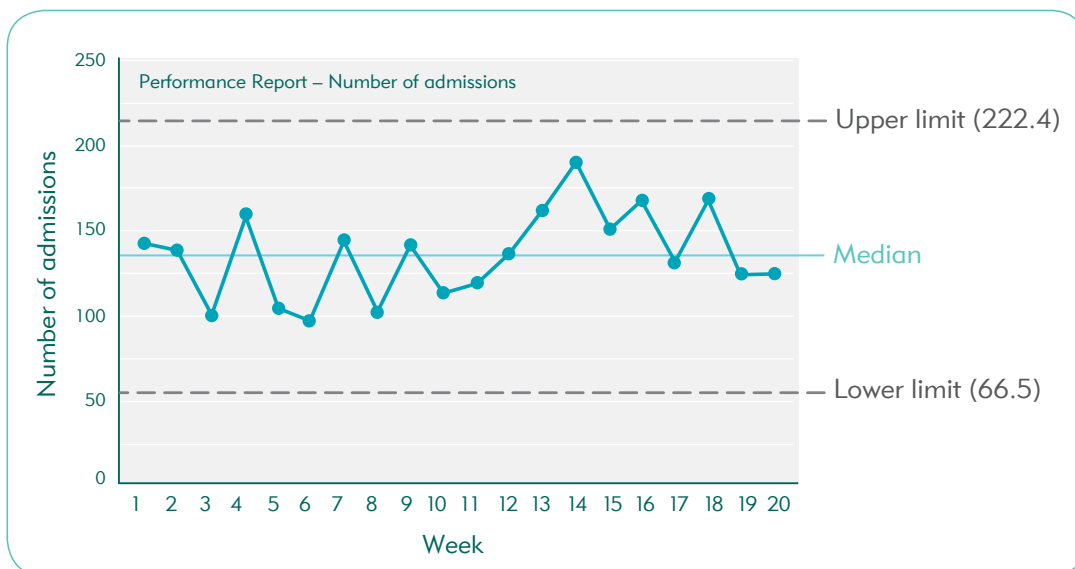
Key components of control charts are:

- Data plots
- A central line which can be mean or median, depending on whether nor not the data is distributed normally
- One or two control limits, upper (UCL) and lower (LCL).

Interpreting control charts

Given that every control chart is made as the basis for an action to occur, each chart needs to be interpreted and reinterpreted with the addition of every new point.

FIRST STEP – Look for any of the following unstable conditions:

RULE 1
Any points lying outside the control limits

Special Causes
Any point outside one of the control limits
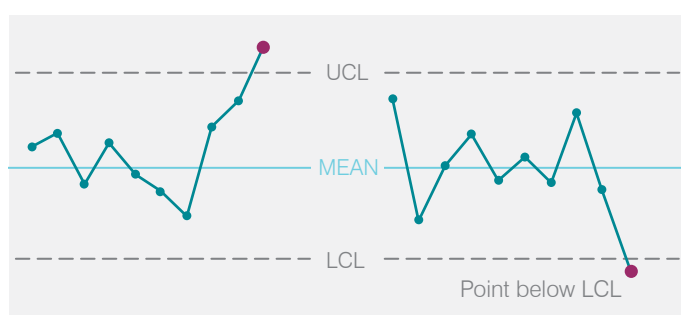
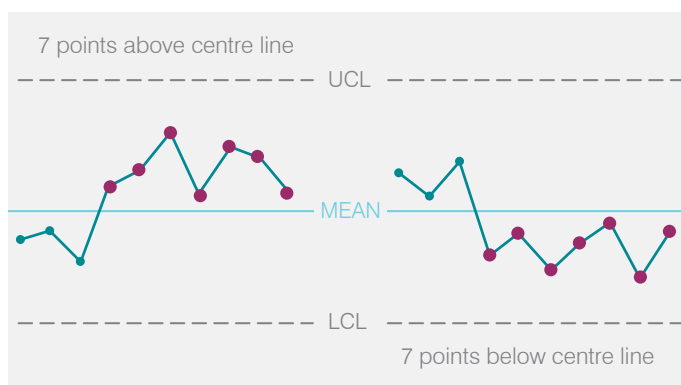Frequently referred to as an astronomical point

RULE 2
A. Run of seven points

Seven or more points in a row above or below the centerline. This is referred to as a **Shift**.

Special Causes
A run of seven points all above or all below the centre line, or all increasing or all decreasing.

Values that fall on the median do not add or break a shift.
Skip values that fall on the median and continue counting.

