IMPROVEMENT FRAMEWORKS

Getting Started Kit

safer healthcare
now!

Safer Healthcare Now!

We invite you to join *Safer Healthcare Now!* to help improve the safety of the Canadian healthcare system. *Safer Healthcare Now!* is a national program supporting Canadian healthcare organizations to improve safety through the use of quality improvement methods and the integration of evidence in practice.

To learn more about this intervention, to find out how to join *Safer Healthcare Now!* and to gain access to additional resources, contacts, and tools, visit our website at www.saferhealthcarenow.ca

This Getting Started Kit (GSK) has been written to help engage your interprofessional/ interdisciplinary teams in a dynamic approach for improving quality and safety while providing a basis for getting started. The Getting Started Kit represents the most current evidence, knowledge and practice, as of the date of publication and includes what has been learned since the first kits were released in 2005. We remain open to working consultatively on updating the content, as more evidence emerges, as together we make healthcare safer in Canada.

Note:

The *Safer Healthcare Now!* Getting Started Kits for all interventions are available in both French and English*.*

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Introduction

The following is intended to serve as a common document appended to the *Safer Healthcare Now!* Getting Started Kits. The goal is to help provide a consistent way for teams and individuals to approach the challenge of making changes that result in improvements.

It is hoped that this appendix will serve as a useful resource for improvement teams and improvement advisors alike. However, as with any approach that relies solely on information transfer, it is unlikely to result in improvement on its own. Experience suggests that the ability of a team, for example, to demonstrate the effective use of a new tool and to apply it in a new situation is low as described in the table below. Despite these limitations, this appendix can be a beneficial part of a system for improvement delivered by *Safer Healthcare Now!*

Table: Effectiveness of Various Training Modes

Training Mode	Understanding of Material (Knowledge)	Ability to Demonstrate New Tools and Concepts (Skill)	Ability to Apply to New Situations (Application)
Lecture / Information Transfer	90%	10%	0%
Demonstration / Modelling	100%	30%	0%
Practice / Exercises	100%	70%	20%
Exercises in Application Area	100%	90%	50%
Coaching / Review / Reinforcement	100%	100%	80%

Source: Quality as a Business Strategy – Associates in Process Improvement, 1999 page 10-11, Based on work by Dr. B. Joyce, Dr. B. Showers, University of Oregon 1982[1]

Definition of improvement

Improvement: to make better

Improvement comes from the application of knowledge. It also comes from action, from developing, testing and implementing changes which alter how work or activity is done, or alters the makeup of a product or service. Improvement should produce visible, positive differences in results relative to historical norms and have a lasting impact.[2]

Overview of Improvement frameworks

The idea of a structured framework for improvement provides for consistency, common thinking and language across organizations. The primary framework followed in the *Safer Healthcare Now!* interventions is the Model for Improvement developed by Associates in Process Improvement.[3]   Organizations and teams have also relied on other frameworks to assist in their improvement efforts. A number of the most common frameworks will be addressed in this section.

It is important to identify which type of problem is being addressed before selecting an approach for improvement. Problems may be characterised as either **Enumerative** or **Analytic** in nature. The methods to address either type of problem are different.

The enumerative study is concerned with describing and judging results and is properly limited to these purposes. The analytic study is concerned with the cause system producing the results and is, therefore, a prerequisite for rational improvement action. **Enumerative** studies address questions of "how many?" whereas **Analytic** studies are concerned with "Why?" are there so many (or so few).[4] The first is where action will be taken on the things counted, like enumerating voters to confirm they meet the criteria to vote in an election. The latter is where action will be taken on the causal system to influence future outcomes, like changing the triage system in an emergency department in order to improve flow for the benefit of future patients.

The important distinction between Enumerative and Analytic problems is vital to all who wish to use data properly and make lasting improvements.[5] See (**Appendix A – Enumerative and Analytic Studies – page 60**) for a more complete description.

> "All models are wrong, some are useful."[6]
>
> *George E.P. Box*

"The innovation journey is a nonlinear cycle of divergent and convergent activities that may repeat over time."

- Associates in Process Improvement

A. The Model for Improvement: An Overview

The Model for Improvement is designed to assist the innovation journey and to accelerate the pace of improvement in complex systems. This section provides an overview of the Model.

Extensive learning from improvement efforts has shown that making system improvements requires the **will** to do what it takes, **ideas** on which to base the new design and **execution** to make change happen. The Model for Improvement is a simple and powerful method for improving the performance of the healthcare system. The model provides a framework for developing, testing and implementing changes that lead to improvement. It has its basis in the scientific method, and balances the desire to take immediate action with the wisdom of careful study.[2]

Experience with the model shows that it has been useful in: [2]

- Facilitating the use of teams to make improvements,

- Providing a framework for the application of effective measurement and use of other improvement tools,

- Encouraging plans to be based on evidence-based theories,

- Emphasizing and encouraging continuous learning,

- Providing a way to empower people to take action,

- Continuing to create the will for improvement.

Figure 1: Model for Improvement

The model consists of two parts: a set of three questions and a cycle for learning and improvement.

Three fundamental questions, which can be addressed in any order, guide the improvement effort. These questions help to provide direction, focus and context for the improvement.
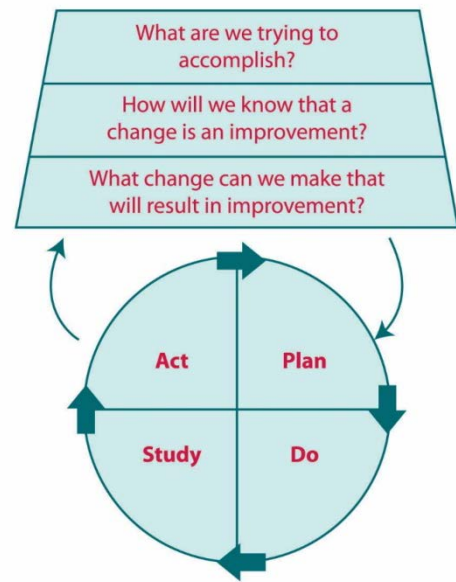
The three questions are:

1. What are we trying to accomplish?

2. How will we know a change is an improvement?

3. What changes can we make that will result in improvement?

An Improvement Charter (see Appendix C - page 73) can be used to answer these questions and is a reference document for the team, a contract with the sponsor and a document that monitors team progress.

The PDSA Cycle (Plan-Do-Study-Act) is a method to turn planning into action and to connect action to learning. It is used to develop, test and implement proposed changes in real time and in real work settings. This is a "trial and learn" approach to improvement based on the scientific method. PDSA Cycle worksheet (see Appendix B - page 66) can help teams design and document their cycles. The PDSA Cycle provides a minimum level of structure, but to use it effectively takes discipline, effort and practice.

The Model for Improvement was developed by Associates in Process Improvement and is fully described in Langley, G, Nolan, K., Nolan T., Norman C., and Provost L. The Improvement Guide: A Practical Approach to Enhancing Organizational Performance (Second Edition). San Francisco, CA. Jossey-Bass Publishers. 2009.

It is often more useful to run smaller cycles quickly, rather than larger cycles more slowly. In this method, knowledge is built on an iterative process of developing a theory, making a prediction based on the theory, testing the predictions in the local environment, analyzing the outcome and improving the theory based on results. This strategy can help teams learn faster and build knowledge sequentially. Through testing, teams learn what ideas work, under what conditions, and why. The strategy in testing is to try out many conditions; including those which are thought will apply in the future. As a result, each cycle provides a basis for further improvement.

