The Patient Safety Education Program™

CANADA

Module 9: Methods for Improving Safety

Visit **www.patientsafetyinstitute.ca** for further information.

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[Revised 2017]

PSEP – Canada Objectives	Related CPSI Safety Competencies
The knowledge elements include an understanding of: • The purpose and role of measurement • Quality improvement models • Change concepts • Continuous improvement methods The performance elements include engaging in exercises to: • Applying various quality improvement tools to advance patient safety	**Domain: Contribute to a culture of patient safety** *3. Health care professionals who maintain and enhance patient safety practices through ongoing learning:* 3.1. Identify opportunities for continuous learning and improvement for patient safety 3.2. Reflect on actions and decisions continuously, with self-awareness and using self-evaluation, to improve knowledge and skills in patient safety 3.3. Analyze a patient safety event and give examples on how future events can be avoided 3.4. Participate in patient and health care professional safety education 3.5. Share information on adaptations to practices and procedures that increase safety for specific individuals or situations 3.6. Contribute to the creation, dissemination, application, and translation of new health care system safety knowledge and practice 3.7. Participate in self- and peer assessments reflecting on practice and patient outcomes *4. Health care professionals who demonstrate a questioning attitude as a fundamental aspect of safe professional practice and patient care:* 4.1. Recognize that continuous improvement in patient care may require them to challenge existing methods 4.2. Identify existing procedures or policies that may be unsafe or are inconsistent with best practices and take action to address those concerns 4.3. Re-examine simplistic explanations for adverse events to facilitate optimal changes to care 4.4. Demonstrate openness to change **Domain: Work in teams for patient safety** *1. Health care professionals who participate effectively and appropriately in an interprofessional health care team to optimize patient safety are able to:* 1.7. Participate in the creation of a team environment where continuous learning is the norm

1.8. Contribute to a defined process for introducing new and emerging evidence into team-based care

1.9. Provide and accept feedback to improve the performance of the team and its members

Domain: Manage safety risks

2. Health care professionals who systematically identify, implement, and evaluate context-specific safety solutions:

2.1. Critically appraise the literature to identify evidence-informed and emerging safety solutions

2.2. Learn from local successes and experiences, assessing their appropriateness to a work setting

2.3. Select the most appropriate solution for a given context, taking into account quality, resources, practicality and patient preferences

2.4. Reflect on the impact of an individual intervention, including the potentially harmful or unintended consequences of a safety intervention

2.5. Evaluate the ongoing success of a safety intervention by incorporating lessons learned

2.6. Adjust policies and procedures to reflect established guidelines, if applicable

Domain: Optimize human and environmental factors

1. Health care professionals who are able to describe the individual and environmental factors that can affect human performance understand:

1.5. How to evaluate the impact of organizational resource allocation, policies and procedures and culture

Domain: Recognize, respond to and disclose adverse events

5. Health care professionals who participate in timely event analysis, reflective practice, and planning for the prevention of recurrence:

5.1. Engage in personal and professional reflection regarding the adverse event

5.2. Recognize the importance of monitoring the outcome of event analysis

5.3. Apply lessons learned from the event analysis

5.4. Advocate for system change as warranted
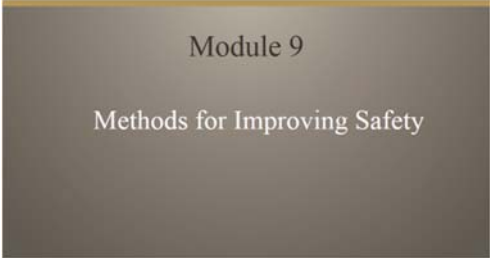
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Healthcare prior to the emergence of patient safety concerns relied on traditional methods of clinical and health services research to generate improvement. However, rigorous methods developed in engineering and long since applied with positive effect to other high reliability industries are now also being incorporated into healthcare.

The first part of this module describes how design improvement depends on understanding healthcare as a system, examining its variations, using change as a source of information, and understanding how humans interact with the system. Types of change made in quality management include managing variation, reducing defects and designing system features for safety.

Measurement is critical for safety improvement. This can include measures of structure, of process or of outcome. Ideally measures are validated, but this is not always possible and improvement teams often have to identify their own measures that are tailored to the process under consideration. Balanced measures should take into account that a change in one part of the system may result in unexpected changes in another part. A benchmark of quality uses the statistical measure, sigma, to denote a particular order of magnitude in defect (e.g. error, failure, adverse event) rates. Six Sigma denotes a low defect, high safety rate. It is also a term used for a training approach to quality management.

The second part of this module looks at safety improvement methods including root cause analysis (RCA) to retrospectively examine what went wrong, and failure modes and effects analysis (FMEA) to prospectively consider what might go wrong in the future, and clinical practice improvement (CPI) including the five step approach to CPI. The Collaborative model, which was pioneered in the Breakthrough Series by the Institute for Healthcare Improvement, in which institutions share successes and adapt them for their own sites, is also highlighted.

Keywords

Quality improvement methods, measurement, data collection, PDSA cycle, change concepts, continuous improvement methods, variation, system of knowledge, clinical practise improvement, breakthrough methods, Root Cause Analysis, improvement tools, flowcharts, Cause and effect diagrams (Ishikawa/ Fishbone), Pareto charts, histograms, run charts, huddles

Teaching method

Interactive lecture, small group exercise

Objectives

Slide 2

Knowledge requirements

- The purpose and role of measurement
- Quality improvement models
- Understand change concepts
- Continuous improvement methods

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Performance requirements

Applying various quality improvement tools to advance patient safety

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The overall objectives of this module are to understand the role of measurement and quality improvement in patient safety, and to know how to use rigorous methods in designing an improvement, implementing it and bringing about and measuring the changes.

Knowledge elements

The knowledge elements include an understanding of:

- The purpose and role of measurement;

- quality improvement models;
- change concepts; and
- continuous improvement methods.

Performance elements

The performance elements include:

Applying various quality improvement tools to advance patient safety.

Clinical case on trigger tape

Slide 4

Trigger tape

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The PSEP – Canada trigger tape for this module shows a team of 3 people performing a RCA for a medication error. The RCA reveals systems breakdowns at multiple levels of care. As a result, the team identifies areas to target for improvement. There are however, any number of videos to choose from to help "trigger" an initial discussion on the topic presented.

Introduction

Slide 5

Introduction

Quality improvement methods are not as controlled as randomized controlled trial studies

However

Key is to understand which methods to use in which setting and why.

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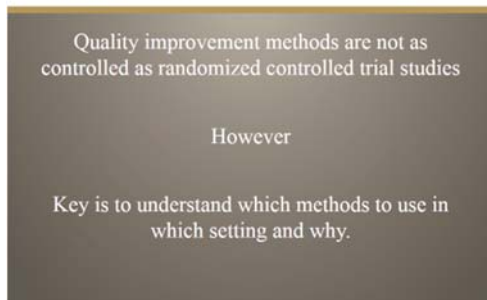
The methods by which knowledge is established have changed over time and quality improvement is now one of the methods used in healthcare to increase knowledge and enhance patient safety.

There has been some hesitation among medical researchers to use methods introduced into healthcare through patient safety, such as the root cause analysis and the rapid cycle improvement methods which will be described below. This hesitation has resulted from the fact that quality improvement methods are not as controlled as the gold standard methods, such as the randomized controlled trial, traditionally used in medicine. In part this concern has a misunderstanding at its base. As this module describes, the methods are the best for the purposes they are designed for. They are also compatible with the randomized controlled trial and other medical research methods. Indeed, safety improvement methods often make use of more traditional medical research methods as well, including vetting improvement projects through an ethical risk framework to mitigate for any ethical risks that may be present.

For some large systems, control groups do not exist, and in some settings insufficient time or resources make randomized controlled trials impossible. In this case it is all the more important to have an appropriate and attainable, rigorous method of evaluating impact such as a run chart for making progress. The key is to understand which method to use in which setting and why.

This module describes the premises underlying knowledge acquisition in change management and the key methods by which process improvement occurs in patient safety.

Background

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Initiated by the Scientific Revolution of the 16th and 17th centuries and formalized in the 20th century discoveries of physics, chemistry and biology, medicine has endorsed the methods of the laboratory - intervention, observation and repetition - discussed by Popper (1959) and others. Applying laboratory knowledge to the sick patient required different approaches. Methods of clinical medicine developed, evolving from case studies to include phased clinical trials and evaluation of interventions using cohort studies, randomized controlled studies and meta-analyses of multiple randomized studies. The gold standard method in evidence-based medicine has remained the randomized controlled trial until recent years.

Stimulated by patient safety research and perhaps by the restructuring of healthcare starting in the 1970s, it became apparent to thought leaders that healthcare delivery is a system. The inevitable consequence of this insight is that engineering methods, key ones of which were being applied and refined in other industries to achieve quality control since the 1920s, also produce valid knowledge and tangible improvements in their application to healthcare.

Patient safety is not restricted to engineering methods, although it depends heavily on them. Rather, it accepts all rigorous methods of knowledge acquisition and asserts that the method must match the type of knowledge needed. The difference is only that it includes engineering methods and notes their particular applicability to quality and safety – not only in other industries but also in healthcare systems.

One of the enduring themes in efforts to reduce harm to patients is acknowledgement of the role played by badly designed systems and the necessity for redesigning and changing the way current systems deliver care. The focus is on how to change current processes to make better and safer processes. What are the engineering methods for creating and implementing improved processes that were so successfully applied by management in the 1950s and since in manufacturing, insurance, transportation and other industries?

Lessons from continuous quality improvement theory, developed by the manufacturing industry, have facilitated different ways of understanding clinical care. Early pioneers of continuous improvement theory included Walter Shewhart, working in the 1920s, who invented statistical process control, and W. Edwards Deming, who developed the plan-do-check-action cycle. Work in the 1970s, by Joseph Juran, Armand Feigenbaum and Kaoru Ishikawa resulted in an approach called Total Quality Management. For these pioneers, quality was not something controlled at the end of the production line but an integral concern to be applied throughout the work process. The shift from quality control at the end of the line to quality assurance/management throughout means a shift in the design of systems to allow for such integration.

Design improvement

Slide 7

Safety improvement usually entails improving the design of the system. Deming described four components of understanding that underpin design improvement. He named this four component body of knowledge "a system of profound knowledge." The components are: appreciation of a system, knowledge of variation and how it can point to design flaws, theory of knowledge or seeing the results of change as a source of information, and psychology.

Using a system does not require such "profound knowledge" but designing or improving its design does. An analogy used by improvement leaders (Langley, Nolan, et al, 1996) is that many people can drive a car without knowledge of how it works, but car designers need profound knowledge.

Appreciation of a system

Thinking in terms of a system is fundamental to the paradigm of quality management. In addition, appreciating how the components of the specific system interact is one of the four sources of "profound knowledge." As most outcomes or services result from a complex system of interaction among its components - people, procedures and equipment - it is necessary to understand the properties of such systems.

The term 'system' comes from the Latin (*systēma)* and denotes a set of interacting, interdependent components that together form an integrated whole. Systems created by people usually have a purpose and some are purpose designed. An open system interacts with things from the outside; a closed system is closed off from its surroundings. In the real world, most systems are at least partly open.

In the context of a healthcare system this helps us to understand the interdependencies and interrelationships among all components (providers, patients, treatments, equipment,

procedures and so on), thereby increasing the accuracy of predictions about the impact of change on the system. In addition, for a system as complex as healthcare it can be particularly important to understand how one system can impact another system beyond itself. For instance, if an emergency room is being analyzed as a system, it may be impacted by a nearby train crash.

Understanding variation

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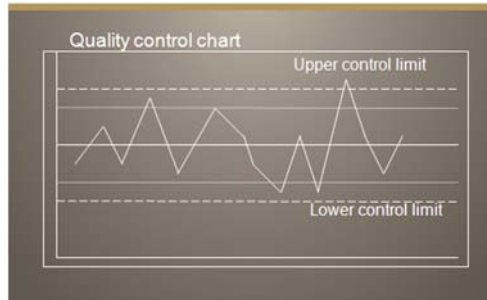
All systems continually exhibit variation. Usually, however, variation is not desirable in matters of quality control. Desired parameters of a process or outcome are best controlled within a narrow range. Outliers often go hand-in-hand with undesired events. By analyzing variation, it is often possible to get clues about how normal variation can be better controlled and about sources of unusual variation that require a different type of inquiry.

Shewhart used a statistical analysis of variation to form the basis of quality control. He introduced what is known today as a quality control chart, illustrated in Figure 1 below.

Figure 1: Quality control chart
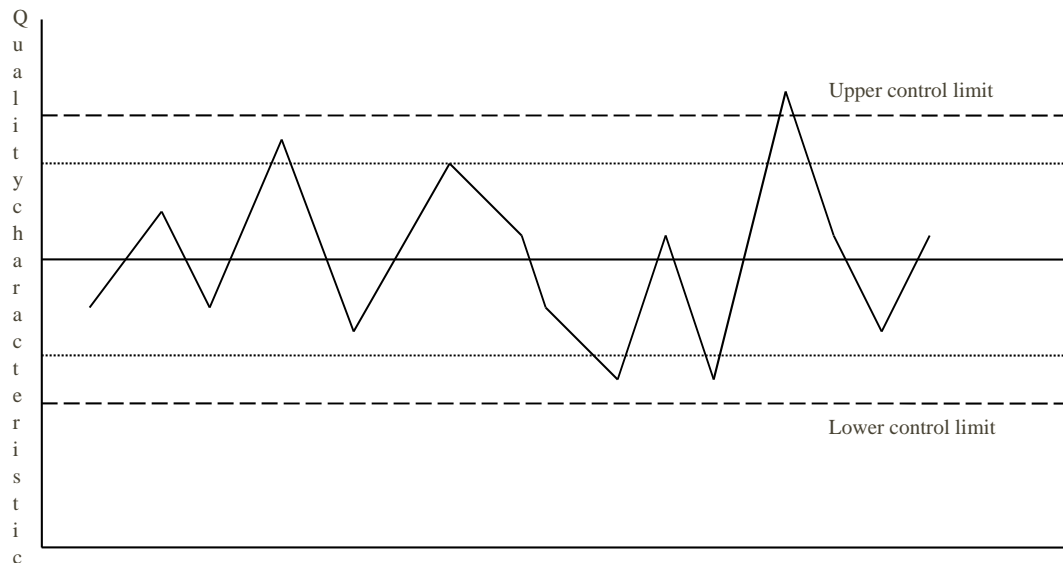
In healthcare, as in all systems, people are forced to make decisions based on interpretations of such variations: 'Will the shortage of staff lead to suboptimal care? Do the three medication errors reported this week indicate a pattern of poor prescribing? Was the improvement we made on decreasing waiting time an improvement or was it luck?' The ability to answer these questions and others like them is part of improvement activities. More dramatically, occurrences that should never happen such as wrong-site surgery are known as "never events" and these events and the "near-misses" that came close to happening should both serve as "sentinel" events to prompt inquiry into how this large variation came about and how the system can be improved so they do not happen – or nearly happen – again.