B. Run of seven points

Seven or more points in a row going in one direction, up or down, is referred to as a **Trend**.

Special Causes
A run of seven points all above or all below the centre line, or all increasing or all decreasing.
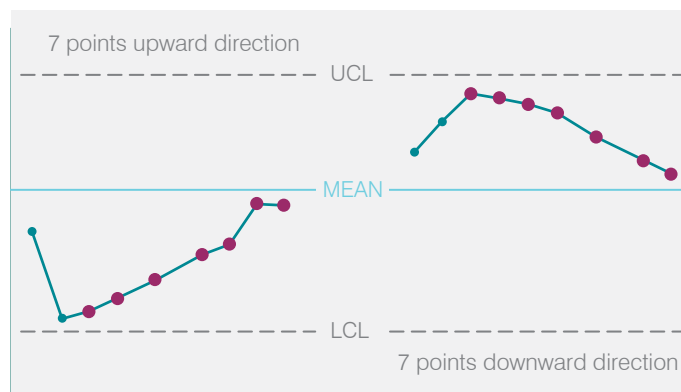
If the value of two or more successive points is the same, ignore one of the points when counting.
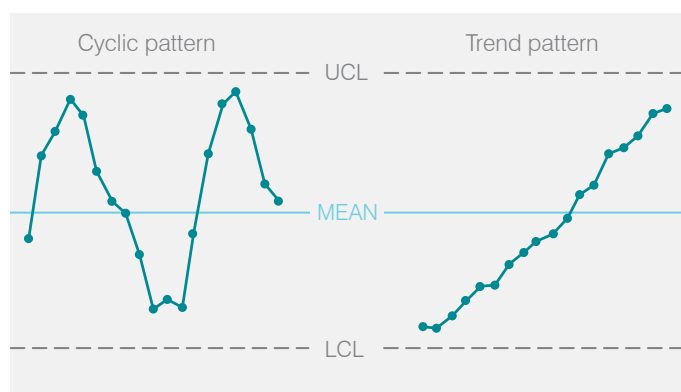
Like values do not make or break a trend.

RULE 3

Any non-random pattern which includes the following typical features:
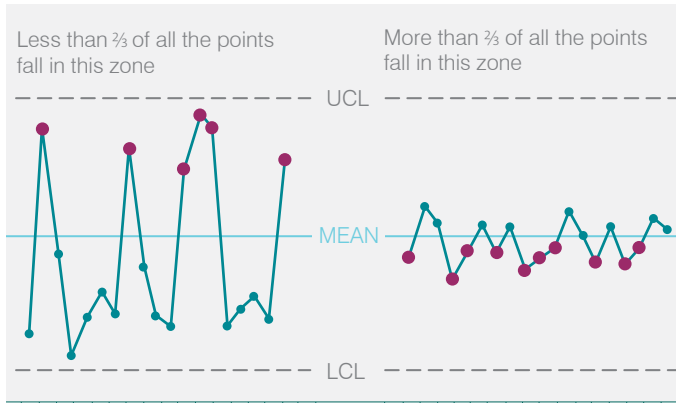
- Cycles

Special Causes
Any unusual pattern or trends within the control limits.

RULE 4

- Too close to the average
- Too far from the average.

Special Causes

Less than ⅔ of all the points fall in this zone

More than ⅔ of all the points fall in this zone

UCL

MEAN

LCL

SECOND STEP – Declare, given the above findings, whether the system is in control (Stable) or out of control (Unstable).

THIRD STEP – Respond to the information that is on the chart.

Rule: If the system is in control and stable but the data clearly is describing a poor process, the improvement team can now commence their work.

> If the system is out of control the team should investigate all out of control issues to discover and then understand what special causes were present to affect the system. **Not all out of control charts indicate trouble.** Finding out what has led to the improvement and making sure that the special cause stays in the system may in fact be the key to continued improvement.

Table interpretation requires a *mental process of flow* that considers the following sequence of questioning when looking at a completed chart.

Question 1: Are any points outside the control limits?

Answer: Yes = Work on special causes

Answer: No = Go to Q2

Question 2: Are there seven or more points above or below the median/average?

Answer: Yes = Work on special causes

Answer: No = Go to Q3

Question 3: Are there more points in an arrow going in one direction up or down?