Figure 2: Building Knowledge Sequentially[2]
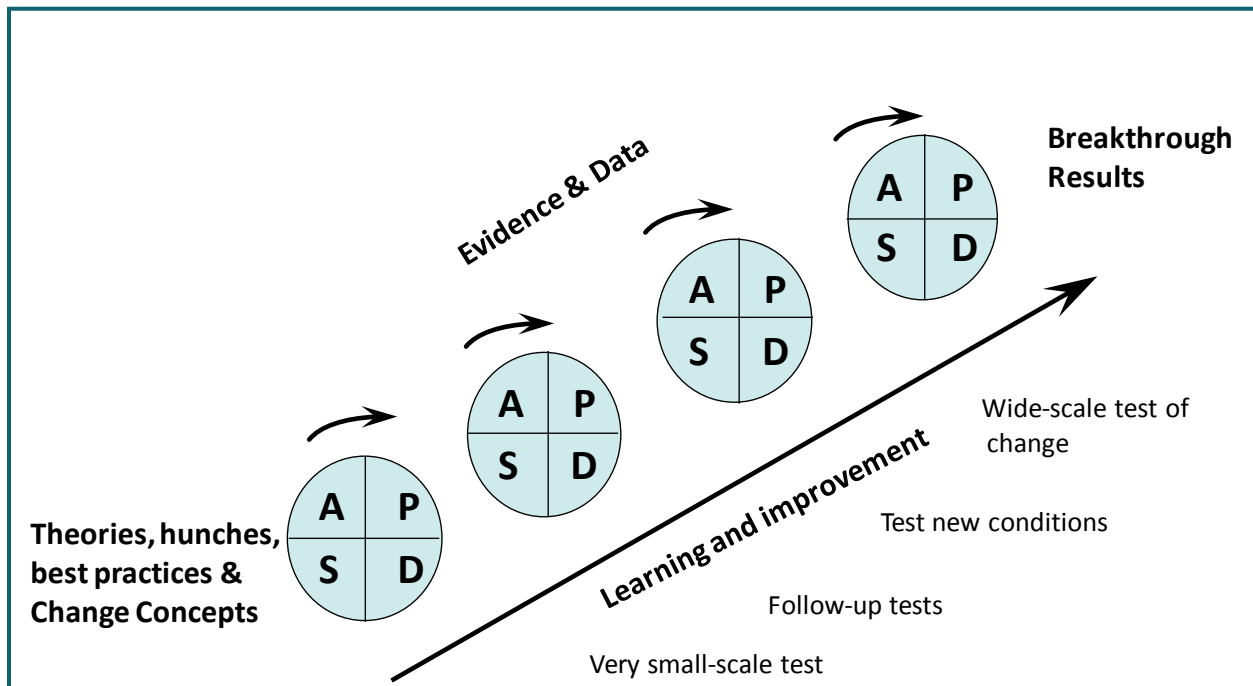
Even if it is counter-intuitive, this approach to change is often effective in large, complex system redesign. Detailed analysis, grand designs and plans for "roll out" are unlikely to uncover all the risks and uncertainties inherent in a rapidly changing environment. Trying to perfect a change without testing in the actual environment is not an effective way to make robust and lasting improvements.

Improvement Science and Other Approaches

The science of improvement uses different methods than those used in traditional research or in accountability frameworks. Each has different goals, different philosophies about the nature of knowledge and therefore requires different methods. Selecting one approach instead of another depends on the goal desired. Because the aim of research is new knowledge, studies are usually designed to isolate causes and avoid risk and technical difficulties caused by complex social situations.

The aim of accountability is generally for comparisons to spur change and relies on historical descriptions. Improvement science is aimed at gaining and applying knowledge to change outcomes in the future. Differences between research, accountability and improvement science are highlighted in the following table.

	Research	Accountability	Improvement Science
<u>Aim:</u>	New healthcare knowledge	Comparison, judgments, springboard for change, promote public choice, reassurance and education	Improvement in care, practice and healthcare delivery
<u>Methods:</u> Test Observability	Blinded tests	No testing, evaluate current performance	Observable tests to build the will to change
Bias	Eliminate bias	Measure and adjust to reduce bias	Accept stable and consistent bias over time
Sample Size	Collect large amounts of data "just in case"	Obtain 100% of available information	"Just enough" data, small sequential samples
Flexibility of Hypothesis	Fixed a priori hypothesis	No hypothesis	Hypothesis flexible, changes as learning takes place
Testing Strategy	One large study	No tests	Many sequential tests
Determining if change is improvement	Hypothesis tests (T-tests, F-tests, Chi-square), p-value	No change focus	Run charts or Shewhart charts
Confidentiality of Data	Research subjects are protected	Results communicated to public and other stakeholders	Data used by those involved in the improvement effort

Source: Based on the table Data for Improvement, Accountability and Research - Lloyd Provost, Associates in Process Improvement and Sandra Murray, Corporate Transformation Concepts – *The Data Guide*, pg. 2-3, 2007

Each approach has a key role to play in improving healthcare. Combining rigorous scientific research and accountability frameworks with improvement science can result in effective knowledge transfer from research to practice and continuous, sustainable improvement in complex systems. A caution is that it is rarely satisfactory to use data which have been collected for one purpose for a different purpose.[7]

Within Improvement Science, using the Model for Improvement as a framework for the *Safer Healthcare Now!* interventions can help teams make improvements in processes and outcomes of complex systems. As an added benefit, teams often enjoy renewed enthusiasm in providing care to patients and increased pride in the work they do.

B. The Model for Improvement: Detailed Application

Any team wanting to make lasting improvements in their organization, department or process can use the Model for Improvement. This section provides detailed guidance on how to apply the model and includes examples from improvement teams.
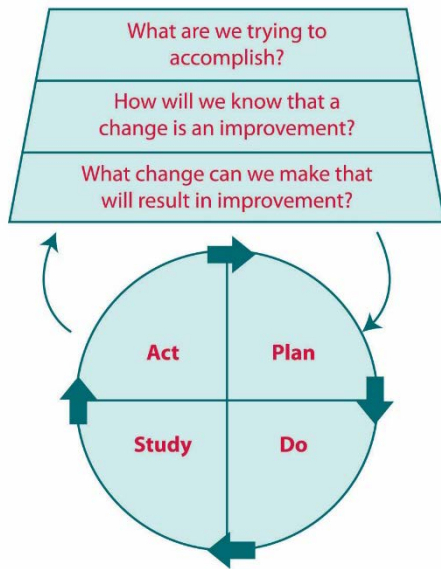
Setting Aims: What are we trying to accomplish?

Improvement starts with agreement on a clearly understood aim. The more specific the aim, the better the chance the team will be successful. It is also helpful to include the project's context, boundaries, and scope.

Useful aims are often bold, comprehensive, and meaningful. Numerical goals that raise the bar of healthcare performance can be an effective way to communicate expectations, level of support needed, and scale of change required. For example, the approach to a 10 per cent improvement is very different from the approach required with a 50 per cent improvement goal. It is also helpful to include timelines on when those goals can be achieved.

By setting a challenging goal as the aim, the team immediately recognizes that the "status quo" is not an option. However, if the goal has no sound basis in research, evidence of empirical examples, or explicit method for achieving the desired result, it may actually hinder team effectiveness. An Improvement Charter can help teams document and communicate their aims. The aim should be a clear, concise statement. It should include a target and deadline; and define the scope, boundaries and constraints for the initiative.[2]

"We have to be bolder than we've been. We will never get there if timidity guides action. Marginal aims can be achieved with marginal change. But bold aims … require bold change."[8]

- Donald M. Berwick, MD, MPP, former President and CEO
Institute for Healthcare Improvement

Examples

Below are effective aim statements, goals and timelines from teams.[9]

Winnipeg Health Region	Decrease ventilator associated pneumonia rate at Winnipeg Health Sciences Centre, surgical and medical ICU's by 50 per cent by improving implementation of preventative strategies for VAP within one year. Attain 90 per cent compliance with preventative strategies within one year.
Jewish General Hospital (Montreal)	Reduce pneumonia rate in the ICU by 50 per cent by April 2006 and ensure 90 per cent compliance to prevention strategies while avoiding any increase in pressure ulcers developing in the ICU.
IWK Health Centre (Halifax)	To reduce the incidence of central venous access line (CVAL) sepsis in the PICU by 20 per cent in one year.
St. Joseph's Health Centre (Toronto)	To decrease incidence of central line bloodstream infections by 50 per cent in 12 months and increase compliance to the bundle to 100 per cent within three months.

Forming Teams

One important success factor for a team is its commitment to work together toward a shared aim. Review the aim and scope of the initiative to determine what areas of the system and disciplines should participate. Ensure that team members can meet frequently, and work efficiently and effectively to institute change.

Three different types of expertise are required:

- day-to-day leadership
- technical expertise
- system leadership

There may be one or more individuals who represent these areas or one individual may represent more than one type of expertise.