Change as a source of learning

Deming pointed out that in the context of improvement, making a change is a prediction that the change will lead to an improvement. The prediction is a necessary step for enabling a plan to be made even though the future is unknown. The more knowledge one has about a particular system and the way it functions or should function, the better the predictions and the greater likelihood that the change planned will result in an improvement. But the main point here is that comparing the predictions made and the results achieved is an important source of learning. Deming asserted that building knowledge by making changes and then measuring the results or observing the differences is the foundation of improvement science.

Comparing this to other methods of acquiring knowledge in medicine, it is remarkable how similar "change" is to "intervention" in bench research and other clinical studies. In all cases, a well-chosen change or intervention is crucial to making an advance.

Psychology

Knowing about and understanding psychology facilitates understanding people and how they interact with each other and the system. It gives an idea as to how people react to change, why they resist change and how their resistance might be overcome. Because people vary enormously in their reactions to similar events this must also be factored in when making an improvement change. Similarly, psychology, anthropometry, biomechanics and systems engineering have contributed to the field of human factors engineering (see also PSEP – Canada Module 2: Human Factors Design: Applications for Healthcare), which is the study of interrelationships between humans, their tools and the environment in which they live and work.

For instance, in healthcare the culture of a physician-directed authority gradient is strong and has specific advantages and disadvantages for patient safety during teamwork. Or in matters of technology, an effective bar coding system for patient identification has to take into account the routines of a nurse's daily life to be sure that the bar codes will be used as intended.

Slide 9

Deming not only defined the four key areas of systems understanding, he also set the foundation for a quality management improvement cycle. He asserted that it is impossible for improvement to occur without developing, testing and implementing changes. This set the stage for the Define, Measure, Analyze, Improve and Control (DMAIC) process that is used in quality management today in many industries. In healthcare, the adapted version of this process is close to the original Deming/Shewhart cycle; it is the Plan-Do-Study-Act (PDSA) cycle of practise improvement which is further described below.

How is quality management related to process improvement? Perhaps because the concepts were developed together, these terms are sometime used too interchangeably. Quality management oversees the activities necessary to design, develop and implement an effective, efficient and safe product or service. A quality manager must have 'profound knowledge' of the system and can direct the implementation of a range of activities and tools (methods) to improvement. Process improvement is one or a set of those activities and it involves the application of specific tools (methods) such as the PDSA cycle to improve existing processes.

Change concepts

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Over the decades since quality management became widely used, it has become apparent that initiatives for improvement fall into categories depending on the type of change. The

notion of a 'change concept' emerged. Change concepts relate to the question 'What changes can we make that will result in an improvement?' A change concept is a general notion (a good idea, an approach) that has been found useful in developing specific ideas for change that will result in improvement.

Nolan and Schall define a change concept as a general idea, with proven merit and sound scientific or logical foundation that can stimulate specific ideas for change that lead to improvement. They say that ideas for change can come from any number of sources: critical thinking about the current system, creative thinking, observing the process, a hunch, an idea from the literature, a patient suggestion, or an insight gained from a completely different area or situation. The team doing the improvement activity takes a concept and then adjusts it to fit the specific local situation or task they are trying to improve. This is an important step because it engages the local team in the process, thereby increasing commitment to the project and allows for local variation as appropriate. Langley and his colleagues have developed over seventy change concepts that have been grouped into nine categories. The following categories are adapted for patient safety from the nine general categories listed in Langley et al. (Langley et al., 2009).

Manage variation

Reducing variation improves the predictability of outcomes and helps reduce the likelihood of poor results. As described above, variation is an important source of knowledge about systems and safety issues.

Design systems to avoid mistakes

Organizations can reduce adverse events by redesigning the system to make it less likely for people in the system to make errors. For instance, one way to help error-proof a protocol is to make the information necessary to perform the tasks available in a physical form, and not just in one's memory. This can be accomplished by writing the information down on a wall chart at the site where the protocol is used. The field of human factors engineering is based on the notion that things and systems should be designed so that they suit the ways in which humans function. If that is not the case, the things or systems are prone to unintended outcomes.

Improve work flow

Improving the flow of work in processes is an important way of improving the safety of the services produced by those processes.

Optimize inventory; minimize waste

Langley et al. says that inventory of all types is a possible source of waste in organizations; understanding what inventory exists and why is the first step in finding

opportunities for improvement. Excessive amounts of inventory tend to be a source of waste; matching inventory to production need is important in reducing waste. Waste is a term in industrial engineering that refers to anything that does not add value to the system.

Change the work environment

Changing the work environment itself can be a high-leverage opportunity for making all other process changes more effective. See PSEP – Canada Module 4: Teamwork: Being an Effective Team Member for content on the importance of teamwork and culture as it impacts the work environment and safety and improvement success and sustainability.

Enhance the provider/patient relationship

For either side to benefit fully from improvements in the quality of healthcare, the patient and family or community as well as the providers in the health service setting must recognize and appreciate the improvements. Satisfaction by all stakeholders within the system should foster good relationships among them.

Manage time

Wait times can be long in healthcare. Time is, however, not a neutral thing when it comes to patient safety. Illnesses can have "windows of opportunity" for effective intervention, so for a number of medical situations waiting can be hazardous. A review of cycle times (the total time from beginning to end of one complete activity or process) for all functions in the organization is important.

Focus on the product or service

Although many organizations focus on ways to improve processes, it is also important to address improvement of materials and services. In healthcare the relevant material things tend to be equipment and devices. As described in PSEP – Canada Module 6: Technology: Impact on Patient Safety, equipment and devices all need to be designed to perform safely. Services also need scrutiny with a safety lens. Is the scope of services offered compatible with safety (for instance, specialization can enhance safety if the practitioner performs the same procedure frequently and over long periods of service)? Is the service state-of-the-art with respect to safety?

One of the benefits of lists, such as this list of categories of change concepts, is that they can speed up the process by not having to duplicate long searches for ideas to test. A number of catalogues have been published covering topics such as medical errors, waiting time, delays, intensive care and asthma.

Measures in patient safety require careful consideration. Measures should be reliable and quantify the aspect or aspects of the system that is / are desired. Measures may also provide benchmarks or indications of a general standard rather than a precise measure of a specific issue. Two authors, highlighted below, have explored quality assessment and proposed models for such measurement.

Donabedian's framework of structure, process and outcome

Slide 11

Measurement in safety improvement

Donabedian's framework:
◻ categorizes system features into
  • structures
  • process
  • outcomes

◻ measures provide feedback about the system

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Donabedian proposed a framework for quality assessment (1966). This framework categorizes system features into structure, process and outcome, each with its own assessments or measures. In so doing, it provides three separate frames for forming the quality picture. Structure, process and outcome assessments and measurements have been used to provide feedback about the system and allow judgments to be made about performance and whether or not a change is necessary.

Structure measures

This type of measure assesses the organization and administration of the healthcare system. It asks, is the setting conducive to quality healthcare? Examples of such measures are the following:

- The number or proportion of registered nurses on staff, and
- The ratio of providers to patients.

Process measures

This type of measure relates to how well the system works, and asks how effectively the parts/steps in the system are working? Here are some examples:

- The percentage of people receiving preventive services (such as mammograms or immunizations), and
- Average daily clinician hours available for appointments.

Outcome measures

This type of measure captures the voices of patients, providers and families. They ask how the system or service is performing. How effective is it in making patients better? Some examples include:

- Adverse drug events per 1,000 doses, and
- For critical care, intensive Care Unit (ICU) mortality or return to ICU.

Plsek's proposed philosophy of measurement

Slide 12

Plsek's philosophy

Other types of measures exist to help improve the healthcare system, for example:
- cross functional processes
- PREM and PROM measure

Plsek, goes further than Donabedian's foundations. He asserts that measurement in quality improvement science requires something different from previous measurements, and makes the following points:

- Other types of measures also exist. We need to think about what we are measuring and whether we have included the right parameters in evaluating the question. Have the views of patients or their providers been included, as well as those of healthcare professionals and managers?
- Quality improvement emphasises cross-functional processes therefore measurements are best viewed as an integrated system managed by a range of healthcare teams; rather than separate sets of measures tracked by different groups – researchers, medical staff, nurses, administrators, pharmacists and so on.
- Quality improvement measures are not about the search for 'bad apples.' Therefore measurement is not about individual rewards and punishments. Plsek and others oppose this traditional use of measurement which has long been important to purchasers and users of health services in enhancing choices. The system of rewards and punishment is not necessary to enhance patient choice. An organization which collects information to understand and improve its own care processes can also improve the choices for users in the system—including their choice of primary care provider, hospital and care plan. The aim in improvement is to make a change in the process or performance, rather than identifying poor performers or bad processes.

The reason why measurement is important in process improvement is that it focuses on the work and the tasks that people do. Many important tasks in healthcare are not routinely measured. By developing appropriate measures and using effective existing measures, people in an organization can make changes that lead to improvement throughout an organization. Examples of measurements that have come to the forefront in quality improvement and are recognized as providing valuable and essential information for achieving health system goals include patient reported experience measures (PREMs) and patient reported outcomes measures (PROMs). PROMs measure aspects of a patient's health status at a particular point in time during an illness or with a health condition while PREMs measures aspects of the patient's view on the delivery of services (CIHI, 2017). These measure are providing valuable data which support ensuring a patient-centred approach to care is maintained.

Measurement is central to using a quality improvement model. The only way a team will know if their efforts were associated with improvement will be by measuring the before and after situation.

Balancing measures

Slide 13

Balanced, reliable measures

❑ Measures must be balanced:
   do changes in one part of a system cause problems in another part?
❑ Measures must also be:
   • reliable
   • valid
   • generalizable

It is critical to look at the system from different directions/dimensions and ask whether the changes designed to improve one part of the system, are causing new problems in other parts of the system. For example, reducing time patients spend on a ventilator after surgery: ensure re-intubation rates are not increasing. For reducing patients' length of stay in the hospital: ensure readmission rates are not increasing. When limiting work hours of residents to reduce fatigue-related error: measure work hours and performance of those who take up the slack.

Using valid measures

Measures that provide valid information are not always easy to come by. Measurement development is a science in itself. To be valid, a measure must be designed and evaluated in such a way that the user can be confident it has face validity (do what it looks like it is supposed to do), content validity (have all the right components to do the job), construct validity (be composed so that its parts perform together correctly – i.e. the way theory

would predict it to work), test-retest reliability (get the same result if used repeatedly), and generalizability (perform suitably in more than one setting). Measures that have not been subjected to such rigorous design and evaluation procedures risk falling down in their performance.

A poor measure may look like it measures the intended feature but actually measures something else, or it may measure the right thing but give the wrong reading, or it may give a reading that would have been valid in another setting but should not be interpreted the same way in the actual setting.

Some areas in patient safety have been developed to the point that valid measures have been constructed. Safety improvement teams should use validated measures whenever they possibly can.

On the other hand, in quality management in general and safety improvement in particular, the relevant thing to measure is often not clear until the part of the system in need of improvement has been identified. Further, systems are in constant evolution and relevant features may be new and previously unmeasured. It is therefore often the case that valid measures are simply not available when they are needed. In such a situation, safety improvement teams have to come up with their own measures in as rigorous a fashion as the situation allows. Safety improvement methods allow for this reality and offer guidance, as described below, on how to attain optimal measures for the situation.

Quality indicators

Slide 14

Quality

- Quality indicator
  measure of something considered necessary for a quality outcome (e.g., training level of providers)
- Benchmarks: sigma levels
  quantifies defects in a process
  goal less than 3.4 defects per 1,000,000

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To evaluate broad quality in healthcare, people use quality indicators. Quality indicators can come from any category of quality assessment. Quality indicators may be measures of things that are considered necessary for or predisposing toward a quality outcome. For instance, an accreditation agency or large health delivery organization may distinguish between healthcare facilities by quality indicators such as the training level of its providers, the use of procedures to limit nosocomial infection, or the prior outcomes of a particular type of surgery for a particular type of population. Some but not all quality indicators are, or use, sophisticated measures.

Benchmarks: Sigma levels

The Six Sigma method is a measure of quality used to quantify defects in a process. Sigma is a symbol used in statistics that denotes standard variation or variability. The Six Sigma method applies the statistical tools of standard deviation and normal distribution to assign a "sigma level" to a given process. The sigma level corresponds to the rate of defects with the goal being less than 3.4 defects per 1,000,000. The higher the number of the sigma level, the lower the defect level. The sixth sigma level has defects at a level of 3.4 per 1,000,000.

Table 1: Six Sigma levels (adapted Chassin, 1998)

Sigma level	Defects per million
1	690,000
2	308,000
3	66,8000
4	6,210
5	230
6	3.4

The definition of what a defect is will vary depending on what is being targeted for improvement. Chassin notes that in the airline industry a defect might be the number of engine parts per million that fail to make it into the end product. In healthcare, he notes that a defect might be the number of women who fail to receive prenatal care in the first trimester.

The goal of 3.4 defects per million has been accomplished in certain sectors of industrial production, but is not as prevalent in healthcare. For example, in a 1998 article Chassin noted that when the Harvard Medical Practice Study came out in 1991, its evidence that

1% of all patients were injured by negligence was seen by many as "comfortingly low." By Six Sigma, standards, however, this number of defects would be too high, running at a rate of 10,000 defects per million, 3,000 times higher than the Six Sigma target of 3.4 defects per million. A number of commentators have noted that the one sector of healthcare which has approached Six Sigma levels has been anesthesiology, in which 5.4 deaths occur per million.