Answer : Yes = Work on special causes

Answer : No = Go to Q4

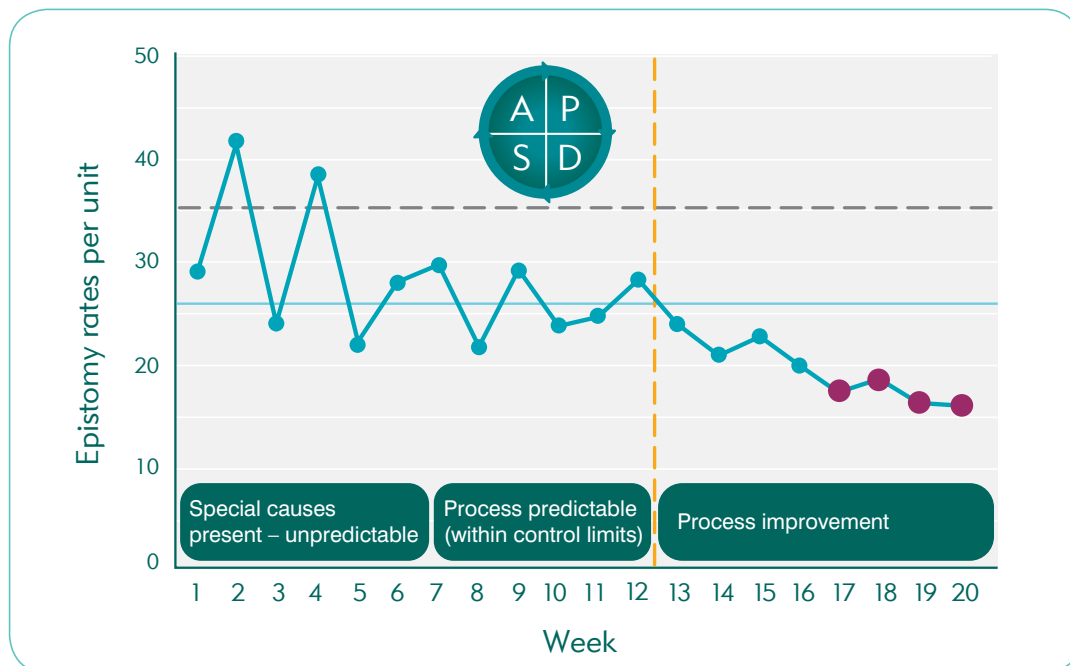**Question 4:** Are any of the non random patterns present? These can be:

1. Cyclic and/or trend pattern
2. Less or more than two thirds of all points fall in/out of 'the zone'.

Answer: Yes = Work on special causes

Answer: No = Common causes of variation

The Improvement Process

Working on causes of *ordinary* events is called working on 'common causes' of variability.

Working on the causes of *unusual* events is called working on 'special causes' of variability.

Important principles of SPC Charts

- SPC charts are most effective when done in real time. Ideally this means that the chart is interpreted as the points are being plotted. These points can guide one to the right kind of action for improvement and/or help sort out problems that need to be stratified. Typically the control chart is then used to compare data that is separated by symptom, time, location or type. In such circumstances, applying this data to a Pareto diagram allows one to separate and differentiate significant aspects of the problem from more trivial ones. By graphically separating aspects of the problem, a team may then identify where to direct its improvement efforts.

- They use the pattern of events in the past to predict with some degree of certainty where future events should fall, if the hypothesis you are testing is a robust one

- They distinguish between natural or common cause variation and special cause variation.

Special cause variation

Characteristics

- Also known as non-random or assignable variation
- Represents variation that arises from a single cause which is not part of the process
- Due to irregular or unnatural causes not inherent in the design of the process
- Can be traced, identified and eliminated or implemented
- Results in an 'unstable' process that is not predictable
- Affects some, but not necessarily all, aspects of the process
- Not viewed as bad variation
- Means that the process is unstable and unpredictable
- Not appropriate to use the Model For Improvement (MFI) until the root cause is understood.

Example: on a particular weekday, the same consultant obstetrician performs an elective caesarean section in the same clinical environment with the same team. On this occasion, the patient is morbidly obese with an unexpected large fibroid.

The duration of the surgery is 93 minutes. This is entirely acceptable and a function of this 'special cause variation patient'. It does not mean there is a problem either in the operating room system or with the operating clinician and the team. In fact it would be wholly inappropriate to readjust the normal operating scheduling for this obstetrician based on this data point.

The performance of the clinician and the operating team should not be judged out of context. Equally the system should not be changed. This astronomical data point should be excluded from the data set. It should not inform future scheduling for that obstetrician in that theatre for elective caesarean sections.

The relationship between frequency distribution of data and SPC charts can be understood as described below

Understanding the characteristics of a normal/frequency distribution curve is helpful in understanding the graphical relationship between a normal distribution curve and an SPC chart.