Day-to-Day Leadership

The team needs front-line people who work in the process on a daily basis and who will understand the effects of the planned changes. These people have the desire and ability to drive the project to its aim. Day-to-day leadership includes a team leader who provides an understanding of expectations and scope, and leads activities to accomplish the desired results.

Technical Expertise

The team needs a subject-matter expert who understands the targeted topic and process of care. Additional support may be provided in using the Model for Improvement, designing and testing changes, facilitating meetings, collecting and interpreting data, and preparing presentations.

System Leadership

The team needs a sponsor with enough influence within the organization to implement and sustain the changes. The sponsor must be able to support the team with time and resources to achieve the aim and remove any barriers to success. Executive leadership, which may include being in the role of sponsor, is another key ingredient in successful improvement projects. Successful projects can be "key leverage points—high visibility moments—in the long-term transformation process."[10]

Better understanding senior leadership project reviews can be helpful. Reinertsen, Pugh and Nolan provide guidance in their paper "Executive Review of Improvement Projects: A Primer for CEOs and other Senior Leaders".[10]

They suggest "the purpose of a senior leader review is:

1. To learn whether the project is on track, or is likely to fail

2. If the project is not achieving the intended results, to understand why:

    a. Lack of organizational **will**?

    b. Absence of strong enough **ideas** for improvement?

    c. Failure to **execute** changes?

3. To provide guidance, support, and stimulus to the project team on will, ideas, and execution

4. To decide whether the project should be stopped."[10]

Detail on actions for each of the above activities is available in the paper.

Membership on most teams includes an administrator, a physician, a nurse and allied health professionals who work on the process of care under consideration (e.g. respiratory therapists, laboratory personnel). The size of effective teams usually ranges from three to eight members. Others may participate as extended or ad hoc team members by providing input into plans and participating in tests of change.

The Improvement Charter can also be used to help teams to document membership, roles and responsibilities, and principles for working together. This document may help provide a base for communication within the team and to sponsors and other stake-holders. The Charter may prevent problems down the road.

Examples

Below are some examples of effective team membership.[9]

Team	Day-to-Day Leadership	Technical Expertise	System Leadership
Falls Collaborative Team (Long Term Care)	Registered Nurse Registered Practical Nurse Personal Support Worker Physiotherapist Recreation Coordinator	Clinical Improvement Advisor	Director of Care
Jewish General Hospital – VAP Team	Intensivist, Pneumologist (Chair) Nutritionist (chair) Nurse educator Physiotherapist Respiratory therapist Infection Prevention and Control Nurse	Clinical Research Assistant	ICU Director Nursing Director, Critical Care Quality and risk management committee
Children's Hospital of Eastern Ontario – Central Line Infections	Pediatric Intensivist Advanced Practice Nurse, PICU Clinical Manager, PICU	Infection Control Practitioner Infection Control Physician	VP Patient Services and Chief Nursing Officer Operations Director, Critical Care PSU

Establishing Measures: How will we know that a change is an improvement?
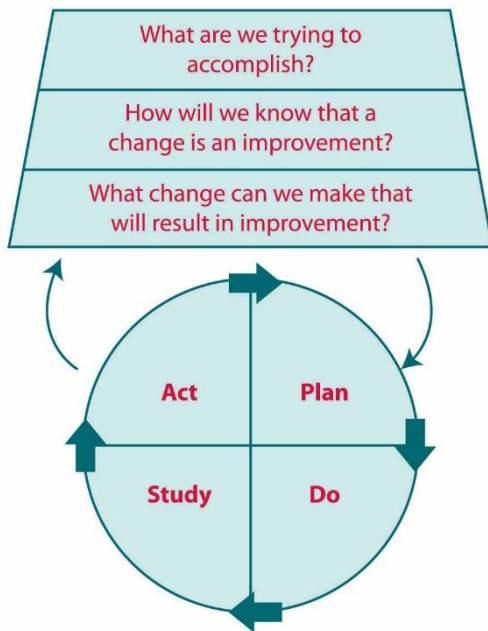
Measurement is not the goal of improvement; however, it plays a key role in understanding if changes are leading to improvement.

Measures for improvement perform a similar function to the vital signs of a patient. They are one way to understand processes and systems of care. Measures can help teams learn about, manage, and improve care. They also provide a common base for communication. Measures may be misused when they are not used as a basis for action or when they are used for judgment and comparisons, not for learning and improvement (see the following table).

> **"You can't fatten a cow by weighing it"**
>
> *- Proverb*

Table: Measurement for Judgment and Learning[9]

Measurement for Judgment	Measurement For Learning
Used to make judgments and comparisons; to reward, motivate (carrots) or punish (sticks)	Used to make improvements to the system
Compares data to standards and specifications (plans, goals, budgets and targets)	Compares data to its historical performance and relationship with other variables
Ignores variation, systems and interactions	Understands variation, systems and interactions
Assumes "if you can't measure it, you can't manage it"	Recognizes that "the most important figures … are unknown and unknowable"[12]

Measures are of greatest value to those working in the system and those who are able to exert direct influence on a process that delivers care. In addition, sponsors should be interested in how measures are developed and be involved in their design as part of their support for the team.

Deciding What to Measure

Using more than one measure will help put the data in context and avoid optimizing one measure at the expense of other measures. Two to six measures are usually sufficient to determine whether changes are leading to improvement. Three types of measures can be included:

Outcome measures are driven by the aim identified in the Improvement Charter. These measures indicate whether changes are leading to improvement and achieving the overall aim of the project.

Process measures indicate whether a specific change or PDSA Cycle is having its intended effect. To affect an outcome measure, it may require changes to several processes in the system and a team may use several process measures in the course of their work. The assumption is that improvements in process measures will eventually improve the outcome measure.

Balancing measures help a team understand the effect of their changes on the broader system and to understand relationships, interactions and subsequent trade-offs between measures. These measures are used to ensure that changes to improve one part of the system are not causing new problems in other parts of the system.

"There is no such thing as a fact in terms of any measurement or observation. Change the procedure for measurement (change in operational definition) or observation produces a new number." [12]

- W. Edwards Deming

The *Safer Healthcare Now!* Getting Started Kits each contain details of recommended measures by intervention. These are supported by an online data reporting system located at https://psmetrics.utoronto.ca/metrics/login.aspx

Examples

Examples of outcome and process measures below are grouped by topic. Teams should also choose one or two balancing measures that would be applicable to their projects and institutions, or consult a *Safer Healthcare Now!* Getting Started Kit at: http://www.saferhealthcarenow.ca/EN/Interventions/Pages/default.aspx

Topic	Outcome Measures	Process Measures	Balancing Measures
Preventing Ventilator Associated Pneumonia (VAP)	VAP Rate per 1,000 Ventilator Days	Compliance with VAP Bundle (all-or-none) Compliance with individual components of the VAP bundle	Family satisfaction Provider satisfaction Relationships with other units outside the core team area
Reducing Central Line Associated Bloodstream Infections	Central Line Associated Bloodstream Infection (CLA-BSI) rate per 1,000 catheter days	Compliance with the insertion bundle Compliance with the maintenance bundle	Average or median Length of Stay Readmission rate within 30 days
Reducing Falls and Injury from Falls	Falls rate per 1000 patient days Percent of falls causing injury	Risk assessments completed on admission "At Risk" patients or clients with falls prevention/injury reduction plan	Culture of Safety assessments Restraint use

Documenting Operational Definitions

Once measures have been identified, teams can work to make operational definitions explicit. Operational definitions give communicable meaning to a concept by specifying how the concept is applied in a particular set of circumstances. They facilitate communication between team members and external groups by using terminology and definitions that have a common meaning to all. Definitions reduce measurement variation, allowing for replication and continuity. A simple test for completeness is to give the measurement definition to a team member and see if they can replicate the procedure and interpretation. Operational definitions can be thought of as useful for a purpose, not right or wrong.

An example of an operational definition is one for resting heart rate: "For a seated patient upon first awakening, place an index finger on the carotid artery and count the number of pulses in 15 seconds. Multiply the result by four and plot the number on a daily run chart." People could agree to this definition, perform the procedure for gathering the data and know how to interpret the results.

What Do We Mean by "Improvement"

The improvement frameworks in this GSK are intended to help make improvements in the systems of care to benefit both patients and providers. But what is meant by 'improvement?"