Six Sigma also became the name for quality improvement methodology in the industrial sector, and became prominent in the 1990s when both Motorola and GE put the methods to widespread use in much of their production processes. Aside from being a name for quality improvement methods, Six Sigma is also a widespread training course, with differing levels of expertise (green belts, black belts, master black belts) that may be gained by attending conferences and training sessions.

Part 2

An overview of safety improvement approaches

Slide 16

Improvement Methods

- Root Cause Analysis (RCA)
- Failure Modes Effect Analysis (FMEA)
- Clinical Practice Improvement Methodology (CPI)

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Three examples of improvement methods will be highlight in the following section. The three methods include:

- Root Cause Analysis (RCA)
- Failure Modes Effect Analysis (FMEA)
- Clinical Practice Improvement Methodology (CPI)

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Root Cause Analysis

▫ Retrospective process to identify factors that cause patient safety incidents.

▫ RCA is about finding all the causes, not about finding a single cause

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Root Cause Analysis (RCA) is a retrospective process analysis method, which can be used to identify the factors that cause patient safety incidents. The RCA process enables an exploration of what happened, why it occurred, and what can be done to prevent it from happening again.

RCA is a method for investigating ('drilling down' into) serious incidents (including near misses) so that the underlying causes can be examined, and solutions found that are designed to prevent a repetition of the event. Despite the singular use of 'cause' in the name, RCA is about finding all the causes, not about finding a single cause. It is not easy to do and requires training and education in their execution. The Veteran Affairs (VA) adaptation of RCA to investigate adverse events has become a prototype for healthcare organizations worldwide.

RCA requires sufficient resources and commitment from the organization to ensure flow of benefits to the system as a whole. Staff selected to participate in a RCA need training in the steps and methods used.

The team

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The team

▫ Multidisciplinary - ideally no more than 6 members
▫ RCA trained members facilitate process
▫ Meet for 5-6 weeks (2-4 hours at a time)
▫ Review documentation, site visit

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The team should be multidisciplinary and consist of no more than 6 people. Lay people should be included, particularly those that may bring a patient's perspective. None of the

participants should have had an actual involvement in the event under review. The team should be comprised of people who can add value, because of their knowledge, position in the organization or the unique perspective they bring.

Trained people in RCA should facilitate the process and guide the rest of the team with just-in-time training about the RCA process, wider system issues and factors that may be associated with the event. A typical team will meet weekly for 2-4 hours at a time over a period of 5-6 weeks.
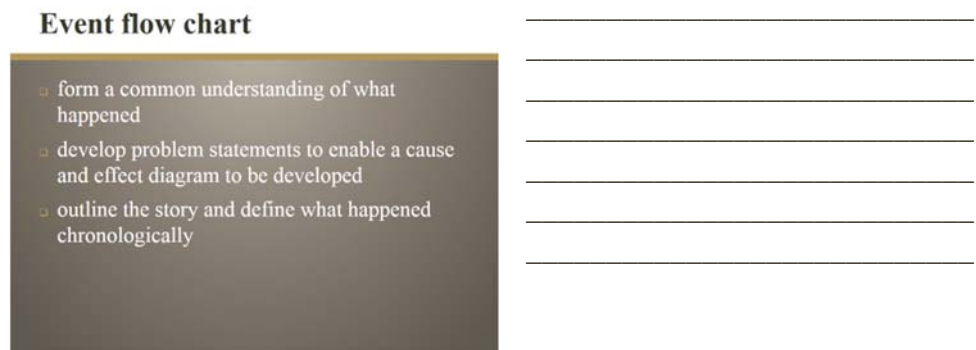
The RCA effort is directed toward finding how the failure happened. This begins with review of documentation (including medical records, incident forms, hospital guidelines, letters from the patient or their family or provider, literature reviews). A site visit is often necessary to visualize the environment, equipment, surroundings and relationships of those working on the site.

The event flow chart

Slide 19

Event flow chart

- form a common understanding of what happened
- develop problem statements to enable a cause and effect diagram to be developed
- outline the story and define what happened chronologically

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The event flow chart is much like a cause and effect diagram described under 'Clinical Practice Improvement' below, except the flow chart is specific for the event being considered. The event flow chart helps to:

- form a common understanding of what happened;
- develop problem statements to enable a cause and effect diagram to be developed; and
- outlines the story and defines what happened chronologically.

The problem statement

One of the team's functions is to write a clear statement of the problem to be addressed. It is important to not focus on solutions but rather think more deeply about the problem(s).

Contributing factors or root causes

Slide 20

Contributing factors

- Environmental factors
- Technology and tool factors
- Organizational factors
- Team staff factors
- Individual staff factors
- Task factors
- Patient factors

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Identify the root causes or contributing factors through brainstorming processes so that all possible factors are identified and examined. Develop an Event Flow Chart of the events including documenting the process of questions about each event and expand the chart on the basis of the answers. Examples of factors that may be generated follow:

- **environmental factors:** insufficient priority given to safety issues; a long-standing blame culture; legal pressures against open discussion to learn from incidents; lighting and physical layout;
- **technology and tool factors:** lack of human factors design in the technical equipment; inadequate technology support; too much reliance on technology instead of looking at / talking with the patient;
- **organizational factors:** inadequate staffing levels; poor or absent policies; a culture in which productivity takes priority over safety (an attitude of 'press on regardless'); high workload and fatigue; limited access to essential equipment and inadequate administrative support, all leading to reduced time with patients;
- **team staff factors:** poor supervision of junior staff; poor communication between professional groups; senior staff discouraging others from seeking assistance;
- **individual staff factors:** lack of knowledge or experience; long term fatigue and stress; having to 'multitask';
- **task factors:** lack of clear protocols and guidelines; non-availability or delay in obtaining test results; task poorly defined; and
- **patient factors:** distressed patients; communication and cultural barriers between patients and staff; multiple co-morbidities.

The VA RCA process is guided by developed questions about the following possible factors for example:

- **Communication:** Was the patient correctly identified? Was information from patient assessments shared by members of the treatment team on a timely basis?
- **Environment:** Was the work environment designed for its function? Had there been an environmental risk assessment?

- **Equipment:** Was equipment designed for its intended purpose? Had a documented safety review been performed on the equipment?
- **Barriers:** What barriers and controls were involved in this? Were they designed to protect patients, staff, equipment and the environment?
- **Rules, policies, and procedures:** Was there an overall management plan for addressing risk and assigning responsibility for risk? Had a previous audit been done for a similar event, were the causes identified, and were effective interventions developed and implemented on a timely basis?
- **Fatigue/scheduling:** Were the levels of vibration, noise, and other environmental conditions appropriate? Did personnel have adequate sleep?
- **Information Technology:** Was the electronic health record up and running and available as needed? If there was a mistake in the IT system, where in the process was it detected?
- **Training:** Was there an educational assessment to determine what training staff actually needed? Did the patient and family/significant others receive necessary education in a timely manner?

<div align="right">(VA National Center for Patient Safety, 2016)</div>

Cause and Effect diagrams

Cause and Effect diagrams are also helpful. This diagram is additional to the Event Flow Chart and is important in avoiding attributing causes to single errors. The Cause and Effect diagram begins with a few problem statements and shows how these may have been caused by a few actions and many latent (underlying) conditions. It is further described below.

Root cause/contributing factors statements

Root cause statements are another helpful tool. Root cause statements should only be made at the end of the process. The VA process provides the following guidance to staff in writing root cause statements:

- the cause and effect relationship must be clearly linked;
- avoid negative value statements;
- identify a preceding system level cause in each human error;
- violations of policy/ procedures must have a preceding system level cause; and
- failure to act is only causal when there was a preexisting duty to act.

<div align="right">(VA National Center for Patient Safety, 2016)</div>

Preventing a recurrence

Preventing a recurrence is an important task for the team. Once the RCA is completed, the team should come up with recommendations that aim to either eliminate it (requires action), control it (requires action) or accept it.

All recommendations should be realistic and should:

- address the root cause(s) of a problem;
- be specific and concrete;
- be easily understood;
- be possible to implement;
- define roles and responsibilities for implementation; and
- define a timeframe for implementation.

Potential challenges

As useful a tool as root cause analysis is, there are some challenges to using it in the healthcare setting as presented by Peerally et al. One of the challenges presented by using an RCA in this setting include implying that the narrative to an event may be more linear and simple than is actually the case (i.e. one root cause). As discussed previously, the RCA is about finding all the root causes, but some of the RCA techniques, favor a more singular narrative rather than a systems approach. It is easy for a team to get caught up in that approach, particularly if there is any sort of time pressure placed upon the participants. (Peerally et al. 2016)

There are also concerns about performing an RCA without the proper training or skilled employees necessary in order to produce a quality report. A survey found that only two in seven RCAs evaluated exhibited exemplary practices (Wallace, 2006).

Having potential challenges does not mean that the RCA is not a useful tool. It simply means that using it requires an awareness of its potential pitfalls so as to produce results that are useful to the quality improvement efforts.

Canadian Incident Analysis Framework

Slide 21

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The Canadian Incident Analysis Framework (the framework) is a resource to support those responsible for, or involved in, managing, analyzing and/or learning from patient safety incidents in any healthcare setting with the goal of increasing the effectiveness of analysis in enhancing the safety and quality of patient care. The framework provides methods and tools to assist in answering the following questions:

- What happened?
- How and why it happened?
- What can be done to reduce the likelihood of recurrence and make care safer? and
- What was learned?

The framework is a resource to help support individual and organizational learning, as well as quality improvement, in response to a patient safety incident(s). Organizations may also choose to use the framework to support quality assurance processes. See PSEP – Canada Module 16: Canadian Incident Analysis Framework for detailed content on the framework.

Failure Modes and Effect Analysis (FMEA)

Slide 22

Failure Mode Effect Analysis (FMEA)

Prospective process based on premise that errors will occur:

· How can a process fail?

· What will be its (the failure's) effect on the rest of the system?

· What action is necessary to prevent the failure?

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Failure Mode and Effects Analysis (FMEA) was first used by industries outside of healthcare, such as the automobile and aerospace industries. Unlike RCA, which is carried out retrospectively in response to a sentinel event, FMEA is a prospective process based on the premise that errors will occur. FMEA may reveal that an error is tolerable or that the error will be intercepted by the system of checks and balances that is part of a health system's risk management system. In other cases, FMEA may reveal that specific steps must be put in place to address potential errors with significant impact—errors that are intolerable.

FMEA is now applied in healthcare to proactively seek to identify and counter weak points in a system. The Institute for Safe Medication Practices Canada (ISMP Canada) has been using FMEA to identify potential failures and weaknesses in all their new products and services with the intent of fixing the problem before errors and problems actually occur. FMEA is a systematic method for resolving questions such as: How can a

process fail? What will be its (the failure's) effect on the rest of the system? What action is necessary to prevent the failure?

ISMP Canada has developed the Canadian Failure Mode and Effects Analysis Framework — Proactively Assessing Risk in Healthcare©, with assistance from healthcare and human factors engineering consultants. It can be applied to all healthcare processes, such as medication use, patient identification, specimen labelling, emergency room triage, and identification of risk of patients' falls. It can be used in acute care, long-term care and community settings.

The eight steps for conducting an FMEA described in the framework constitute a straightforward and understandable technique that users can readily apply to their own practise settings.

Undertaking a FMEA includes review of the following:

- steps in the process;
- failure modes (what could go wrong);
- failure causes (why failure would happen); and
- failure effects (the consequences of each failure).

FMEA is particularly useful in evaluating a new process prior to implementation and in assessing the impact of a proposed or actual change to an existing process. FMEA analyses a process' risk without and then with likely changes.

To analyze the steps of a process, consider changes, and calculate the risk. This is done by asking three questions:

1. How likely is it to occur?
2. How serious would the outcome be?
3. How likely is it to be hidden?

The Risk Priority Number (RPN) methodology uses these three questions about Occurrence (O), Severity (S), and Detection (D) and assigns a like scale, usually one to five or one to ten, to each and then multiplies the number to reach the assigned value for any hazard under consideration. That is RPN = OxSxD (or the scores on questions 1, 2, and 3 multiplied altogether). A hazard (e.g. wrong site surgery) that has a low chance of occurrence but a high severity or high risk of remaining hidden might stack up with an RPN that is similar to another hazard (e.g. late delivery of a medication) with a high occurrence chance and a low severity or low risk of remaining undetected. The RPN method allows prioritization of focus on the most important hazards to consider and try to pre-empt.

In addition to using the FMEA tool to help evaluate the impact of changes under consideration, teams can calculate the total risk for a process and then track the risk over time to see if changes being made to the process are leading to improvement. FMEA can

also be used to design a system that can be resilient in the face of exposure to an outside event or an extremely rare internal event.

Two other FMEA resources to note are the Veteran Affairs' 5-step approach to FMEA and the Structured What-if Technique (SWIFT). SWIFT comes from a prospective hazard analysis tool kit developed by the UK Department of Health in 2010 and is one of several tools that they discuss for prospective analysis (J. Ward et al., 2010).

Clinical Practice Improvement (CPI)

Clinical Practice Improvement (CPI) methodology is used by health-care professionals to improve the quality and safety of health care. It does this through a detailed examination of the processes and outcomes in clinical care. The success of a CPI project depends on the team covering five phases.

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CPI has the following five recognized steps:

- project phase;
- diagnostic phase;
- interventional phase;
- impact and implementation phase; and
- sustaining and improvement phase.

CPI Project phase

CPI project phase

4 fundamental actions:
- decide on process that needs improving
- form teams
- write an aim or mission statement
- consider appropriate measures

There are four fundamental actions that need to take place at the start of the improvement process:

1. decide on the area of work or process that needs improving;
2. form teams;
3. write an aim or a mission statement; and
4. consider appropriate measurements.

Decide on the process that needs improving

Before deciding on a process to be improved, it is important to collect as much data as required to confirm that there is a problem with the process. There are a range of possible sources: variation data, complaints data, clinical indicators and/or aggregated incident data. The data may be population-based, facility-based, clinician-specific or specific to a particular context. The process chosen may:

- involve high cost procedures or conditions;
- relate to a high volume diagnosis related group (DRG), procedure or condition;
- be associated with documented patient and families dissatisfaction;
- be one where there is dissonance between the evidence and clinical practice; and
- result in high levels of complications or incidents, and sometimes a 'never event' or 'near miss' will have served as a sentinel event that points to the process.