A normal/frequency distribution curve has the following characteristics:

1. It tracks the performance of a process across a group of measurements or observations

2. It shows on the y axis the number of times that each possible value (plotted on the x axis) occurred eg count, percentage, rate, proportion.
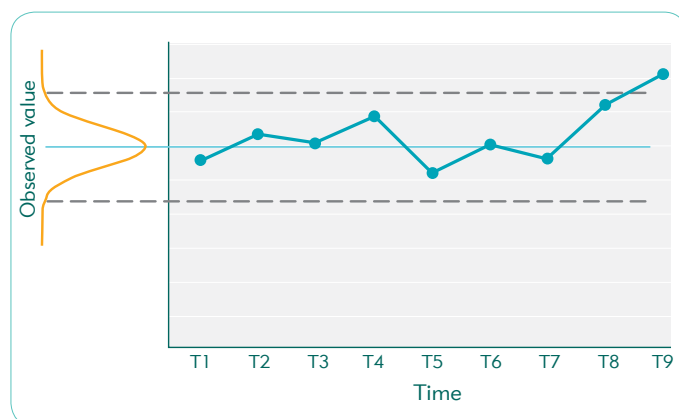
Standard Distribution Curve
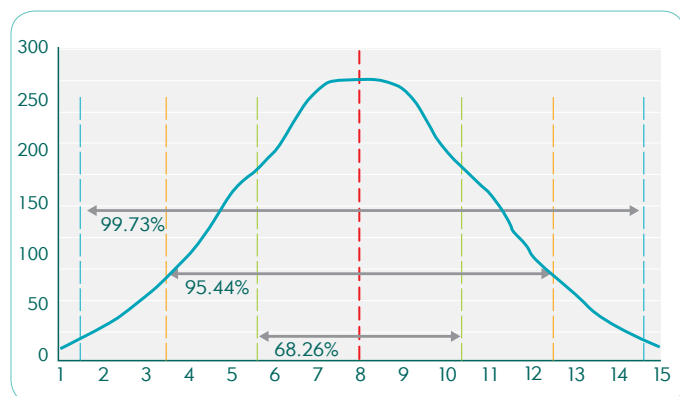
NHS Institute for Innovation and improvement: Safer Care
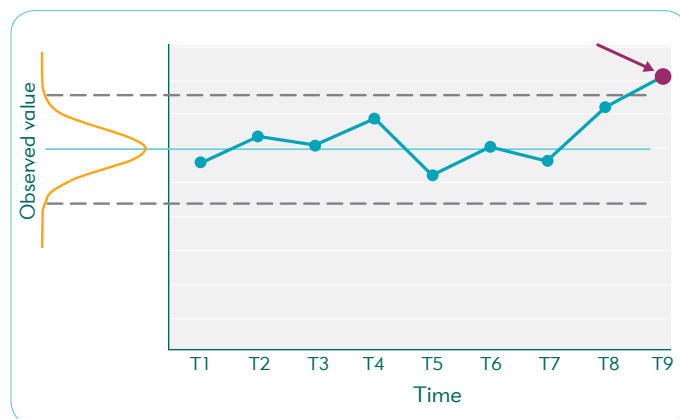
With SPC charts the control limits should **always be three standard deviation limits** (or three sigma limits) i.e. 99.73 per cent.

Beware! 'Two sigma' is a concept which we are all familiar with in statistics. Sometimes these are incorrectly referred to as 95 per cent confidence limits and for many people two standard deviations is an iron clad rule of thumb for declaring 'significance'. The issue is then that there is a potential five per cent risk of treating a common cause that falls between the 2nd and 3rd sigma limits as if it were a special cause. This may then lead to an inappropriate improvement approach.

> With special cause variation the appropriate action is to understand the special cause, respond accordingly and not immediately change the system/process in response to a single event.

This graph demonstrates a key principle about the relationship between a standard distribution curve, a process and the predictability of a process.

While it is not possible to exactly predict any single future observation for the process, the frequency distribution gives an area (under the curve) within which nearly all of the process's future measures should fall.

In essence, how the process behaved in the past will predict how it should behave in the future. It is therefore appropriate to apply the Model for Improvement (MFI) to improve the process.

Common cause variation

Characteristics:

- Also known as random or unassignable variation
- Represents appropriate variation
- Follows the laws of probability – it behaves statistically as a random probability function
- Because it represents the sum of many small causes, it cannot be traced back to the root cause
- Is inherent in the design of the process
- Is due to regular, natural or ordinary causes
- Affects all the outcomes of a process
- Results in a 'stable' process that is predictable, which may not be acceptable as it does not mean good variation.