A useful operational definition of improvement is defined by Moen et. al. below. It states "Improvement is the result of some design or redesign of the system. The result is positive, relevant and has lasting impact on measures that matter to the organization."[3]

The graphic below also suggests the context for the data by displaying variation over time and annotating where a fundamental shift occurred coinciding with a change introduced upon the system. In other operational definitions of improvement the context is often lost due to summarization and aggregation of the underlying data. Before and after 'measures of improvement' which show only two data points would be an example. As Dr. Wheeler indicates "no data have meaning apart from their context."[13]

Figure 3: Operational Definition of Improvement

1

Improvement is the result of some design or redesign of the system.

4

on *measures* (balancing) *that matter* to the organization

Cycle time

2

result is *positive*, relevant

CHANGE

before   *after*

WEEK

and *lasting* impact

3
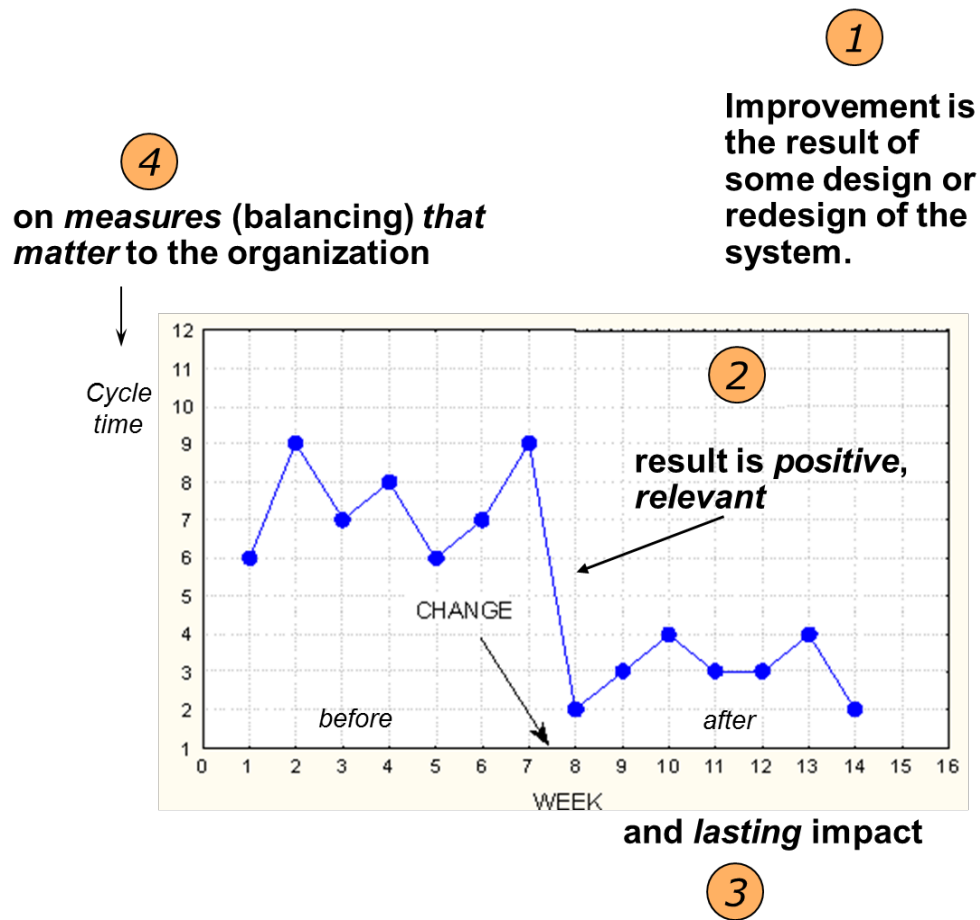
Reference: *The Improvement Guide*, 2nd edition. Langley, Moen, Nolan, Nolan, Norman & Provost

Examples

Below are additional examples of operational definitions. (*Safer Healthcare Now!* provides operational definitions for each outcome and process measure associated with each intervention. Refer to the intervention Getting Started Kits at http://www.saferhealthcarenow.ca/EN/Interventions/Pages/default.aspx.

1.0 Percent of Patients with Medication Reconciliation at Admission – Technical Description

Intervention: Medication Reconciliation

Definition: The percentage of patients who received medication reconciliation at admission

CALCULATION DETAILS:

Numerator Definition: Number of patients who received medication reconciliation at admission

This is a process measure to determine the degree to which medication reconciliation is performed and to evaluate whether the system is performing as planned. The goal of this process is to move toward having as close to 100% of patients reconciled upon admission as possible.

Include as an event for medication reconciliation if steps are taken to achieve the following:

1. Generate a comprehensive list of all medications the patient has been taking prior to admission (Best Possible Medication History);

2. Use the BPMH to create admission medication orders (proactive model) or make a timely comparison of the BPMH with admission medication orders (retroactive model);

3. Discrepancies are identified, discussed, and resolved with the prescriber; and appropriate modifications to medications are made where necessary.

Numerator Inclusions: Total number of patients reconciled at admission.

Numerator Exclusions: Patients who did not receive medication reconciliation at admission.

Denominator: Total number of patient admitted in sample.

Denominator Inclusions: Patients admitted in sample.

Denominator Exclusions: None

Measurement Period Length and Sample Size:

Random Collection strategy:

$$\text{Percentage of patients who received medication reconciliation on admission} = \frac{\text{Total number of patients reconciled on admission}}{\text{Total number of patients admitted in sample}} \times 100$$

Methods to Generate a Random Sample: [14]

Nth Client Method: Based on admission histories, teams will estimate the average number of clients for a month. Then, based on this number, calculate the nth number of clients to sample to ensure a random sample of at least 20 clients is achieved. For example, service area A has an average of 200 clients per month. The independent observer will select every 10th client to achieve a sample of at least 20.

Notes for Method 1:
For the Nth client method, it is important to start at a random starting point, i.e. not always with the 3rd or 4th client. If one is sampling every 10th client, the first client sampled should be a random digit selected between 1 and 10, and then every 10th client thereafter.

X Days in a Month Method: Based on admission histories, teams will estimate the average number of clients for a month. Then, based on this number, calculate the mean number of clients per day, followed by the number of days required for the independent observer to ensure a random sample of at least 20 clients. For example service area B has an average of 200 clients per month resulting in an average of 6 clients per day. With this method three to four days could be randomly selected (random number generator) out of the month to conduct measurements.

Notes for Method 2:
Less preferable method due to several types of potential bias, such as selected days (i.e. 3 Mondays vs 3 Thursdays) having different performance. For the X days per month method, once the number of days to be sampled per month is determined, these days need to be randomly sampled within the month.

Additional Notes for Selecting a Random Sample:
Once an organization has selected one of the sampling strategies, this approach must be used consistently throughout the data collection period. To reduce potential bias, the independent observer should be the only one to know which sampling strategy is selected, and which cases will be reviewed.

2.0   VAP Rate per 1000 Ventilator Days – Technical Description

Intervention: Prevention of Ventilator Associated Pneumonia

Definition: The number of ventilator-associated pneumonias per 1000 ventilator days is the standard measure for surveillance by the CDC. The specific surveillance criteria are outlined in the CDC's National Healthcare Safety Network (NHSN), Patient Safety Component Protocol, Division of Healthcare Quality Promotion National Center for Infectious Diseases, Atlanta, Georgia.[15]

CALCULATION DETAILS:

Numerator Definition: Total number of VAP cases in all ICUs in the organization during the set time interval

Numerator Exclusions:

- Exclude non-invasive ventilation days

- For adult population: Exclude patients less than 18 years of age at the date of ICU admission

- For paediatric population: Exclude patients 18 years old and more

Denominator Definition: Number of ventilator days in all ICUs in same time interval used in numerator (see definition below)

Denominator Exclusions: Same as the numerator

Calculate as:

$$\frac{\text{Number of Ventilator-Associated Pneumonias}}{\text{Number of ventilator days}} \times 1000 = \text{VAP rate per 1000 ventilator days}$$

Measurement Period Length: measure monthly

Definition of Terms:

- Ventilator-Associated Pneumonia: Pneumonia occurring in patients requiring a device intermittently or continuously to assist respiration through a tracheostomy or endotracheal tube. Further, the device must have been in place within the 48-hour period before onset of infection and for at least 2 consecutive days

- Ventilator Day: Total number of days of exposure to ventilators by all patients in the selected population during the selected time period

COLLECTION STRATEGY:

Sampling Plan:

Report the monthly VAP rate for the last several months (minimum 3 months). This will serve as your baseline. Continue to track the measure monthly. If possible, track the rate in an annotated run chart, with notes reflecting any interventions you made to improve.