Problems may be given to a team to investigate or a team may choose the problem to be studied. Sometimes problems are suspected but there are no supporting data. Data must be collected to verify the existence of a problem before deciding that the process needs to be improved. At the very least, this ensures that there is a baseline for subsequent measurement of improvement. A literature search may be required for identifying national and international best practise for the particular problem or condition being studied. Conducting a literature review can avoid 're-inventing the wheel' and help to identify gaps in current practise. Key words for the search and articles should be distributed to all team members for review.

Form teams

Slide 25

Guidance & Project team purposes

Guidance team and project team purposes

Type	Guidance Team	Project Team
Purpose	Provide direction and support Trouble-shooting Approve recommendations for action Report to Area Health Service Quality Committees or equivalent	Investigate process, test change and analyse results Recommend improvements or changes Implement improvements or changes in practice
Membership	High level managers with decision making authority Could be single 'sponsor' or an Executive Team	People with fundamental knowledge of process Includes team leader and quality improvement facilitator Ideally maximum 9 members
Time orientation	Varies if overseeing more than one project	Limited to discrete project and short term

Having decided the nature of the project, the next step is to gather the appropriate people to work on solving the problem that has been identified. It is helpful to establish a **Guidance Team** to provide support for the project team. The guidance team will usually be comprised of high-level managers who do not work directly on the project and who can ensure that appropriate resources are provided. The Guidance Team can also play an important role in ensuring that barriers to the successful functioning of the project team are removed or at least minimized.

The guidance team should be at a sufficiently high level in the organization to have the authority to address any difficulties encountered by the project team. Alternatively, such authority can be given to the project by including a high level manager on the project team.

The **Project Team** should be comprised of people who, together, meet the following criteria:

- They must have a fundamental knowledge of the process and therefore should be people who work with or have a particular interest in the process. For example, a team looking at refining the admission process for children with cystic fibrosis should include pediatric respiratory physicians, physiotherapists, pediatric nursing staff, children's ward clerical staff and parents (at a minimum), all of whom have first hand experience of the issues involved.
- They must represent all parts of the process and, as appropriate, the various levels of the organization. It is easy to unintentionally omit those people who are considered to be external to a process, for example, representatives of the pathology or x-ray departments, allied health professionals, family physicians and private health providers.
- At least one of the team members should be trained in quality improvement methodology. Ideally, the team leader should have training in the facilitation of teams.

- Consideration also must be given here to including patients and families on the project team. They are able to bring a different perspective of the process and areas for improvement.
- The ideal size of a team is five to nine members. If your team is becoming too large, it may indicate that the scope of your project is too ambitious.

Improvement takes time and, in a stressed work environment, it is reasonable for clinicians to claim they do not have the time to participate as active team members. Meetings should therefore be structured to ensure that these people are able to contribute their fundamental knowledge of a given process in the most time-effective manner. Clinicians should not be expected to run team meetings unless they have a particular interest in doing so.

Figure 2: Guidance team and project team purposes

Guidance team and project team purposes

Type	Guidance Team	Project Team
Purpose	Provide direction and support Trouble-shooting Approve recommendations for action Report to Area Health Service Quality Committees or equivalent	Investigate process, test change and analyse results Recommend improvements or changes Implement improvements or changes in practice
Membership	High level managers with decision making authority Could be single 'sponsor' or an Executive Team	People with fundamental knowledge of process Includes team leader and quality improvement facilitator Ideally maximum 9 members
Time orientation	Varies if overseeing more than one project	Limited to discrete project and short term

Write an aim or a mission statement

Slide 26

Aim or mission statement …

Should be SMART:
  Specific
  Measureable
  Appropriate
  Result oriented
  Time scheduled

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Slide 27

... Aim or mission statement

Example statements:
- to decrease the rate of infections in joint replacement surgery to less than 1% in 12 months
- to decrease the number of admissions with a primary diagnosis of asthma by 50% within 8 months

The first team meeting is used to decide exactly what it is the team plans to do. This is recorded as an aim or a mission statement. The aim or mission statement should be SMART, i.e. it should be:

- **S**pecific;
- **M**easurable;
- **A**ppropriate;
- **R**esult oriented; and
- **T**ime scheduled.

Agreement on the team's aim or mission will be more easily achieved if team members are provided with relevant information before or at the first meeting, e.g. baseline data about the process being investigated: admission rates, infection rates, length of stay and so on.

A good aim or mission statement identifies a 'stretch goal' that is achievable but difficult to achieve. Teams are advised to avoid drifting from the original aim, but be prepared to re-focus the aim.

Examples of aim or mission statements which will 'stretch' a team to achieve improvement are:

- to decrease the rate of infections in joint replacement surgery to less than 1% within twelve months, and
- to decrease the number of admissions with a primary diagnosis of asthma by 50% within eight months.

Teams must avoid mission statements that suggest the desired solution to the problem, e.g., to implement an appendectomy protocol into the Division of Pediatrics.

At this stage teams should also consider whether they need to modify their membership to include other people with knowledge and experience of the problem area. To avoid a team becoming too big, additional members can be co-opted for their expertise as and when needed. The power of co-option should be included in the team's terms of reference.

Consider appropriate measurements

Slide 28

Appropriate measures

Identify data (measures) to support the issue needing attention

Teams should already have data (measurements) supporting the assertion that there is an issue needing attention, e.g. variation in rates of admission, mortality rates, specific procedure rates, infection rates or a number of related clinical incidents. These measures are needed to establish whether a planned change results in an improvement.

To demonstrate improvement, it should be possible to plot the variable(s) being measured on a run chart.

Other data also needs to be collected to give an accurate view of the whole picture. All quality improvement activities should focus on improvements in balanced clinical outcomes. In addition, measurement can be thought of as falling into the six traditional dimensions of quality improvement:

1. safety;
2. effectiveness;
3. appropriateness;
4. patient participation (and satisfaction);
5. access; and
6. efficiency.

For example, if the primary aim is to decrease the length of stay in hospital for a particular group of patients thereby improving the level of efficiency, it is essential that changes do not result in a decreased level of safety or effectiveness of the care provided. Patient satisfaction is another important component to measure in any quality improvement initiative.

CPI Diagnostic phase

Slide 29

The diagnostic phase follows the project phase and the importance of the diagnostic phase cannot be overemphasised. Having decided on the process or problem to be investigated, and agreed on a mission statement defining the boundaries of the project, the next phase is to find the causes of the problem. The focus should be on developing theories to explain why a particular problem or situation exists.

It is a trap to take short cuts at this time. Short cuts invariably risk a team starting to put their efforts into a potential solution only to discover it is unrelated to the cause of the problem.

The diagnostic phase involves collecting and analysing quantitative and qualitative data on the process being investigated to establish the causes of, and potential solutions to, the problem. Discussion of how the different causes interact to produce the problem helps the team to prioritize the causes and solutions to ensure effective action.

Is the problem really a problem worth solving? This is the time to establish the full extent of the problem and identify the changes that could be made that will lead to an improvement. A decision about how to measure the improvement needs to be resolved during this phase.
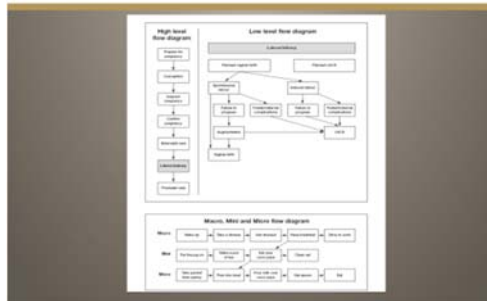
A number of tools and activities are useful to help identify and organize information, such as:

- process flow diagrams;
- brainstorming;
- patient/family focus groups;
- nominal group technique; and
- tally charts.

Flow diagrams

Flow diagram

The first task for the project team is to construct a flow diagram of the existing process. As all processes are hierarchical, both the macro and micro level of the process should be documented. This activity should take place after the aim or mission statement has been developed. Flow diagrams visually present the sequence of steps or decision flows in a process. They help a team reach consensus on the process and how it can be improved. They can be complex in nature and should be kept as simple as possible.

The process of developing a flow diagram facilitates:

- understanding of the process as it currently exists;
- open criticism of the process, comparison with other more effective processes and identification of improvement points, as and when applicable;
- identifying the complexity of the process and its management;
- identifying 'outcome' and 'process' steps;
- establishing process measures; and
- a better, less complex process.

Boxes or other symbols represent different steps or actions. These step-by-step pictures can be used to plan a project, describe a process, and identify the steps that led to an incident or document a standard method for doing a job. They can help group members understand what is happening now in a process, as well as help them agree on the order of activities in a new, improved process.

It is useful to flow diagram a process at two levels:

1. a high level flow diagram (macro level) that describes the overall process, and
2. a low level flow diagram (mini level) with more detail of the major stage in the process under examination.

The diagram in Figure 3 below represents the macro process of having a baby and the mini process of one stage of the macro process, namely labour and delivery.

Figure 3: Example flow diagrams
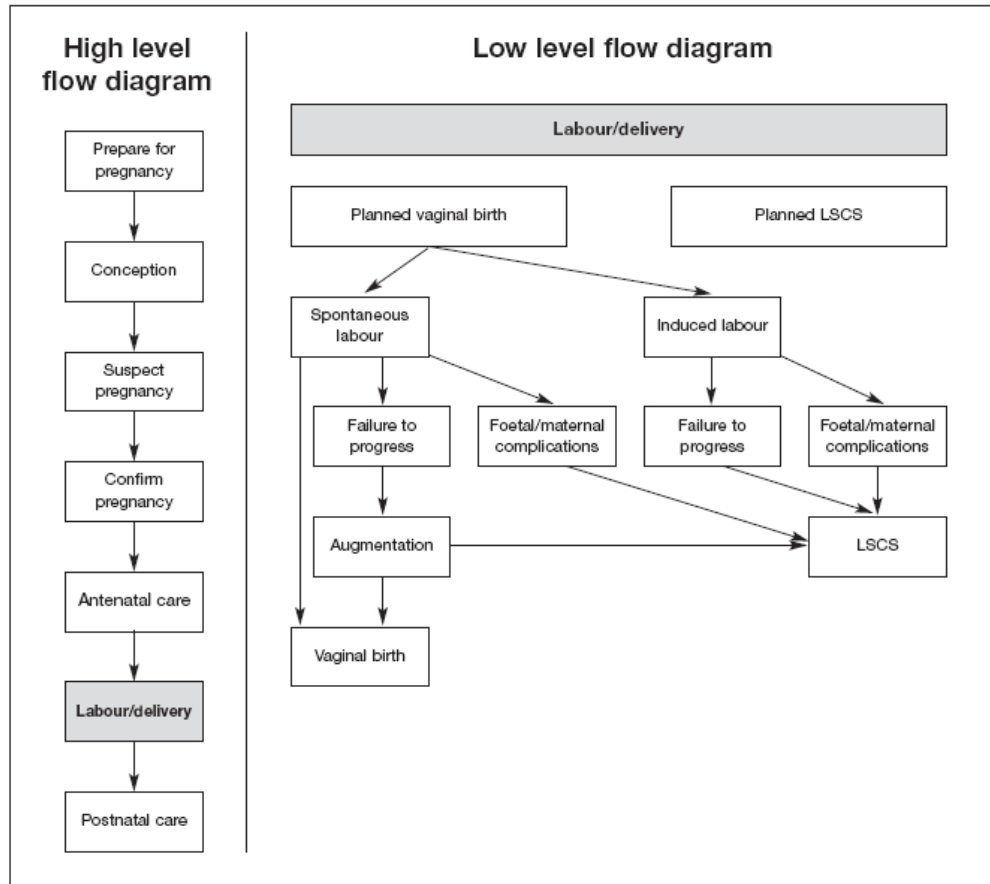
Some people further break down the process into macro, mini (meso) and micro levels of the process being examined. The 'simple' process of getting up and going to work each day is mapped below in the macro, mini and micro level in Figure 4.

Figure 4: Example flow diagram
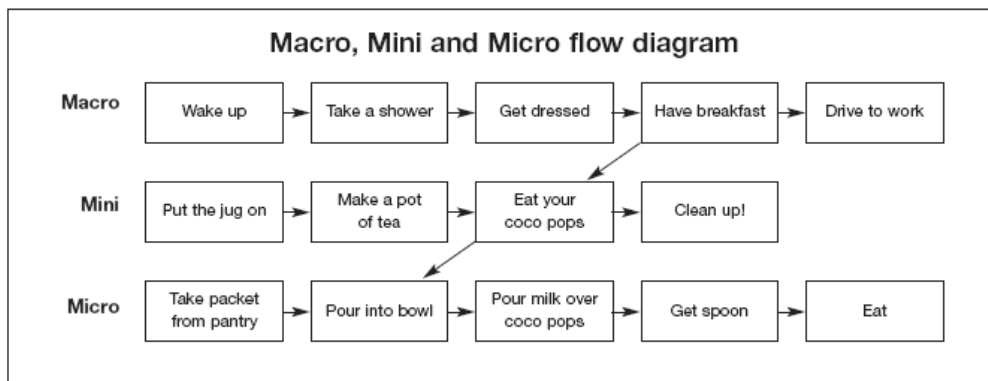
The key steps in developing a flow diagram are to:

- define the process to be studied, making sure to establish the boundaries of the process (where it starts stops and interfaces with other processes);
- identify the steps within the process (as it currently happens, not how the team thinks it should be) and identify key activities or operations, as well as decision points (may highlight the potential for blockages, errors or miscommunication in the system);
- brainstorm as a useful way of developing a list of all major activities and decisions involved from start to finish in a process; and
- draw the chart, using the appropriate symbols (use 'Post-It' notes or a white board when a group of people are contributing their ideas), keep the flow chart simple and use arrows to show the direction of all steps in the process.

Participants should make sure the steps in the process are arranged in the order they are carried out. Having people with knowledge of the process involved in the activity should help ensure the flow chart is a true reflection of what actually happens.

When constructing a flow chart, some basic symbols are used. A circle designates the begin point, followed by a diamond used for a decision point. Process steps are encased in rectangles. Finally, documents produced are designated by a rectangle with an undulating inferior border.