Example: when looking at the time a consultant obstetrician takes to perform an elective caesarean section, one could anticipate that the length of the operation per patient will be between 25-35 minutes. This variation in duration is to be expected and anticipated. Therefore, when scheduling an elective caesarean section list it is reasonable to use this data to allocate appropriate operating times in accordance with this predictable variation.

What do you do when you identify common cause variation?

Given that common (random) variation is a physical attribute of a process, in order to reduce the random variation you need to find a *new* process, with a new level of random variation that is superior to the original process. Frequently this new improved process is a variant of the old process.

Because common cause variation by definition implies a stable process that may need to be improved, it is appropriate to apply the MFI tool. Using rapid test of change through PDSA cycles allows you to quickly identify a stable improved reliable process as previously described.

Group Exercise – Can you spot any of the rules in this Run Chart?
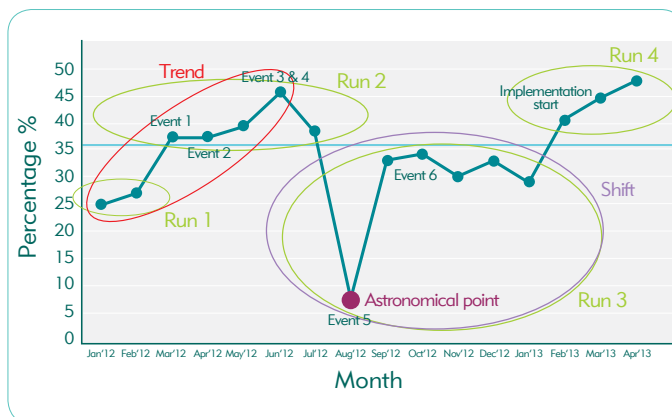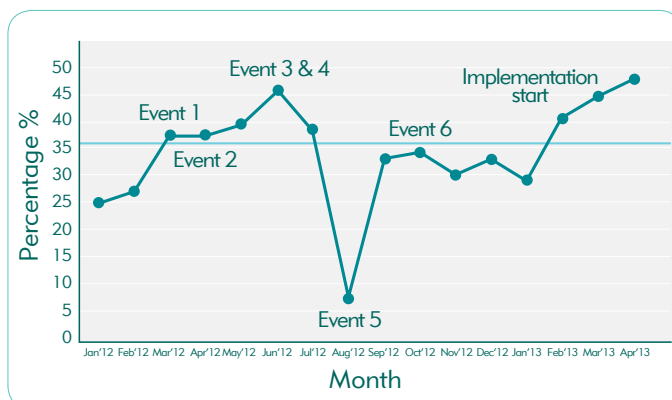
Conclusion

The importance of robust data measurement, analysis and interpretation cannot be underestimated. A range of measures (outcomes, process and balancing) are often required to understand the full picture of change. There are inherent risks associated in making assumptions about trends or causes of data variation without applying the rules of interpretation as outlined in this chapter. Unsophisticated analysis of data can affect the subsequent decision making process, sometimes detrimentally. Senior clinicians, leaders and managers will benefit from encouraging rigorous analysis and correct interpretation of data, and in building the measurement capacity of services and teams.

CHAPTER 11

Driver Diagrams in more detail

A Driver Diagram

- **Is a simple tool that will assist you to plan and structure an improvement project**
- **Is a living document that can be regularly updated**
- **Uses columns for the aim statement, primary drivers, secondary drivers and change ideas**
- **Provides a visual tool for explaining the project's purpose and how the project activities will deliver that aim**
- **Facilitates stakeholder buy-in and commitment.**

A Driver Diagram is a simple visual tool that will assist you to systematically plan and structure your improvement project. It will help you understand the logic of your project and where you are going with your improvement initiative. It is a living document that can be updated at every team meeting where drivers and change concepts can be discussed and agreed upon.