If your organization's infection control practitioner reports data quarterly, we strongly encourage you to disaggregate this data and report monthly.

Sample Graph
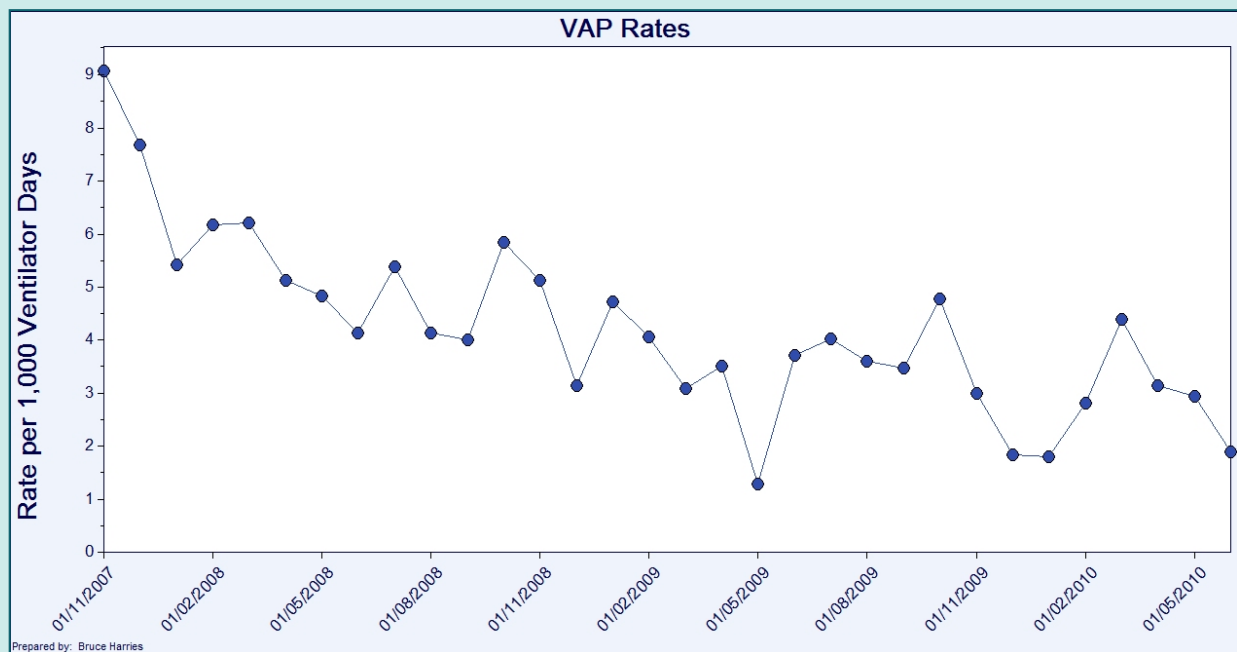
Accelerating the Use of Measures

Teams sometimes delay testing and implementing changes until they have collected baseline and supporting data. For teams doing improvement work measurement should be used to speed things up not slow them down. To accelerate the pace of improvement, accelerate the use of measures by:

Plotting data over time. Improvement requires change, and change happens over time. Use time as your teacher. Much information about a system and how to improve it can be obtained by plotting data over time and observing trends and other patterns. Tracking a few key measures over time is the single most powerful tool a team can use.

Using sampling*. Sampling is a simple, efficient way to help a team understand how a system is performing. For example, teams could monitor all patients in the ICU every day for head of bed compliance. This kind of data collection would consume many resources. Instead, a team could choose a sample of one day per week. Sampling for improvement purposes means collecting just enough data to address the questions the team is trying to answer. Often, it means smaller sample sizes collected more frequently and displayed over time.

Integrating measurement into the daily routine. Useful data are often easy to obtain without relying on information systems. Use or modify existing forms and information systems rather than designing new ones. Don't wait two months to receive data from the information systems department. Instead, develop and use simple manual data collection forms. Make collecting the data part of someone's job. Often, a few simple measures will yield all the information the team needs.

Stratify the data. Once an initial measure is plotted and somewhat understood it may be helpful to separate and characterize other potential sources of variation. Stratifying the data by units, individuals, timing or some other rational grouping can help teams better understand how a system is working and see the effects of changes being tested.

Using qualitative and quantitative data. In addition to collecting quantitative data, collect qualitative data, which often are easier to access and are highly informative. Ask people in the system what issues are important or what they observe. Later, the team can confirm perceptions with quantitative data. For example, if working on the VAP intervention one could ask the nursing staff how weaning from medications is going or how could the sedation protocol be improved? In order to focus your efforts on improving patient and family satisfaction, ask patients and their families' open-ended questions about their experience.

Seeking usefulness, not perfection. Remember, measurement is not the goal; improvement is the goal. In order to move forward to the next step, a team needs just enough data to know whether changes are leading to improvement. Avoid collecting data "just in case."

*Further notes on Sampling[16]

Different methods for sampling healthcare data can be employed. As indicated by Provost and Murray[16] a distinction between three of the approaches is useful. These are:

- simple random sampling,
- systematic random sampling,
- judgment sampling.

A **simple random sample** involves the selection (by mechanical means or random numbers tables) of units of a frame drawn from a population. The frame contains the items of interest to be studied. For example, patient wait times for the past month at a walk-in clinic could be used as the frame from which a random sample of individual wait times could be obtained. (The population would potentially be all walk-in patients, past and future.)

A **systematic random sample** is obtained in a similar fashion but the random starting point for collecting the sample is defined, followed by a selected repeating interval for subsequent samples. For example, the starting point for a sample of patient wait times could be the first day of the month followed by an interval collected every third subsequent day. The systematic random sample is often simpler and therefore easier to apply in healthcare settings than a simple random sample.

A **judgment sample** is the primary method of sampling for analytic problems in improvement work. Subject matter experts use their knowledge to select a sample which will best represent the sources of variation likely to occur in future affecting the outcomes being studied. For example, when studying wait times at a walk-in clinic it may be useful to sample from evening and day shifts, or weekends and weekdays, or when staff with different experience levels are providing care. For practical purposes the sample may also be done in a way that is most *convenient* for the improvement team. A **convenience sample** might include the easiest place to begin getting data, or identifying units or providers who are willing to work on a specific improvement initiative. A convenience sample is not 'random'. It is a form of judgment sample.

Selecting an appropriate sampling plan begins by determining which type of study is to be undertaken – enumerative or analytic. Random or systematic sampling is most often done in enumerative studies, while judgment sampling is most often done in analytic studies. As Provost and Murray indicate "because most improvement work uses judgment or convenience samples and there is rarely a frame from which to select random samples if we wanted to, confidence intervals have little use in improvement work."[16]

For a more complete description of these important considerations see **Appendix A – Enumerative and Analytic Studies – page 60**.

Interpreting Results

When changes are developed, it is predicted that they will be an improvement but many teams have experienced changes that were not. How will people know that changes are leading to improvement? Simple before and after evaluations may not be enough. Because change occurs over time, interpretation should include plotting data over time on run charts or process control charts. Below is an effective annotated run chart.