Slide 31

Standard flow chart symbols
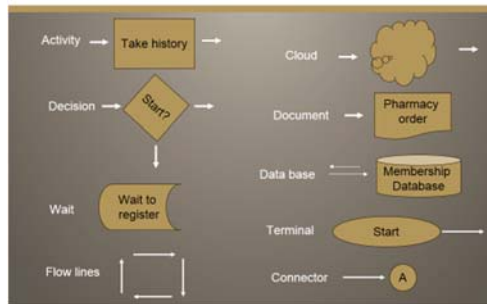
It is not essential to use these symbols but they may be helpful. Finalize the chart after a process of reflection. Make sure it contains all key steps, including re-work and decision loops and the start and end points. Label the flow chart with the title of the process, the date, and members of the team involved in its preparation. The team will usually refine the process flow chart at its second meeting.

Brainstorming

Slide 32

Brainstorming

- Structured
  - nominal group technique
  - organize and prioritize
- Unstructured
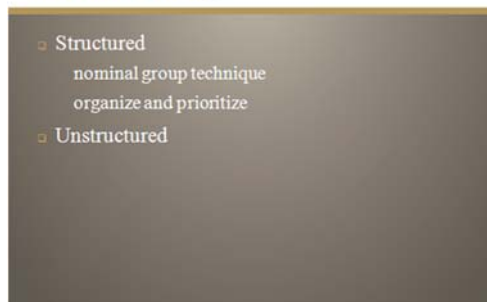
The objective of brainstorming is to generate as many ideas as possible from team members. Such sessions are usually useful either when the team is trying to identify the causes of a particular problem or when the team is trying to identify the solutions to the causes. A more structured alternative to brainstorming is the Nominal Group Technique (NGT) described later in this section. With the right team – that is, all those people who have a fundamental knowledge of the process being improved – this process can quickly identify causes and solutions.

There are two common methods for brainstorming:

1. **structured,** where participants **g**o around the group and have each person contribute one of their ideas in turn, until everyone is out of ideas; and
2. **unstructured,** where participants call out an idea in no order, until all ideas are exhausted.

Guidelines for brainstorming

Below are some guidelines for brainstorming sessions:

- appoint a 'scribe' to write up the ideas;
- write the problem or idea or use a well-structured question on flipchart or board;
- start by reviewing the topic; make sure everyone understands the issues;
- give people a minute or two of silent thinking time;
- write all ideas on 'Post-It' notes and place them on flipcharts or a board so everyone can see them;
- agree to no discussion during the brainstorm (that will come later);
- agree to no criticism of ideas – not even a groan or grimace;
- build on ideas generated by others in the group;
- leave historical solutions behind; think fresh, be creative;
- focus on creating a new order rather than on band-aiding old problems (do not use words like less, more, better, and not as they tie participants to current problems); and
- use complete sentences (five to seven words) with noun, verb, and object to help clarity.

The next step is to identify the priority issues for the group. Some form of voting usually achieves this. In a small group discussion a show of hands may be sufficient. When the issue is more complex and more people are involved, consensus may be unlikely in the time allowed. In this instance, multivoting may be the best option.

Nominal Group Technique (NGT)

The Nominal Group Technique (NGT) is another structured method of generating a list of ideas or condensing the ideas to a more manageable number. It is a more formal approach than brainstorming or multivoting. It is called 'nominal' because, in the process of generating ideas, the group does not engage in the usual amount of interaction typical of a real team. The relatively low level of interaction means the NGT is good for controversial issues. NGT also allows every team member to have an equal say and vote on issues raised. The NGT may be used to make decisions by consensus or allow each team member to have equal input into discussions. This may be useful to defuse a domineering staff member or influential employee who would otherwise control the discussion and dominate the process.

The NGT is usually conducted in two stages – a formalized brainstorm followed by a selection process.

Stage one: formalized brainstorm

During a formalized brainstorm, participants should:

- define the task in the form of a question, usually prepared by the team leader or team facilitator before the meeting;
- describe the purpose of the discussion including rules and procedures;
- introduce and clarify the question, and display the question on the wall or include it in handouts to team members for easy reference (may also be helpful to read the question aloud to the group to ensure it is understood by all participants);
- encourage anyone who does not understand the question to ask for more explanation (should not develop into a discussion of the issue itself);
- generate ideas (the most important step in the process);
- ask team members first to write down their answers in silence (a proven method of eliciting good ideas), and participants should not allow any distractions at this stage such as joking, moving around, or whispering;
- list the ideas when everyone is finished by asking each participant in turn to read one idea from their list, writing every answer on a flipchart (maximum of 30 minutes suggested with no discussion allowed at this stage to expedite the process and prevent the exercise becoming tedious);
- clarify and discuss ideas by displaying all of the flipchart pages in full view of the entire group and asking if anyone has questions about any items listed; and
- number each item on the list for ease of reference.

During the clarification portion of the brainstorm, the person who contributed the idea should be the one to answer a question. Other members may join in the discussion to help define and focus the wording. The wording may only be changed with the agreement of the person originally proposing the idea. When there are no more questions, condense the list as much as possible. If the originators of the ideas approve, the leader may combine ideas. If the originators think there is a difference, then ideas should remain separately listed.

Stage two: Making the selection

This stage is a more formal type of multivoting, used to narrow or condense a list of options, and to select the choice or choices preferred by the team. When the first stage has generated more than 50 items, try some method to reduce the list to 50 or less, e.g. one or two rounds of multivoting, or simply let members withdraw the less serious items they put on the list. No member is allowed to remove another person's item, unless the originator agrees.

Once the list is reduced (as necessary), the session leader should:

- give each participant a set of 5 cm x 10 cm cards or pieces of paper (the number of cards is a rough fraction of the number of items still on the list e.g. four cards apiece for up to 20 items; six cards for 20 to 35 items; etc.);
- ask members to individually select items from the list according to their own preference or ranking of importance (one item per card);
- ask members to assign a point value to each item, based on their preferences, with the highest point value being given to the most important item (the top value again depends on the number of items selected);
- collect the cards and tally the votes (it is easiest to score directly on the flipchart, noting the point value of each vote against the specific item, then adding up these values); and
- review the results as a group, and discuss the reaction.

If there is time, the session leader should display the results on a Pareto chart to highlight the items which received the most votes and which have the greatest point total (these are not always the same items). This will make it easier to see if there were any surprises, as well as allow for discussion of objections or requests for a revote.

If members do not agree on the top priority item, the team may focus its efforts on investigating more than one (two or three) of the items receiving the highest scores. If members agree on the importance of the highest scoring item, the NGT can be concluded. The team then has to decide its next action.

Another resource for brainstorming activities can be found on the Liberating Structure website http://www.liberatingstructures.com. This websites host over 30 innovative ways to approach problem solving and to include and engage people in work initiatives.

Organize and prioritize information

Slide 33

There are many different methods for organizing and prioritizing information collected. The following methods will be discussed in this module:
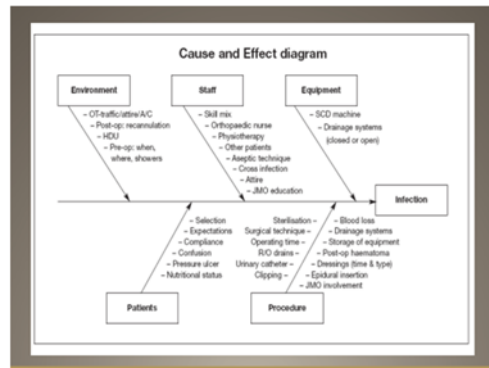
- Cause and effect diagram;
- Affinity diagram;
- Pareto chart;
- Histogram;
- Graphs of current data-run and statistical process control (SPC) charts; and
- Huddles.

Cause and effect diagram

Slide 34

A cause and effect diagram was originally developed by Dr Kaoru Ishikawa in 1943 as a problem solving tool to help identify causes that may lead to a particular defective outcome. They are also known as Ishikawa or "fishbone" diagrams. Today the diagram is a tool used to explore and display the possible causes of a certain effect. The contents of the diagram are generated by a brainstorming session.

A cause and effect diagram has a variety of benefits:

- it helps teams understand that there are many causes that may contribute to an effect;
- it graphically displays the relationship of cause to effect, and to each other; and
- it helps identify areas for improvement.

Affinity Diagram

An Affinity diagram is another useful tool for gathering and organizing ideas, opinions, or issues identified by a team. Ideas generated through activities such as brainstorming are usually naturally related. The Affinity diagram identifies the theme for each group of ideas and gives each group a header or title. An Affinity diagram may be used when a team is seeking to:

- add structure to a large or complicated issue (e.g. useful when identifying the central issues involved in developing a new service or product);

- break down a complicated issue into broad categories (e.g. useful when identifying the major steps in the completion of a complex project); and
- gain agreement on an issue or situation (e.g. useful when needing to identify the direction to be taken to achieve a particular goal and for minimizing the potential for conflict).

Figure 5: Affinity diagram

Affinity Diagram
Problem – Ineffective meetings, why do they happen?

Structure and conduct of meetings	Participation in meetings	Preparation for meetings	Meeting follow up
No agenda	Lack of trust in confidentiality of discussions	No pre-reading material	Action not taken as agreed at previous meeting
No ground rules	Too much time involved in meetings	Minutes of previous meetings not read	Lack of volunteers to take on tasks
No one willing to take minutes	Unfocussed discussions	Lack of time to attend meetings	
Ineffective chairman	Discussions dominated by 1-2 people	Poor minutes	
Meetings not starting on time	People not listening	Minutes not distributed within agreed time of meeting	
	Uninterested members		

Steps in constructing an Affinity Diagram

To construct an Affinity diagram, participants should:

- Start with a clear statement of the problem or goal to be explored and provide a time limit for the session (45-60 minutes is usually sufficient);
- Brainstorm ideas related to the issue or problem. Ask each participant to write their ideas clearly on index cards or 'Post-It' notes, one idea per card (five to seven words per card in large print is suggested).
- With the assistance of a facilitator, group the cards or 'Post-It' notes in columns according to ideas that appear to have a common theme. This is best done in silence. Do not allow discussion of issues at this point.

- Review the lists to ensure all ideas are appropriately grouped under a common theme.
- Regroup if necessary. Do not search for relationships between issues. It is sometimes best to leave a single issue (single card) on its own rather than add it to a group and blur the issue.
- Give each grouping a title or heading that best describes the theme for each group of ideas. This should express why the group believes the particular set of ideas 'go together' and is usually written as a short action statement (verb).
- Having reduced the number of ideas to manageable groupings, discuss and prioritize the issues according to their relative importance and potential impact on current performance.

Pareto charts

Slide 35
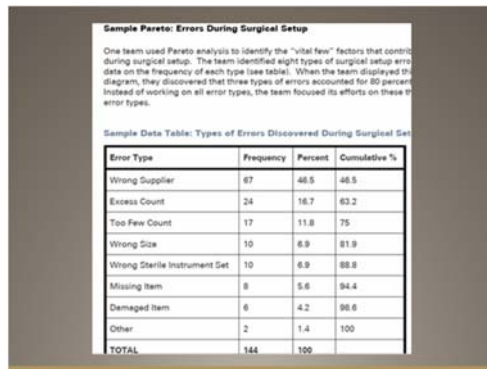
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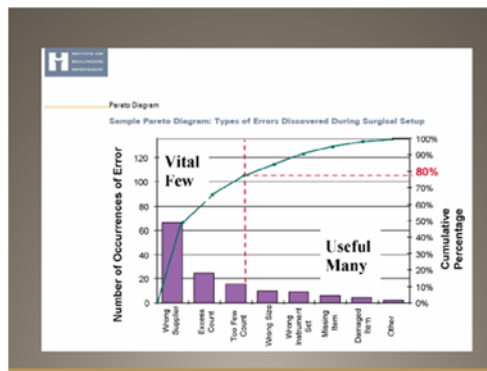
In the 1950s Dr Joseph Juran coined the term 'Pareto Principle' to describe a large proportion of quality problems being caused by a small number of causes. This is sometimes referred to as 'the vital few and the trivial many.' Specifically, this principle suggests that 80% of the problem may be caused by 20% of the events. The notion that a few contributions account for the majority of the effect is employed to determine where to focus the effort in attempting to fix a problem. This is done by prioritizing problems,

highlighting the fact that most problems are affected by a few causes and indicating which problems need to be solved and in what order.

A Pareto chart is a bar chart in which the multiple factors that contribute to the overall effect are arranged in order, according to the magnitude of their effect. The ordering is an important step because it helps the team concentrate its efforts on the factors that have the greatest impact. It also assists them in explaining the rationale for concentrating on particular areas.

Slides 35 and 36 come from the IHI tool for making a Pareto chart. Slide 35 shows a sample data table, setting out the types of errors discovered during a surgical setup. Slide 36 is a bar chart depicting the magnitude of the contributing factors in descending order. Many common software packages (including Excel) can create Pareto charts.

Histograms

Slide 37
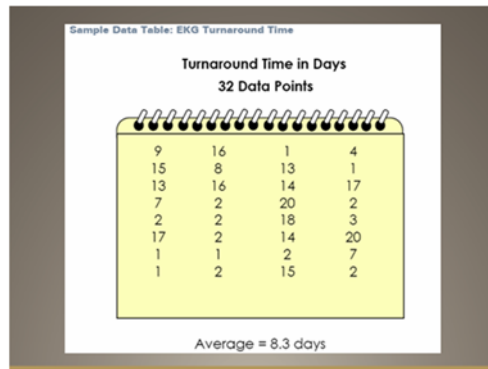
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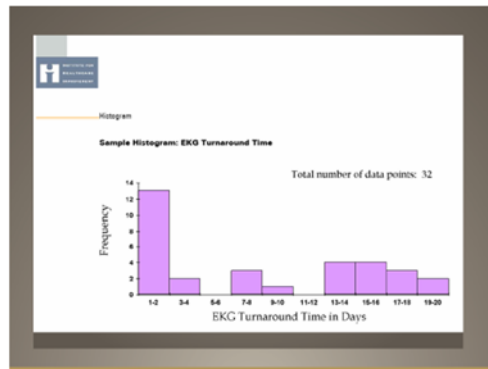
A histogram is a particular type of bar chart used to display the variation in continuous data--such as time, weight, size or temperature. It is used mainly to allow the team to recognize and analyze patterns in data not readily apparent simply by looking at a table of data or by finding the average or median. They are best used to understand the variability

of a process. Histograms, bar charts and Pareto charts look similar but have different purposes:

- **histogram -** used for continuous data (classified into intervals);
- **bar chart -** used for original data (or categorical) data; and
- **Pareto chart:** used for categorical data in descending order of frequency.