A Driver Diagram organises information on proposed activities so the relationships between the aim of the improvement project and the changes to be tested and implemented are made clear. It is set out using columns consisting of:

- **An aim statement** outlining the project goal or vision. The aim statement is derived from the problem you are trying to address, i.e. *'What are you trying to accomplish?' (first questioned from the Model For Improvement)*
- **Primary drivers:** these are high-level factors you need to influence in order to achieve the aim. They are improvement areas that must be addressed to achieve the desired outcome. Primary drivers should be written as straightforward statements rather than numeric targets.
- **Secondary drivers:** these are specific factors or interventions necessary to achieve the primary drivers. They are targeted areas where you plan specific changes or interventions. Each secondary driver will contribute to at least one primary driver (drawn using 'relationship arrows'). They should be process changes that you have reason to think will impact the outcome (should have an evidence base). They should be necessary and (collectively) sufficient to achieve the aim. The secondary drivers are found by brainstorming the causes of the problem.
- **Change ideas:** these are well defined change concepts (possible solutions) or interventions to address the secondary drivers, i.e. what exactly are you going to do and how are you going to do it? Each change idea will contribute to at least one secondary driver (drawn using 'relationship arrows'). The change ideas address the question in the Model For Improvement: *'What change(s) can we make that will result in improvement?'*

Prioritisation of change ideas – All change ideas need to be assessed to determine which ones you will test as a priority via a PDSA cycle. For each change idea, determine if it will:

- Have a high or low impact on the aim
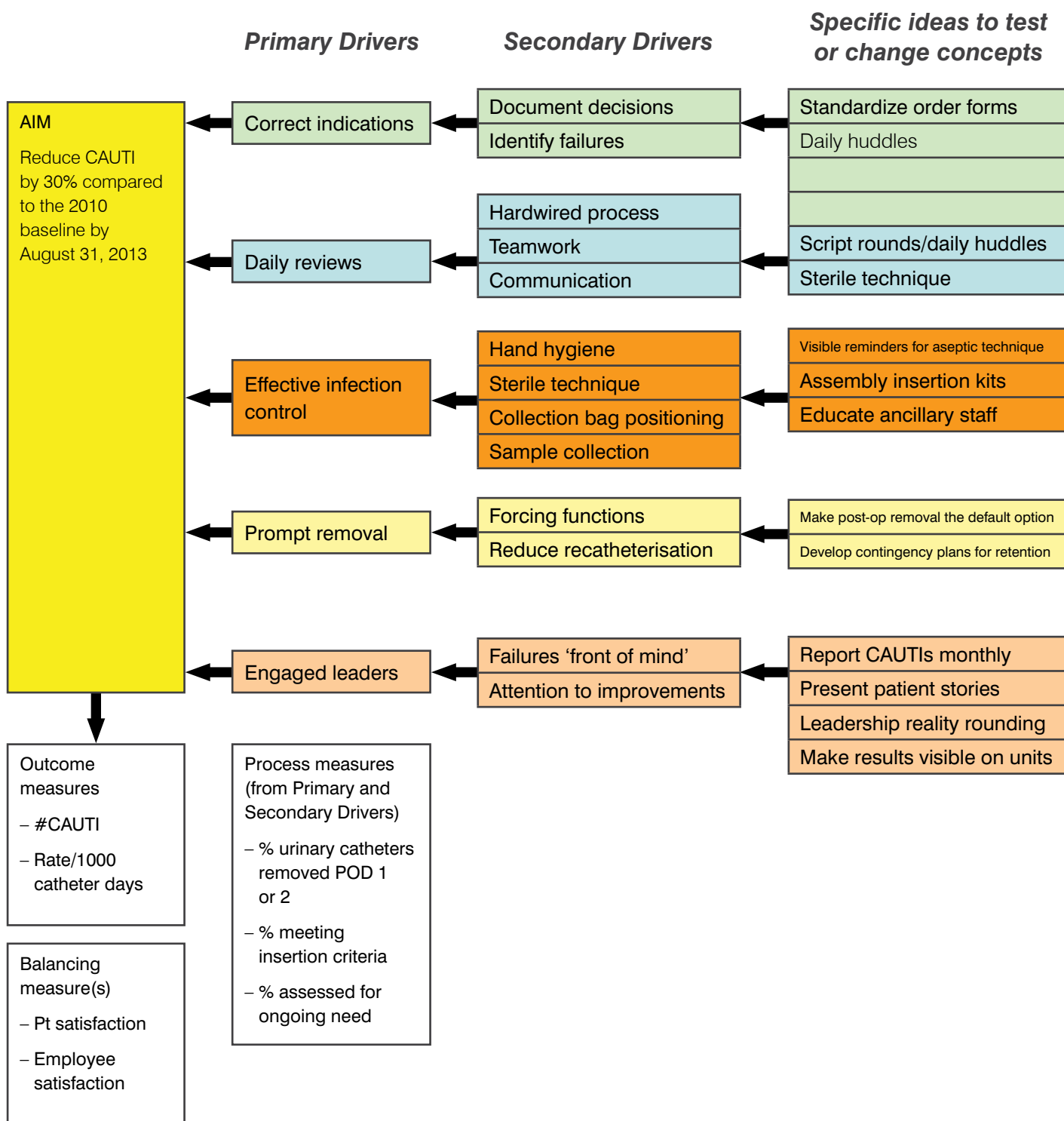- Be easy or hard to implement.