Figure 4: Compliance with Head of Bed Elevation

Sir MB Davis Jewish General Compliance to Head of Bed 30-45 Degrees
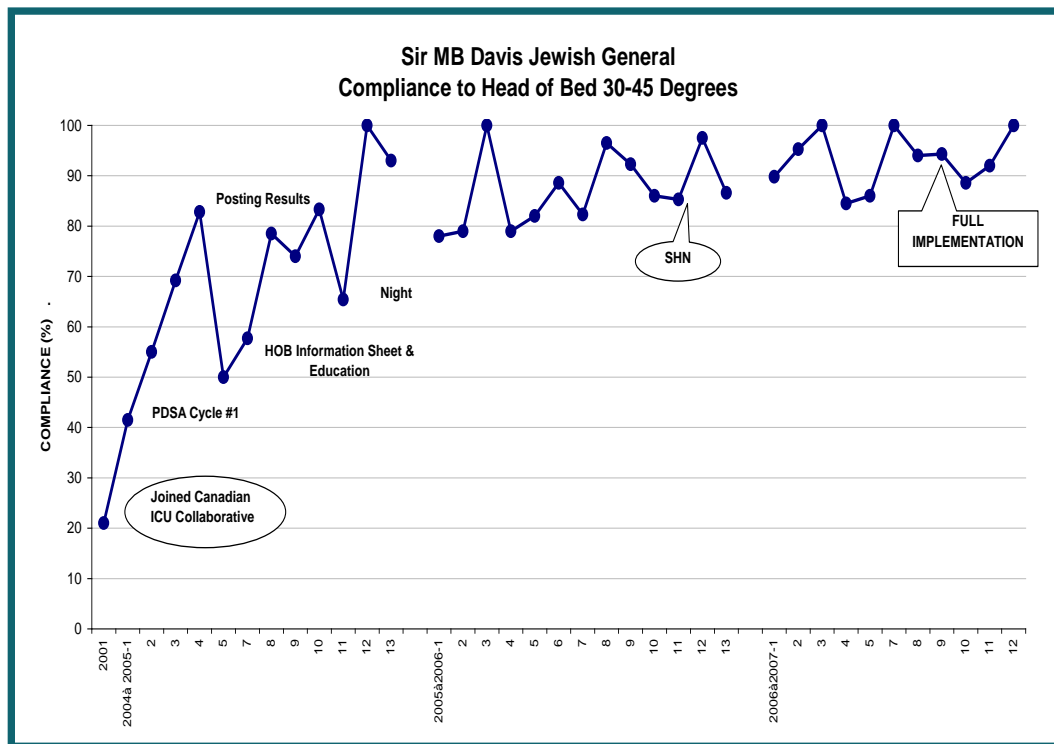
Family of Measures

When looking at performance of a system it is helpful to view it from a balanced perspective. This has led to the increased use of a "Family or Measures" also known as a "Vector of Measures (VOM)". Family refers to measures which are different but related while vectors help describe both magnitude and direction. Multiple measures are categorized and displayed together to provide a balanced view.

Many examples of categorization schemes exist including Balanced Scorecards popularized by Kaplan and Norton,[17] the Institute of Medicine's Dimensions of Quality[18] and provincial healthcare organizations like the Saskatchewan's Health Region's Dashboard.[19] These approaches share the idea that all systems contain inter-related components. The systems (organizations) need to be managed to optimize the interactions. A VOM displays multiple measures over time to help understand performance. The example below shows measures organized by three main categories - chronic disease, long-term care and wait times:[19]

Figure 5: Saskatoon Health Region - Selected Indicators

Source: http://qualityinsight.ca/indicators/shr
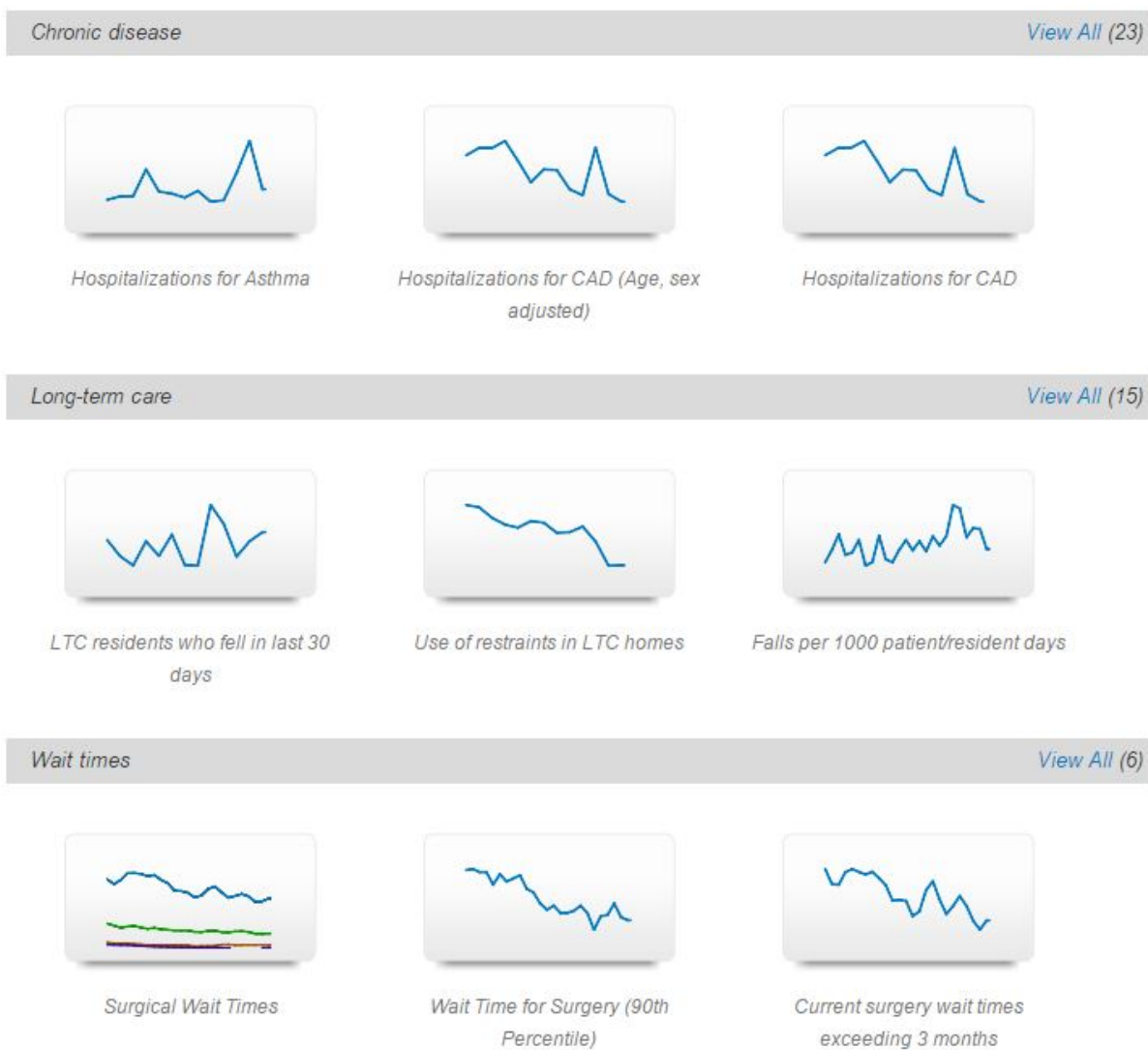
"The use of the vector of measures provides a method for leadership to predict the impact of …strategic changes on their system, study the effect of their changes as reflected in their VOM, and compare the actual impact to their predictions. A vector of measures should become a key leadership tool for learning and for managing into the future."[16]

- L. Provost and S. Murray

Displaying the data

Almost all of the potential learning from data is available through graphical display. Effective displays help users make sense of data and graphics tend to highlight variability or trends. Natural graphics – pictures, drawings, photos, and video recordings – support a systemic view and help communicate important messages. Most data displays are quick and easy to prepare. Generally, graphical excellence is found in simplicity of design and complexity of data.[20]

Using Measures Appropriately

It is an ongoing challenge to use measures appropriately. Many understand that data should provide a basis for action. Before taking appropriate action, we need to know if a difference has occurred and whether the difference is important and likely to continue. In addition, if the focus of improvement is an entire system or organization, then data should be provided in a way that builds an understanding of the entire system. Ideally measurements should also be designed to reflect differing levels of detail or scope for use by senior management and front-line providers.

Some issues affecting the use of measures:

Issue	Potential Solutions
Simplification	Guidance on aggregation and summary
Common and special cause not recognized	Data over time in Run Charts or Control charts
Multiple perspectives not understood	Quality characteristics and graphical display
Methods of analysis inappropriate	Use tools appropriate to the type of problem
Targets over-used	Understand process capability – work on improvement

Simplification may occur in an effort to reduce complexity and misunderstanding for the audience using the data. Often simplification is done by aggregating data to reduce the 'confusion' of variation. The confusion may occur because there is no known or agreed upon method for interpreting variation. Instead of seeing many data with the variation displayed over time, a summary (an average or other aggregation like quarterly summaries) is provided. Single numbers replace original data. The context is lost. Also lost is the temporal spread which contains much of the knowledge in any data set.