Continuous data is a measurement that can take any numerical value within a prescribed range. To construct a histogram, the continuous data are first categorized into a finite number of intervals or ranges. The number falling into each interval is then graphed.

Run charts

Slide 39

Sample run chart
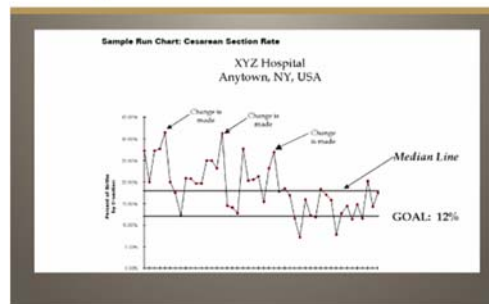
A run chart helps the team know if a change is an improvement over time or just a random fluctuation, wrongly interpreted as a significant improvement. Run charts help identify if there is a trend. A trend is formed when a series of seven consecutive points continually rise or fall. A control chart is a specific type of run chart.

The benefits of using run charts include:

- helping the team to formulate aims by depicting how well or how poorly a process is performing;
- helping determine when changes are truly improvements, by displaying a pattern of data that one can observe as the changes are made; and
- giving directions, as one works on improvement and information about the value of particular changes.

Huddles

Huddles

Frequent but short briefings so that the team can stay informed, review work, make plans and move ahead rapidly.

A huddle is a viable alternative to a longer one hour meeting. The idea of the huddle arose because of the need to speed up the improvement activity. They allow the team members to have frequent but short briefings so that they can stay informed, review work, make plans and move ahead rapidly. Discuss the huddle concept with the team, agree on the time and place that huddles will occur, bringing the team together in a place that is most convenient for member with least availability. Have a clear set of objectives and try to keep the huddles to 15 minutes or less and try to huddle frequently.

The benefits are that it:

- allows for fuller participation of front line staff and bedside caregivers, who find it difficult to attend longer meetings;
- keeps the momentum going; and
- enables Plan-Do-Study-Act (PDSA) cycles to proceed rapidly.

CPI Intervention phase

Interventions phase

1. Identify appropriate interventions
2. Implement changes identified in the diagnostic phase
3. Undertake one or more PDSA cycles

Interventions Phase

Decide on interventions

Undertake one or more PDSA cycles

(NSW Department of Health. Easy Guide to Clinical Practice Improvement, 2002)

The intervention phase is when the suggested changes selected in the diagnostic phase are tested. The CPI testing method is based on the trial and learning process summarized below; which uses Plan-Do-Study-Act (PDSA) cycles and ideally starts with small tests of change, observing the changes and acting on the results.

During the testing of a change many things may happen that are unexpected. This is why it is important to test regularly. The cycle begins with a plan and ends with an action. The cycle is designed to build new knowledge. This is a vital step in improvement science because the new knowledge allows better predictions about the impact of changes.

The application of the model can be simple or complex, formal or informal. It can be used to improve waiting times in the clinic or decrease surgical infection rates in operating rooms. A formal improvement activity may require detailed documentation, more complex tools for data analysis and more time for discussion and team meetings.

The steps to the intervention stage are as follows:

- examine the information collected throughout the diagnostic phase, noting high priority problems that have been identified by the team that are of particular importance;
- achieve consensus within the team on where to focus improvement energy; and
- decide on the interventions or changes most likely to bring about improvement.

Some broad examples of strategies include education for staff, implementation of a protocol or pathway and introduction of prophylactic antibiotics.

Testing a change is not always easy. Things may happen that were not planned, the change may not have an impact on the problem, or there may be unwanted side effects. To help people develop tests and implement changes, it is best to use the PDSA Cycle as the framework for an efficient trial-and-learning methodology.

The PDSA Cycle

Slide 42

The PDSA cycle

(Langley, Nolan, Nolan Norman & Prevost, 1996)
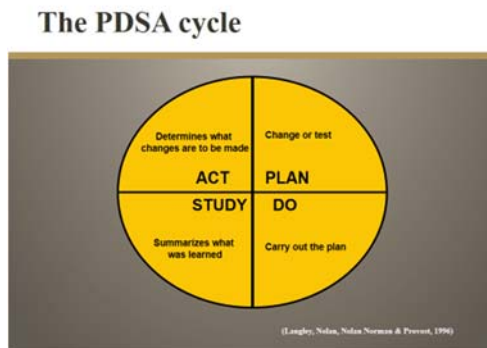
The cycle begins with a plan and ends with an action based on the learning gained from the Do and Study phases of the cycle.

Plan to test selected improvement or change.

Testing should demonstrate your belief that change will result in improvement. Testing also ensures you adapt change to suit conditions in the local environment, helps to

evaluate costs and side effects of the change and minimizes resistance upon implementation.

Do the test (i.e., carry out the plan) and collect data for analysis

Data collection may be as simple as counting observations and recording them on a tally sheet. It is essential to document problems and unexpected observations as these will help in understanding why a change did or did not result in improvement.

Study the results and compare data to predictions

From this, one can determine:

- if the test resulted in an improvement, and
- the likelihood of a larger scale implementation.

Analysis of the data will help to identify where change was well executed, where support processes were adequate or where hypotheses or hunches were correct. Where data does not support the process, the conclusion may be that the solution may be inappropriate.

Act on the results and implement the improvement or changes or select another possible improvement to test

Action should be rationally based on what was learned from testing the planned intervention.

Running early small PDSA cycles is often better than waiting to run large cycles after a long period of planning. Even when the change is ambitious and innovative, it should be tested on a small scale (e.g. with only one or two clinicians, or with the next three patients, or in one ward).

A PDSA cycle may be completed in as short a time frame as a day, a week or a month. Each PDSA cycle, properly carried out, is informative and provides a basis for incremental improvement. If a change works on a small scale and is improved in successive PDSA cycles, it can then be implemented on a larger scale.

Slide 43

**How to use the PDSA cycle**

- Use plan-do-study-act cycles to conduct small-scale tests in settings
    - plan a change
    - do it in a small test
    - study its effects
    - act on what was learned
- Team uses and links small PDSA cycles until ready for broader implementation

(NSW Department of Health. Easy Guide to Clinical Practice Improvement, 2002)

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Completion of each PDSA cycle leads directly into the start of the next cycle. A team learns from testing what worked and what did not work, what should be kept, changed, or thrown out. This new knowledge can be used to plan the next test. The team continues linking PDSA cycles in this way, refining the change until it is ready for broader implementation.
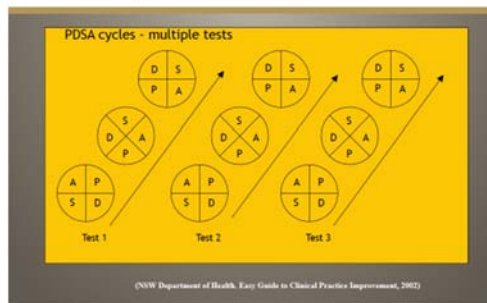
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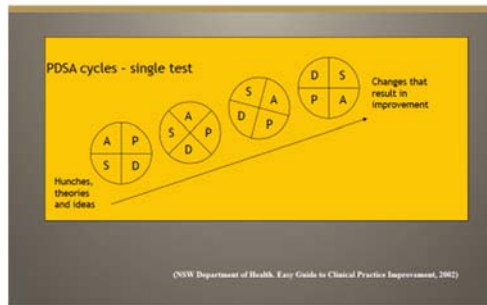
These linked PDSA cycles are called 'ramps.' Linking small cycles in this way helps overcome the natural resistance to change.

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Teams may also be involved in testing more than one change at a time, ultimately aiming to achieve the same goal. In healthcare and in science, it is not necessary to initiate tests one at a time, but it may be appropriate to introduce the things you know are going to work, together. Therefore testing a number of changes at the same time is appropriate and teams should continue testing interventions or changes to achieve the best practice possible.

PDSA cycles take time. Improvement takes investment. One important way to reduce the resources required is to establish and maintain measurements of important performance variables over time. Brief, measurable snapshots of performance over time may be sufficient. If clinical groups keep track of such measurements, the effects of deliberate changes can easily be assessed.

CPI Impact and implementation phase

Slide 46

Achieving success in a PDSA cycle does not guarantee sustained improvement. The successful interventions then need to be formally implemented. Implementing a change means making it a permanent part of normal business. To be successful, it is wise to implement only those changes you are sure will result in improvement.

Implementation differs from testing in several important ways:

- since testing a change is not permanent, there is no need to create a support structure e.g. training, documentation, and standardization;
- to implement a change, the relevant support processes have to be implemented at the same time;
- while the results of testing a change are uncertain, it is wise to implement only those changes you are sure will result in improvement;
- since the PDSA tests are usually conducted on a small scale, fewer people are involved than in the actual implementation of the change (greater resistance to change is likely to be associated with implementation and therefore will require an effective change management plan); and
- often implementation is conducted throughout the institution, well beyond the area where the intervention was tested and refined.

Sustaining and improvement phase

Slide 47

This phase involves determining how the changes will be monitored and how plans for future improvement of the process will be made.

Once improvements have been shown to be valid then a process to sustain the improvement needs to be implemented. This may involve:

- standardization of existing processes and systems for undertaking work activities;
- documentation of relevant policy procedure protocols and guidelines;
- measurement and review to enable the change to become routine; and
- education and training of staff.

Standardization

Standardization should ensure that the new work methods or processes are implemented consistently over time. The team needs to communicate its recommendations for improvement to management so that the changes become part of policy and day to day practise. Management in turn needs to incorporate the recommended changes as appropriate in 'standards' or 'best practise guidelines' and to promulgate them to all who need to know.

They may take the form of clinical pathways or decision-making trees, more conventional narrative policies and procedures, manuals, procedures, or a mixture of all of these.

Documentation

Documentation of the policy in the institution's standards operating procedures is easy to overlook but necessary if it is to be sustained. Institutions vary on how institutional policy is established. The project leader will be able to ensure inclusion of the adopted policy in formal, documented institutional procedure.

Measurement and review

The standardized, adopted policy must include selection of one or a few quality assurance measures that become part of the institution's "dashboard" or list of routinely assessed measures. This allows the institution to receive continuous feedback on key outcome measures and to initiate change wherever needed.

Education and training

Whereas the Impact and Implementation phase may well entail education and training of relevant staff, the Sustaining and Improvement phase involves widespread education and training so all workers can be aware and integrate the relevant aspects of the new policy and its associated features.

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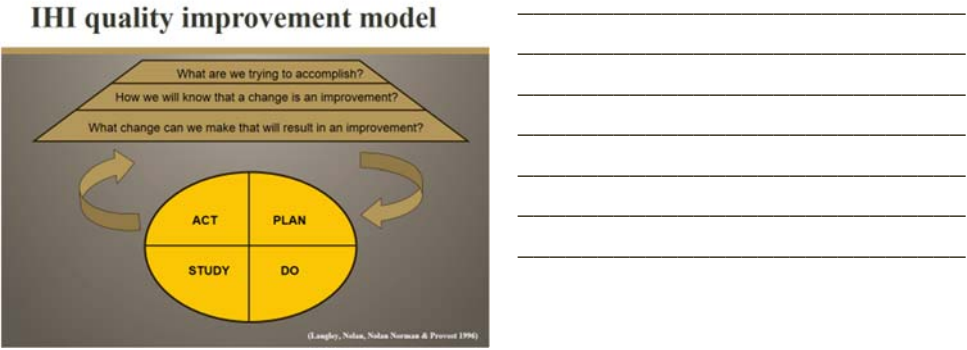
A similar quality improvement method to the CPI methods described above is promoted by the Institute of Healthcare Improvement (IHI); it is also developed from Deming's methods in this case by the Associates in Process Improvement. The IHI version of quality improvement is distinct in at least one key attribute. It seeks to accelerate improvement using three anchor questions in addition to the PDSA cycle. The three overarching questions are followed by use of the PDSA cycle, which in turn feeds back into the questions, creating a cyclic process of continual improvement. Hundreds of healthcare organizations have successfully used the model to improve healthcare processes and outcomes. (See also 'Breakthrough Series' below).

Three anchor questions

The model starts by asking the three questions listed below:

1. What are we trying to accomplish?
2. How will we know that a change is an improvement?
3. What changes can we make that will result in an improvement?

The questions can be asked and answered in any order. This model takes the simple concept of "trial and error" and transforms it into the PDSA model, which can then be used to make improvements, irrespective of the size of the problem.

The idea behind the question 'What are we trying to accomplish?' is to provide an aim for guiding and focusing the efforts of the improvement team. The problem selected for improvement should have some supporting evidence (qualitative or quantitative) that it is in fact a problem. It is not a good idea to put a lot of effort into something that only one person thinks is a problem. This is where organization, state or disease specific data are useful, particularly for benchmarking. The use of data, at this stage, is important because it allows the team to focus on the right area. There may be no perfect answer or complete data to help them, but neither does it matter. The simple rule is to keep the answer short and concise.

Measures are required to answer the second question 'How will we know that a change is an improvement?' If a change was made, but the measures indicated no improvement, than an improvement cannot be said to have been made. If a change is made and the right measures show improvement over time, than an improvement can be said to have been made.

The last question 'What changes can we make that will result in an improvement?' involves testing a range of interventions or strategies to learn about the different alternatives to achieving improvement.

Testing a change requires details about who will do what, when and where. The PDSA cycle, as previously described, is the method used in this model for testing a range of ways to see if they work.

The Breakthrough Series

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The Institute for Healthcare Improvement developed the Breakthrough Series to help healthcare organizations make "breakthrough" improvements in quality while reducing costs, disseminating improvement and changing norms of healthcare. The series was designed to help multiple organizations collaborate, creating a structure in which they can learn from each other and from recognized experts in topic areas where they want to make improvements. This collaborative approach allows for changes to be implemented on a scale much broader than an isolated institution.

Two of IHI's founding physicians, Don Berwick and Paul Batalden, developed the series with the belief that low quality healthcare derives in large part from the under-use of already existing scientific evidence, making "unscientific care" an enormous problem (the IHI estimates that half of all medical care could be classified as unscientific). From their perspective, a large factor in causing these problems has been the lack of both information sharing and standardization amongst the large array of healthcare institutions. The goal of the Breakthrough Series then, is to bring these institutions together and create a community where these problems are addressed using proven scientific improvement methods.