Measures:

It is important that you measure the impact of your improvement project, i.e. *'How will you know if a change is an improvement?' (the second question from the Model For Improvement)*. A driver diagram will help you determine outcome, process and balancing measures by focusing on:

a) How much improvement do you want to see; and

b) By when.

How a Driver Diagram can assist in your improvement journey:

- Reinforces the desired project outcome or aim
- Provides a simple visual tool for explaining the project's purpose and showing how the project activities will deliver that aim
- Helps a group to explore the factors (drivers) that they believe need to be addressed in order to achieve a specific overall goal or result
- Shows how the factors (drivers) are connected
- Defines the key leverage points (drives) in the system
- Acts as a communication tool to explain a change strategy
- Links the specific project activities and changes (the 'hows') to key components in the system
- Helps define how project progress and results should be measured and monitored
- Facilitates stakeholder buy-in and commitment to the changes that the project will require.
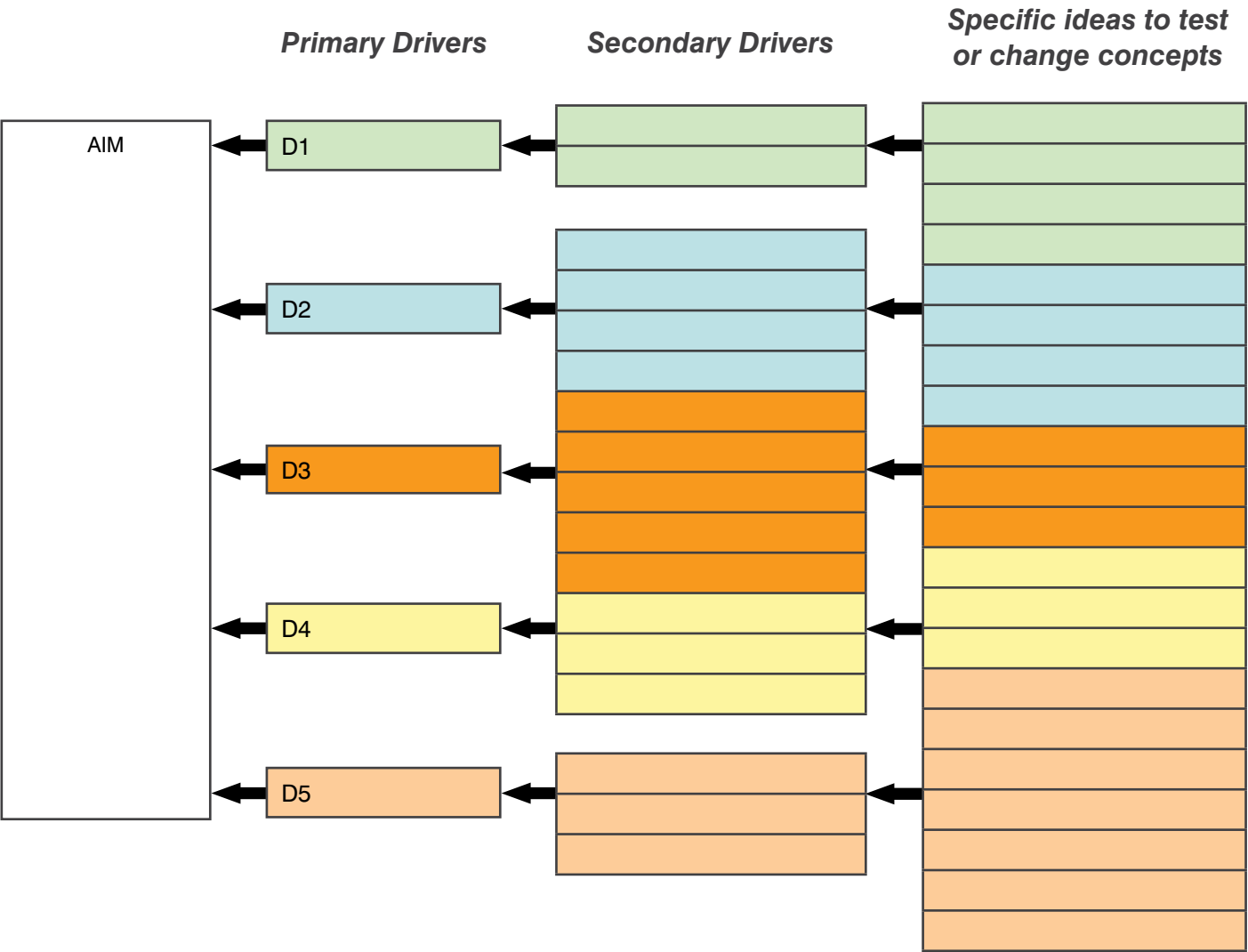
DRIVER DIAGRAM