"Design graphics to give the viewer the greatest number of ideas in the shortest time with least ink in the smallest space."[20]

— *Edward Tufte, PhD, Visual Display of Quantitative Information*

Two rules suggested by Shewhart offer guidance:

> **Rule 1.** Original data should be presented in a way that will preserve the evidence in the original data for all the predictions assumed to be useful.

> **Rule 2.** Any summary of a distribution of numbers in terms of symmetric functions should not give an objective degree of belief in any one of the inferences or predictions to be made therefrom that would cause human action significantly different from what this action would be if the original distributions had been taken as evidence."[21]

Walter A. Shewhart

Common and special cause are important distinctions to be understood because the choice of action will be different for these two types of variation. If a process exhibits only common cause variation, efforts to improve should be directed at the entire causal system. If special causes are present, action should be directed at the special cause.

As Dr. Wheeler and others[21] suggest "when managers fail to understand the difference between these two types of variation, their efforts to remove variation will be misdirected, and will therefore increase costs, waste effort, lower morale, and ultimately, be ineffective.[13] The use of run charts or statistical process control charts are tools to help understand variation.

For a more complete understanding of common and special cause see: Wheeler, J. *Avoiding Man-Made Chaos*[13] or Provost, L.; Murray, S. *The Health Care Data Guide: Learning from Data for Improvement*.[16]

Multiple perspectives are needed to help understand performance of a system and to avoid improving one measure at the expense of another. Different quality characteristics should be viewed to give a balanced view. An example in a clinic setting would be measuring quality characteristics like timeliness (time to treat), cost ($ per case) and patient perception (satisfaction). It is also helpful to view different measures together on the same page. This approach builds understanding by viewing changes within and between measures over time. See Figure 5: page 29

Methods of analysis should be selected based on which type of problem is being addressed – enumerative or analytic. For example, while descriptive summaries may be interesting, "they should never be mistaken for analysis."[13] A number of different tools and methods are appropriate for each type of study. See Appendix A – Enumerative and Analytic Studies page 60 for a more detailed discussion.

Targets can indicate the magnitude of change required but are often over-used. As Deming suggested "Only the method is important, not the goal (target). By what method?"[22]

There is a risk that goals or targets which are beyond the current capability of the system can lead to distortion, gaming and faking. Brian Joiner indicated that there are three ways to meet a target: distort the numbers, distort the system or make changes to improve the system.[23] When an organizational culture implies that looking good (get the right number) is more important than doing well (learn, improve), the temptation to distort either the number or the system can overwhelm good intentions to improve the system.

An even stronger view of targets is held by John Seddon in reference to governing in the United Kingdom.[24]

"Targets are still thought of as a means to accountability, a favoured claim amongst politicians. But in truth they are a means to sub-optimisation. Ignorance is no defence, so if we must talk about accountability, shouldn't politicians be held accountable for causing people to act in ways that sub-optimise public services?"

- John Seddon

As a way to move beyond targets, a helpful approach is to measure current performance with the aim of making it predictable (stable) by removing special causes. Then work on the system of causes to improve performance in the future. Improvement will come from building knowledge, not from targets.

Developing, Testing and Implementing Changes: What changes can we make that will result in improvement?
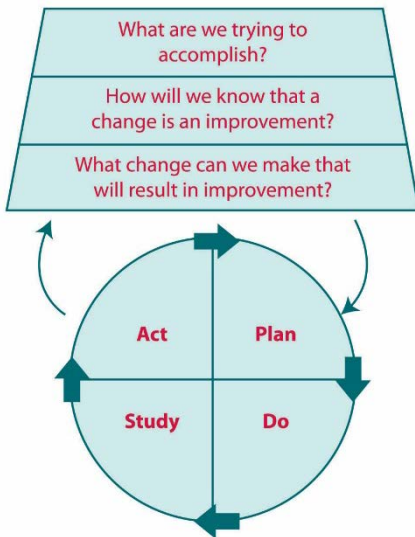
All improvements require change but not all changes result in improvement. Where do ideas for change come from? They must be developed. Some ideas may be successful, some will not. Testing is required. Which ideas should be implemented? Only the ideas where there is a high degree of belief that the changes when implemented will result in improvement. The illustration that follows shows how degree of belief is increased through the three phases of developing, testing, and implementing change.

Figure 6: Developing, Testing and Implementing a Change
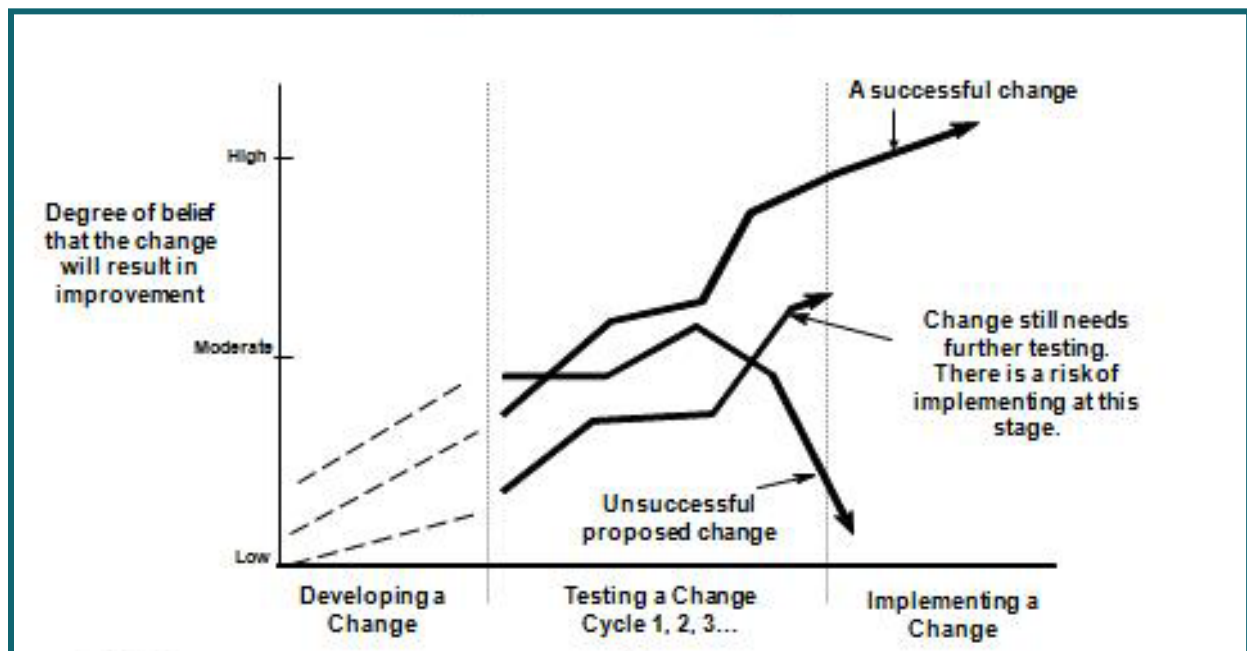
Source: The Improvement Guide, page 145[2]

One's degree of belief in a prediction depends on two considerations: (1) the extent to which the prediction can be supported by evidence, and (2) the similarity between the conditions under which the evidence was obtained and the conditions to which the prediction applies.

Developing a Change

When developing ideas for change, the team is making a prediction that the change will be beneficial in the future. There are several sources for developing good ideas for change:

- Applying high leverage Change Concepts. Seventy-two concepts for a number of topics are described in detail in The Improvement Guide.[2] In healthcare, there are a number of packaged changes often described as "bundles" like the bundle of four change ideas in the Ventilator Associated Pneumonia (VAP) bundle;

- Using critical thinking tools such as flowcharting, brainstorming, and process analysis tools;

- Using creative and lateral thinking tools like Edward deBono's six- thinking hats, random word provocations, other types of provocations and TRIZ[25] (theory of inventive problem solving) techniques;

- Watching the process in action;

- Using observation, focus groups, and surveys for feedback;

- Following a hunch or theory;

- Getting insight from research and benchmark data;

- Asking process participants or subject matter experts for ideas.