The Breakthrough Series method proceeds in two ways. The initial step is to isolate and bring focus to specific issues that are particularly in need of improvement. Once problem areas are pinpointed, institutions are brought together into a Collaborative so as to create a sustained focus on the issue. As noted however, the idea is not simply to raise awareness, but to make changes that will create sustained and lasting improvement.

The Breakthrough series does this by using improvement methods discussed in the previous section. However, instead of a team within one institution deciding on a problem and then moving forward, the problem is identified from the outset, with teams from many institutions subsequently brought together to tackle it.

For example, the first breakthrough series, chaired by Bruce Flamm, MD, brought together 28 institutions, with a 12 month goal of reducing caesarean section rates by 30 percent. The second series, or Collaborative as they are normally called, was chaired by Tom Nolan, PhD and set a 12 month goal of reducing hospital wait times by 50 percent.

These goals are not met 100% of the time, but the IHI is encouraged by the progress that has been made so far. In the case of the caesarean section Collaborative, "15% of the organization reduced their caesarean section rates by 25% or more, and 50% of the organizations achieved reductions of 10% to 25%." In the second Collaborative, which sought to reduce wait times, IHI noted that one hospital in Pennsylvania was able to reduce wait times from 55 minutes to 25, and that MetroHealth in Indiana was able to begin offering appointments within seven days 100% of the time, up from 42%. The IHI report *The Breakthrough Series: IHI's Collaborative Model for Achieving Breakthrough Improvement* gives a number of other examples of successful Collaboratives.

Since 1995, IHI has sponsored over 50 collaborative projects on several dozen topics involving over 2,000 teams from 1,000 different healthcare organizations. The Collaboratives range in size from 12-160 organizational teams. Each team typically sends three of its members to attend Learning Sessions (three face-to-face meetings over the course of the Collaborative), with additional members working on improvements in the local organization. Dramatic results have been achieved by participating teams, including reducing waiting times by 50%, worker absenteeism by 25%, ICU costs by 25%, and hospitalizations for patients with congestive heart failure by 50%.

Overall structure

The bulk of the work during a Breakthrough Series Collaborative takes place within two central stages of the process: the Learning Sessions and Action Periods. However, there are six other stages in the process which are vitally important as well. The 8 total stages are similar to those used by the CPI method but are worth going over briefly.

Topic selection

As opposed to the CPI method, in which problem areas are decided on after the institution's team has been chosen, the problems/topics are already selected by IHI leaders prior to the formation of project teams.

Faculty recruitment

IHI looks for two categories of faculty in this stage: subject matter experts and application experts. Between five and fifteen faculty are chosen for each project, one of whom is chosen to chair each Collaborative. The chair devotes one to two days per week for as long as the Collaborative is active.

Enrollment

There is basic application process which each institution must go through. IHI states that they traditionally accept "all applicants who agree to commit to these expectations." Senior leaders must play an important role in guiding the project for their particular institution. There is some amount of prework done during this stage, as it directly precedes the active participation of the learning session stage. IHI has increased the prework load in recent years.

Learning sessions

The learning session involve all of the participants from each institution coming together and meeting each other. Three of these sessions are typically held during each Collaborative. Teams here are taught the Model for Improvement, described in the previous section on PDSA cycles.

Action periods

The action period is when the teams are testing out changes at their home institutions. They occur in between learning periods. Monthly progress reports must be submitted and communication with other institutions is facilitated.

Documentation/presentation

This stage takes place directly after the Collaborative is complete. Results and mistakes are presented.

Measurement and evaluation

Measurement and evaluation are required throughout the whole Collaborative process.

Clinical research v. rapid cycle improvement

The following chart, adapted from IHI materials, profiles how rapid cycle improvement compares and contrasts with clinical research.

Table 2: Clinical research vs. rapid cycle improvement

	Measurement for clinical research	**Measurement for process improvement**
Purpose	To discover new knowledge	To bring new knowledge into daily practice
Tests	One large "blind" test	Many sequential, observable tests
Biases	Control for as many biases as possible	Stabilize the biases from test to test
Data	Gather as much data as possible, in one large study	Gather "just enough" data to learn and complete another cycle
Duration, resources	Can take long periods of time and large amounts of money to obtain results	"Small tests of significant changes" accelerate the rate of improvement

As helpful as this comparison chart is, it also is important to recognize that many methods are used both in safety improvement and in clinical research; indeed, the distinctions between the two approaches can easily blur. The randomized controlled trial (RCT) has an important place in safety improvement as well as in clinical research and the rapid cycle improvement methods are not intended to replace the randomized controlled trial. They have features in common with approaches used in clinical research aimed at developing and refining an intervention such as beta testing, feasibility testing, and so on. The important point is that in any effort, the method and the measures must be suited to the purpose.

Guidelines & protocols: disseminating and sustaining change

In healthcare, standards at the level of patient care are usually referred to as protocols or guidelines. Many terms are used to describe a medical guideline; protocol, clinical guideline, clinical protocol and clinical practice guideline are all used interchangeably. A guideline is usually a written document designed to guide decisions and criteria in specific areas of healthcare, as defined by a group of experts and a rigorous examination of current evidence. Evidence-based practice (EBP) guidelines are also usually endorsed by a national or international body of established and respected experts and include summarized statements about the latest knowledge and preferred clinical interventions.

This involves an examination of the best evidence and most current data about prevention, diagnosis, prognosis, therapy risk/benefits and cost effectiveness.

EBP is a set of principles and methods intended to ensure that to the greatest extent possible, clinical decisions, guidelines, and other types of policies are based on and consistent with good evidence of effectiveness and benefit. The bed rock of EBP is the use of guidelines. These (EBP and practice guidelines) provide a stronger scientific foundation for clinical work. They aim to achieve consistency, efficiency, effectiveness, quality, and safety in clinical care. With the advances made in electronic health records and associated embedded clinical decision support, there is general ease in the dissemination of guidelines. When adoption is supported by change management methodology, there is greater likelihood of successful changes in practice.

Objectives of guidelines

Slide 50

Objectives of guidelines

- Define the most important question
- Attempts to identify all possible decisions options and their consequences
- Minimize variation

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Principles of good guidelines are that they:

- define the most important questions relating to clinical practice in a particular field;
- attempt to identify all possible decision options and the known consequences of those decisions; and
- identify each decision point followed by the respective courses of action according to the clinical judgment and experience of the health professionals.

An important objective of clinical guidelines is to minimize the variation in the way care is provided. Variation caused by overuse, under use, and misuse of medical care is a major issue facing healthcare. EBP uses the best evidence available to lessen variation and reduce risks to patients.

Health professionals at the local level usually do not have the resources or the available experts to produce their own set of guidelines. Instead they are encouraged to adapt established guidelines and modify them to suit their local environment

Guideline databases

Guideline databases

- Cochrane Library
- RNAO – Nursing Best Practice Guidelines
- AHRQ's National Guideline Clearinghouse
- National Institute for Health and Clinical Excellence (NICE)

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There are many sources available for safe and effective guidelines including:

- The Cochrane Library, which is a collection of six databases containing high-quality, independent evidence to inform healthcare decision-making, and a seventh database that provides information about Cochrane groups. The site provides free access and can be found at the following web page: http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME.
- The Registered Nurses Association of Ontario's Nursing Best Practice Guidelines found at http://www.rnao.org/Page.asp?PageID=861&SiteNodeID=133;
- AHRQ's National Guideline Clearinghouse - a public resource for summaries of evidence-based clinical practice guidelines found at http://www.guideline.gov/; and
- The National Institute for Health and Care Excellence (NICE) provides guidance in many forms including guidelines (clinical, social care, public health, medicines practice), technology appraisals, interventional procedures, medical technologies, diagnostics and highly specialised technologies. The site can be accessed on the following web page: http://www.nice.org.uk/aboutNICE.

Introducing a new guideline

Guideline introduction

- Everyone informed about necessity for guideline
- Guideline must be credible, accessible and adaptable
- Case for change must be made
- Guidelines must be endorsed
- Review to incorporate new knowledge/evidence

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Given that guidelines and protocols today are recognized as the main instruments for best practise in healthcare, it is crucial that they are accessible and have been adapted to the work place where they are to be used. This means that those who are required to use the protocol must understand it and see its relevance. It may be that some of the steps are inappropriate for a particular site or because the personnel are not available. In these cases the organization or the healthcare team needs to make an adjustment to ensure that when the guidelines are implemented that everyone knows and can apply them. If people get used to skipping steps and avoiding particular areas they will not be vigilant in applying them. Ownership of a protocol is important. Commitment of the whole team is necessary for successful implementation of guidelines or protocols.

There are a few important steps that must be taken when introducing a new protocol or guideline:

- everyone on the team needs to understand why the guideline is important and the problems associated with the old ways of providing care;
- the proposed guideline must be credible and supported by the evidence-based literature;
- a compelling case must be put forward for change by a respected member of the healthcare team or organization;
- the guidelines must also be endorsed by other health professionals working in the same area; and
- the guideline must be reviewed in a timely way so that new knowledge and evidence can be evaluated and incorporated if appropriate.

Getting everyone to adopt a new guideline can be difficult because different professional groups have their own way of practicing. Some team members may think their autonomy is being compromised and questioned when requested to work differently and apply treatment prescribed within a guideline. They feel their clinical discretion is being removed with a team approach. They are not used to sharing knowledge and information with others in the team however this is absolutely necessary for continuity of care and achieving the best outcomes for the patients.

Encouraging others to participate

Encouraging participation

Many techniques available to assist with change including:

· targeted education programs
· using trend data to highlight improvements
· incorporating guidelines into credentialing/accreditation requirements

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A range of techniques exist to encourage health professionals to change their practice when introducing new guidelines. This is best achieved using a range of methods:

- offer rewards and punishment with the carrot and stick approach;
- specially designed education programs that use explicit images and pictures to convey the learning messages;
- identify providers and teams and report their progress using trend data;
- professionals who are resistant to change can be individually counseled about the benefits by senior leaders;
- respected and trusted professionals can provide their reasons for adopting the new guidelines (academic detailing is when a senior and respected clinician describes the problems, identifies the research and puts a case for the protocol implementation);
- the new guidelines can be incorporated into credentialing/accreditation requirements;
- track and publicize the outcomes of treatment using the guidelines and treatment not using the guidelines; and
- state the implications for the institution if best practice is not followed, such as public reporting implications, financial implications, or legal implications.

Documentation

Teams are responsible for documentation of all stages of the project from planning through testing, review of progress, implementation of change and all follow-up activities including project closure. This serves as 'the organization's memory of the team's work'.

Organizations depend on the documentation for education and training of staff during the implementation of the change, consistency from one group to another, understanding of a method or process and for developing a common definition of the change.

Documentation may take the form of minutes of meetings, copies of reports, correspondence, and worksheets. This forms the basis for reviewing progress and

achievements, helps the team keep track of developments over time, and provides information to brief new members who may join the team after the project has started. Complete and up-to-date documentation makes it easier to prepare presentations on the work of the team.

Measurement

Measurement of the process ensures that the implemented changes are in fact being carried out, and provides a source of learning during implementation and a method of maintenance after implementation. Measurement provides the basis for continuous review and improvement. Displaying process and outcome measurements in a prominent place will ensure a continuous focus on that process.

Some of the measurements developed and used in the testing and the implementation stages should be considered for permanent use after implementation. Viewing measurements over time allows a clinical team to determine whether it is continuing to achieve the desired results and whether it can expect these results to be achieved in the future. Regular, ongoing review of the measures should also occur to ensure relevancy and utility of the measurements.

Training and education

Some form of training (providing action skills) and education (providing underlying knowledge) is always required to implement a change. New methods or work processes also need to be documented and people trained in the new way of doing things. When considering how much training is required, the team needs to take into account:

- the type of change being proposed;
- who will be asked to implement the change; and
- the skill level and work experience of the target group.

If the desired change is a simple extension of the work currently being performed, a discussion of the change with the clinicians and managers affected may be all the training required. Such training can be done on the job or by reviewing the new standards at a meeting. Learning by doing is usually the method used with this style of training.

If the change is more complex and extensive (e.g., if it involves the use of new technology), formal classroom training may be required to support implementation of the change. Most effective here is interactive workshops or seminars. They may also need to be followed by on-the-job training, coaching or some other form of staff education.

Summary

Slide 54

Summary

- Patient safety introduces methods to bring new knowledge into daily practice

- Need to understand the complex healthcare system and which method and measure to use in which setting to improve care

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Patient safety is a developing field that incorporates many methods in order to generate and measure improvement. By understanding the complex design of the healthcare system, and using quality improvement tools, positive changes can be made and disseminated. Reliable measurement is also important for safety improvement. In order to provide adequate feedback and understanding of the system, methods from the fields of both engineering and traditional healthcare research must be employed. This module explores the importance of system design, change concepts, measurement and continuous improvement methods used to improve and implement change in the healthcare system.