	Primary Drivers	**Secondary Drivers**	***Specific ideas to test or change concepts***

AIM

Reduce CAUTI by 30% compared to the 2010 baseline by August 31, 2013

Correct indications
- Document decisions
- Identify failures
  - Standardize order forms
  - Daily huddles

Daily reviews
- Hardwired process
- Teamwork
- Communication
  - Script rounds/daily huddles
  - Sterile technique

Effective infection control
- Hand hygiene
- Sterile technique
- Collection bag positioning
- Sample collection
  - Visible reminders for aseptic technique
  - Assembly insertion kits
  - Educate ancillary staff

Prompt removal
- Forcing functions
- Reduce recatheterisation
  - Make post-op removal the default option
  - Develop contingency plans for retention

Engaged leaders
- Failures 'front of mind'
- Attention to improvements
  - Report CAUTIs monthly
  - Present patient stories
  - Leadership reality rounding
  - Make results visible on units

Outcome measures
- #CAUTI
- Rate/1000 catheter days

Balancing measure(s)
- Pt satisfaction
- Employee satisfaction

Process measures (from Primary and Secondary Drivers)
- % urinary catheters removed POD 1 or 2
- % meeting insertion criteria
- % assessed for ongoing need

Source: John W. Young, MBA RN
National Association of Public Hospitals and Health System

In summary:

A Driver Diagram is a useful tool for planning an improvement initiative. It will help teams stay focused and on course when used as regular reference for improvement work. A Driver Diagram will also help to define which aspects of the system should be measured and monitored to see if the changes/ interventions are effective, and if the underlying causal theories are correct. It should be updated regularly as the team acquires new knowledge and experience.

Can you think of a local problem that you would like to tackle in your ward or unit? Why not have a try on the empty Driver Diagram below?

Primary Drivers	*Secondary Drivers*	*Specific ideas to test or change concepts*

AIM

D1

D2

D3

D4

D5

ACKNOWLEDGEMENTS

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USEFUL WEBSITE LINKS

See the CEC QI Academy website for the Driver Diagram Starter Kit and template at http://www.cec.health.nsw.gov.au/

The Kings Fund – UK http://www.kingsfund.org.uk/projects/pfcc/driver-diagrams

IHI – USA http://www.ihi.org/education/ihiopenschool/resources/Pages/Activities/GoldmannDriver.aspx

NHS Health Scotland – UK http://www.healthscotland.com/OFHI/Resources/resources_driverdiagrams.html

NHS Scotland QI Hub -UK http://www.qihub.scot.nhs.uk/quality-and-efficiency.aspx

What's your theory – Driver Diagram serves as tool for building and testing theories for improvement by Brandon Bennett & Lloyd Provost: http://www.apiweb.org/QP_whats-your-theory_201507.pdf – July 2015

Carnegie Foundation Summit – Slides http://www.slideshare.net/NextGenLC/carnegie-foundation-summit-on-improvement-in-education-driver-diagrams – 2 March 2015.

SESLHD – http://www.seslhd.health.nsw.gov.au/IA/dd.asp

IHI – The Model For Improvement http://www.ihi.org/resources/Pages/HowtoImprove/default.aspx

IHI – PDSA http://www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementTestingChanges.aspx

YouTube videos:

Driver Diagrams – Lesson 1 of 3: Introduction https://www.youtube.com/watch?v=2mBpJIzzYl8

Driver Diagrams – Lesson 2 of 3: Reasons to use Driver Diagrams https://www.youtube.com/watch?v=xXRym4aFLa4

Driver Diagrams – Lesson 3 of 3: How to develop a Driver Diagram https://www.youtube.com/watch?v=BhY-rw9ejDk

http://www.ihi.org/education/IHIOpenSchool/resources/Pages/AudioandVideo/Whiteboard9.aspx