Potential pitfalls

Slide 55

Potential pitfalls

- Try not to find solutions until you understand the problem and the processes
- Avoid forming a team on a traditional professional or hierarchical basis
- Break quality improvement activities down into bite size pieces

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1. Try not to find solutions until you understand the problem and the processes

2. Avoid forming a team on a traditional professional or hierarchical basis

3. Break quality improvement activities down into bite size pieces

Pearls

Slide 56

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1. Improvement comes from the application of knowledge

2. Team engagement and leadership are vital (early and often)

3. Reinforce and support front line team involvement (including nonclinical support services) in improvement activities

4. Suggest an examination of existing programs and consolidation using valid improvement methods

5. An improvement can only be said to be made when it produces measureable improvement

Toolkits & outcome measures

- **Flowchart**: Flowchart Institute for Healthcare Improvement Boston, Massachusetts USA 2004.
  http://www.ihi.org/resources/Pages/Tools/Flowchart.aspx
- Incident Analysis Collaborating Parties. **Canadian Incident Analysis Framework.** Edmonton, AB: Canadian Patient Safety Institute; 2012.
  http://www.patientsafetyinstitute.ca/en/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20Framework.PDF
- **How to Innovate**: How to Innovate AHRQ Healthcare Innovations Exchange. Veteran Affairs Administration. http://www.innovations.ahrq.gov/
- **Improvement Methods**: Improvement Methods Institute for Healthcare Improvement Boston, Massachusetts, USA.
  http://www.ihi.org/IHI/Topics/Improvement/ImprovementMethods/Tools/
- **Use the FMEA Tool**: Use the FMEA Tool Institute for Healthcare Improvement Boston, Massachusetts, USA.
  http://www.ihi.org/ihi/workspace/tools/fmea/CreateTool.aspx
- ARECCI Ethics Screening Tool. Alberta Innovates. (2010). ARECCI Ethics Screening Tool. Retrieved from www.aihealthsolutions.ca/arecci/screening

- **Measurement for Improvement Toolkit**: Measurement for Improvement Toolkit The Australian Commission on Safety and Quality in Health Care 2007 Level 7, 1 Oxford Street, Darlinghurst NSW 2010 GPO Box 5480, Sydney NSW 2001. https://www.safetyandquality.gov.au/wp-content/uploads/2012/01/measurement-for-Improvement-toolkit-a.pdf
- **Ask "Why" Five Times to Get to the Root Cause**: Ask "Why" Five Times to Get to the Root Cause Institute for Healthcare Improvement Boston, Massachusetts, USA. http://www.ihi.org/resources/Pages/ImprovementStories/AskWhyFiveTimestoGettotheRootCause.aspx
- **Systems Analysis of Clinical Incidents: the London Protocol**: Systems Analysis of Clinical Incidents: the London Protocol Sally Taylor-Adams, Charles Vincent Clinical Safety Research Unit Imperial College London Department of Surgical Oncology and Technology 10th Floor QEQM Building St Mary's Hospital Praed Street London W2 1NY. https://www1.imperial.ac.uk/resources/C85B6574-7E28-4BE6-BE61-E94C3F6243CE/londonprotocol_e.pdf
- **SWIFT**: Card AJ, Ward JR, Clarkson PJ. Beyond FMEA: the structured what-if technique (SWIFT). *J Healthc Risk Manag*. 2012;31(4):23-9. Review. PubMed PMID: 22528401. http://onlinelibrary.wiley.com/doi/10.1002/jhrm.20101/epdf.
- **VA National Center for Patient Safety** *The Basics of Healthcare Failure Mode and Effect Analysis* May 2014 https://www.patientsafety.va.gov/professionals/onthejob/hfmea.asp

Resources

- **Morbidity and Mortality Rounds on the Web**: Morbidity and Mortality Rounds on the Web Agency for Healthcare Research and Quality 540 Gaither Road Rockville, MD 20850. https://www.ahrq.gov/cpi/about/otherwebsites/webmm.ahrq.gov/index.html
- **Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices.** Comparative Effectiveness Review No. 211. (Prepared by the Southern California-RAND Evidence-based Practice Center under Contract No. 290-2007-10062-I.) AHRQ Publication No. 13-E001-EF. Rockville, MD: Agency for Healthcare Research and Quality. March 2013. www.ahrq.gov/research/findings/evidence-based-reports/ptsafetyuptp.html.
- **Safety and Ethics in Health Care: A Guide to Getting it Right**: Runciman B Merry A Walton M Safety and Ethics in Health Care: A Guide to Getting it Right Ashgate publishers 2007.
- **The New Economics for Industry, Government, Education Institute for Healthcare Improvement**: Deming WE The New Economics for Industry,

Government, Education (2nd ed.) Cambridge, Massachusetts, USA: The MIT Press; 2000. http://www.ihi.org/resources/Pages/Publications/NewEconomicsforIndustryGovernmentEducation.aspx

- **VA National Center for Patient Safety**: *NCPS National Patient Safety Improvement Handbook*, March, 2011. https://www.patientsafety.va.gov/professionals/publications/handbook.asp
- **Health Care Improvement Skills Center**: Health Care Improvement Skills Center Academy of Post Graduate Medical Care Education University of Missouri, Columbia Case Western Reserve University Division of Information Technology Services. http://www.improvementskills.org/
- **Executing for System-Level Results**: Executing for System-Level Results: Part 1 by Tom Nolan, IHI Senior Fellow Institute for Healthcare Improvement Boston, Massachusetts USA. http://www.ihi.org/resources/Pages/ImprovementStories/ExecutingforSystemLevelResultsPart1.aspx
- **FAA website:** http://www.faa.gov/
- **ISMP Canada tools and resources.** http://www.ismp-canada.org/fmea.htm
- **Health Quality Ontario tools and resources.** http://www.hqontario.ca/Quality-Improvement
- **BC Patient Safety & Quality Council tools and resources.** https://bcpsqc.ca/
- **Saskatchewan Health Quality Council tools and resources.** http://hqc.sk.ca/improve-health-care-quality/
- **Health Quality Council of Alberta tools and resources.** http://hqca.ca/health-care-provider-resources/

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Nolan TW, Schall MW. *Reducing Delays and Waiting Times Throughout the Healthcare System*. Boston, MA: Institute for Healthcare Improvement; 1996.

New South Wales Health Department. *Easy Guide to Clinical Practice Improvement: a Guide for Health Care Professionals*. Sydney: New South Wales Health Department; 2002.

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VA National Center for Patient Safety. *Root Cause Analysis Tools* Washington, DC: REV. October 2016. https://www.patientsafety.va.gov/professionals/onthejob/rca.asp

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Wallace LM. From root causes to safer systems: international comparisons of nationally sponsored healthcare staff training programmes. *Qual Saf Health Care*. 2006 Dec;15(6):388-9. PubMed PMID: 17142583; PubMed Central PMCID: PMC2464902.

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World Health Organization**:** *The Multi-professional Patient Safety Curriculum Guide*. World Health Organization, 2011. Accessed August 2017. http://apps.who.int/iris/bitstream/10665/44641/1/9789241501958_eng.pdf

Principal message

This module looks at the role of measurement and quality improvement in patient safety, and how to use rigorous methods in designing an improvement, implementing it and bringing about and measuring the changes.

Module overview

The module is divided into two parts. Part 1 discusses how healthcare prior to the emergence of patient safety concerns relied on traditional methods of clinical and health services research to generate improvement. However, rigorous methods developed in engineering and long since applied with positive effect to other high reliability industries are now also being incorporated into healthcare. In part 2, three examples of improvement methods are highlight including Root Cause Analysis (RCA), Failure Modes Effect Analysis (FMEA) and Clinical Practice Improvement Methodology (CPI).

Preparing for a presentation

1. Assess the needs of your audience

Choose from the material provided in the module according to the needs of your expected participants. It is better for participants to come away with a few new pieces of information, well learned, than to come away with a deluge of information from which they can remember little or nothing.

2. Presentation timing

The suggested timing for a section of this module is:

Introduction	2-3 minutes
Trigger tape & discussion	5-7 minutes
Presentation	30 minutes
Debrief about teaching methods	5 minutes
Summary	2-3 minutes
Total	45 minutes

3. Number of slides: 56

4. Preparing your presentation

The text in the module was not designed to be used as a prepared speech. Instead, the text provides material you may want to use. The slides have been designed to trigger your presentation. Although the slides closely follow the text of the module, they do not contain all of the content. Their use presumes that you have mastered the content.

You may want to make notes on the slide summary pages to help you prepare your talk in more detail and provide you with notes to follow during your presentation.

Remember that you can adjust the slides to suit your presentation content, your style, and to make it feel fully familiar and your own.

Practice your presentation using the slides you have chosen, and speaking to yourself in the kind of language you expect to use, until it is smooth and interesting and takes the right amount of time. The most accomplished presenters and teachers still practice prior to a presentation; don't miss this step.

5. Preparing a handout for participants

The module text and slides were designed to be reproduced and provided to participants as a handout. Take the portion you need; they can be used in their entirety, module by module, or for just one specific topic. Please ensure to acknowledge the source of the material, the PSEP – Canada Acknowledgment Page at the front of the module provides the formal citation.

6. Equipment needs

- Screen, computer and projector
- Flipchart and markers for recording discussion points

Test your equipment beforehand to ensure that it works.

Review your video to assess which portions you would like to use.

Have a back-up plan so that if there is any equipment failure you can move without panic to your back-up plan. For instance, have in mind that:

- if the video fails, you can read the vignette of the trigger tape story;
- if the slides cannot be shown, you can refer to the hand out slides; and
- if flipcharts and markers are not available, you can have participants list items on their hand outs that you would have written up for all to see.

Making the presentation

1. Introduce yourself

If you have not already done so, introduce yourself. Include your name, title, and the organization(s) you work for. Briefly describe your professional experience related to the information you will be presenting.

2. Introduce the topic

Show the title slide for the module. To establish the context for the session, make a few broad statements about the importance of topic as a patient safety matter. Tell participants the format and time you will take to present the session. Identify the teaching styles that you intend to use.

3. Review the session objectives

Show the slide with the session objectives listed. Read each objective and indicate those that you are planning to emphasize.

4. Show the trigger tape

After reviewing the objectives for the session, show a trigger tape. The trigger tape should engage the audience and provide appropriate context for the session. The trigger tape does not need to demonstrate an ideal interaction, but to "trigger" discussion.

Trigger tape content

The trigger tape for this module shows a team of 3 people performing a root cause analysis (RCA) for a medication error. The RCA reveals systems breakdowns at multiple levels of care. As a result, the team identifies areas to target for improvement.

Keep in mind that the facilitator may choose to use any one of a number of trigger tapes. Since the vignettes are rich and overlap in their teaching points, it may make sense to do this, for instance if an audience has seen the trigger tape already or if a trigger tape from another module is easier for the audience to identify with.

A teachable moment: discussion after the trigger tape

After the trigger tape, ask the participants for their comments about the issues and the interaction they have just seen. To affirm what they contribute, consider recording the important points on a flipchart or white board.

If the discussion is slow to start, you may want to ask more direct questions, like:

- What does this type of discussion achieve?

- Have any of you participated in a similar process and what were some benefits and challenges?
- What skills do you think team members would require to carry out this process?

Use the discussion to set the stage for the material to follow. Do not let the discussion focus on a critique of the technical quality of the video or how "real" the players seemed. If the participants do not like something that was said or done in the video, acknowledge that there is always room for improvement and ask them how they would do it themselves.

Setting limits to discussion time

It is usually best to limit discussion of the video to no more than five minutes, then move on to the presentation. To help move on if the discussion is very engaged, try saying something like:

- let's hear two last points before we move on, and
- now that you have raised many of the tough questions, let's see how many practical answers we can find.

For the more advanced facilitator who is very confident of both the patient safety material and his or her pedagogic skills, it is possible to use the trigger tape as a form of case-based teaching and to facilitate the discussion to draw out the teaching points of the module. The hazard of this approach is that the discussion will not yield the desired teaching points. Feel free to return to the slides if this happens. If this approach is used, it is essential to write up the points on a flip chart as they arise, to fill in any gaps and to summarize at the end. Again, use this method with caution and only if you are really ready.

5. Present the material

Recommended style: Interactive teaching

An interactive lecture will permit you to engage your audience, yet cover your chosen material within the time.

Ask the participants about their major concerns regarding Methods for Improving Safety and to give you a case from their institution or experience. Once you find a case that resonates with the group, you may choose a focus. Have a backup case from your own experience in case you there are reasons to not go into the ones from the audience. Choose the focus so that you can deliver specific content you have prepared.

Interactive exercise

Divide into groups of three to four participants. Tell participants (count off) that they are the chief executive officer (CEO), chief medical officer (CMO), or quality improvement officer (QIO). Working in groups, they will assemble a Leadership team and a Project

team and identify transient members and how they would be tasked. Select one to three members of the Leadership team, and three to eight members of the Project team. This should take approximately ten minutes.

Have one representative from each group display teams on flip charts. Invite discussion on the following topics:

- Who would change what, how?
- What are the realistic barriers?
- Run through the phases of CPI – is an adequate skill available for each?

The goal of this exercise is to create a competent, nimble and effective team that can work together across disciplinary boundaries to get the job done.

Situation Description

Described below - collective hospital data indicate below target reductions in rate of MRSA. We are the Worcester site.

The Trust has now received formal feedback on the UK Department of Health MRSA/Cleaner Hospitals Support Unit visit on 27th March 2007.

The summary and further actions recommended are as follows:

> 'The MRSA Improvement team would like to thank the […] for arranging the round table review meeting which took place at […] on the […] 2007.

- ➢ Your 06/07 trajectory was 22; you experienced 40 MRSA bacteraemias.
- ➢ Your 07/08 target is just 12 bacteraemias, so your challenge is great.
- ➢ Your data shows that 74% of your bacteraemias occur after 48 hours.
- ➢ Your hot spot areas are Medicine and General Surgery.
- ➢ Your own data analysis shows that 49% of bacteraemias are occurring within Medicine at the Worcester site.
- ➢ An analysis of pre-48 hour bacteraemias demonstrates that 58% were readmissions.

Taken from web published UK Infection Control Report – 7 June 2007

Materials

- 2 flip charts
- Easy Guide to Clinical Practice Improvement (NSW Health)
- Possible members of the Leadership or Project teams; one list / card set per group:
  - o Epidemiologist from affiliated medical school's department of public health (PhD)
  - o Hospital infection control officer who has an MBA and an MPH
  - o Charge nurse from Medicine

- Charge nurse from Surgery
- Charge nurse from Emergency Ward
- Floor manager from Medicine
- Floor manager from Surgery
- College graduate with major in [insert]
- Nurse's aide
- Pharmacist
- Head of bacteriology lab
- Design engineer from University Dept of Industrial Engineering
- Patient
- Family member
- MSW with discharge responsibilities
- Case manager
- Rehab nurse
- Facilities maintenance assistant manager
- [Write your own]
- [Write your own]

6. Key take-home points

1. Improvement comes from the application of knowledge.
2. Team (including front line, nonclinical support services and leadership) engagement is vital.
3. Reinforce and support front line team involvement in improvement activities.
4. Suggest an examination of existing programs and consolidation using valid improvement methods.
5. An improvement can only be said to be made when it produces measurable improvement.
6. Try not to find solutions until you understand the problem and the processes.
7. Avoid forming a team on a traditional professional or hierarchical basis.
8. Break quality improvement activities down into bite size pieces.

7. Summarize the discussion

Briefly, review each part of the presentation. Recap two or three of the most important points that were discussed.