Testing a Change

Teams start with specific ideas for testing in their setting. These ideas may have been developed from high leverage Change Concepts like those included by topic in *the Safer Healthcare Now!* Getting Started Kits. The ideas are then tested on an appropriate scale to increase the degree of belief that there will be an improvement, and to reduce risk and ensure that there are few or no failures upon implementation.

A change may not be an improvement, even if a team has:

- Spent a lot of time, energy, and analysis on developing the idea;

- Buy-in and agreement from sponsors and stakeholders;

- Planned and analyzed every detail of the new design and there do not appear to be any problems;

- A business case to justify the cost and benefit;

- Benchmarking studies to prove the idea has worked in other healthcare systems.

The following table helps teams decide on an appropriate scale of testing.

Table: Deciding the Scale of Testing	Minor consequence of failed test	Major consequence of failed test
Low degree of belief that the change idea will lead to improvement	Medium- scale test	Very small-scale test
High degree of belief that change idea will lead to improvement	One cycle to implement change	Small- to medium- scale test

Source: Based on Deciding the Scale of a Test, *The Improvement Guide* (first edition) 1996 pg. 107[3]

The importance of testing cannot be understated. Uncertainties about future conditions and unplanned events often arise between the time when a change is identified to the time it is implemented. The environment may change, the intended impact on the measures may not materialize or there may be unintended, undesirable impacts in other areas. Most ideas should be tested on a small or medium scale and under multiple conditions before implementing. Collecting data over time is critical to see when a change is leading to an improvement.

Using one cycle to implementation should only be considered when there is a high degree of belief that the change will be successful; when there is evidence that the losses from a failed implementation would not be significant, and when there is no way to test the change on a smaller scale.

If tests are not yielding expected results, teams are wise to stop and try something else. Failed tests are a gift that every team should value as they are critical in building knowledge and learning how to refine ideas for implementation. Tests often may fail; implementation should not.

Using PDSA Cycles
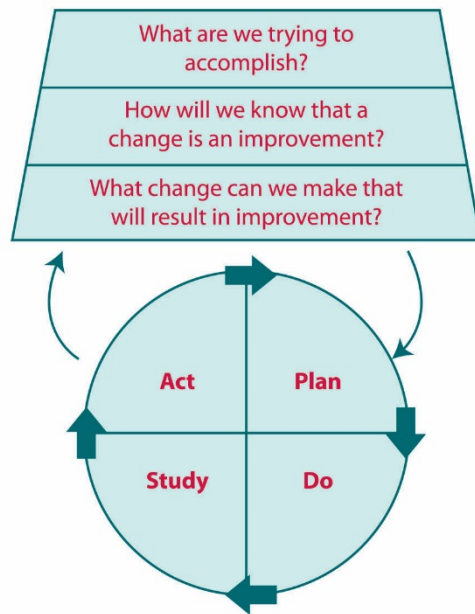
Changes can be tested by planning the details of the test including predictions and theories (PLAN), trying the idea out on a small scale and collecting data (DO), comparin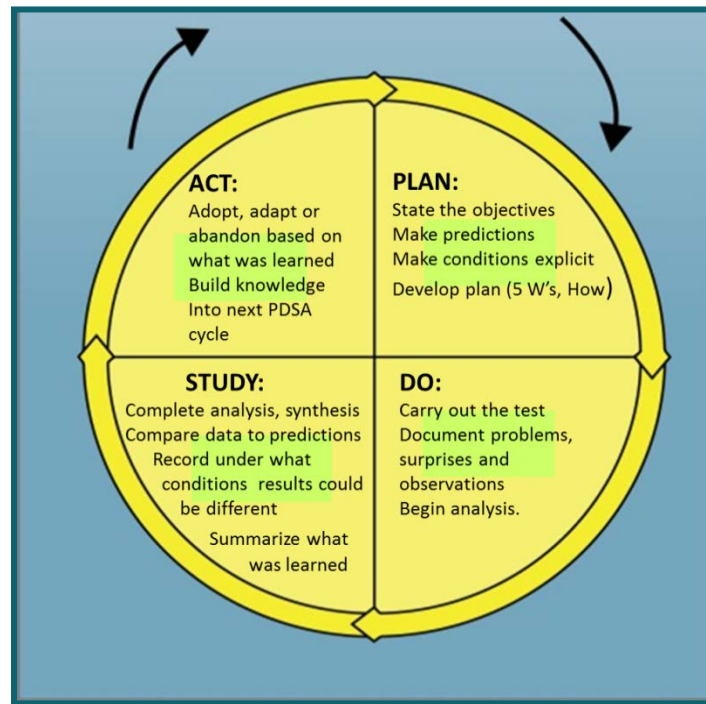g the results of the test with plans and predictions (STUDY), and then transforming what was learned into action (ACT). Often, each cycle provides a basis for the next PDSA Cycle. The diagram below provides detail on what should be considered in each phase.

Building knowledge and degree of belief is an iterative process. Small-scale and frequent PDSA Cycles conducted under multiple and varying conditions will help the team learn as they go. During the design of PDSA Cycles, teams can continually ask themselves how they can still gain knowledge about the change while reducing risk to the system.

There are many ways to design useful small-scale tests to accelerate learning, such as:

- Simulating the change;

- Having others review the change for feasibility;

- Conducting the test over a short period of time. Instead of saying "We need two weeks to run the test," ask "What COULD we do by next Tuesday?"

- Using the 1:1:1 rule. Conduct the test in one location with one clinician and one patient. Scale down each test into manageable cycles and then expand conditions as knowledge about the change builds;

- Using manual data collection methods and sampling;

- Recruiting a small group of volunteers. Use the improvement team as the initial sample or identify "early adopters," those who like change and will try anything. Delay consensus or buy-in until later stages;

- Breaking the change into smaller pieces;

- Thinking a couple of cycles ahead. Imagine what the results might be and think about what the next few cycles could be;

- Consider using the one, five, all rule to expand the scope of a test. i.e. one patient, five patients, all patients;

- Using temporary support systems for testing, such as manual forms.

Figure 7: The PDSA Cycle in Detail

ACT:
Adopt, adapt or abandon based on what was learned
Build knowledge Into next PDSA cycle

PLAN:
State the objectives
Make predictions
Make conditions explicit
Develop plan (5 W's, How)

STUDY:
Complete analysis, synthesis
Compare data to predictions
Record under what conditions results could be different
Summarize what was learned

DO:
Carry out the test
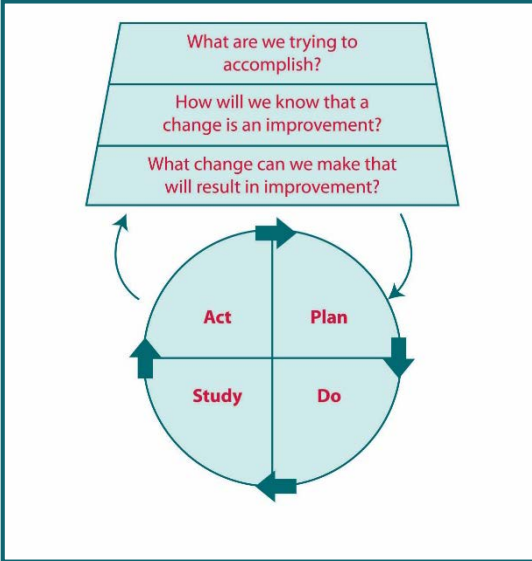Document problems, surprises and observations
Begin analysis.

Source: adapted from The Improvement Guide, page 97[3]

Examples

Following is an example of testing a change using a PDSA Cycle, and an example of building knowledge through the use of multiple PDSA's.

Increasing Use of a Falls Risk Assessment Tool in a Long-Term Care Facility using a PDSA[26]

Plan:

The overall aim of our improvement team is to increase falls risk assessments of residents in our long-term care home. We believe that a simplified assessment tool might help. The purpose of this PDSA cycle is to test "Will a new simplified assessment tool increase the number of assessments completed?" Our prediction is that it will because the tool will be easier for nursing staff to use. The test is set to use an on/off strategy; three days with the new tool being used, followed by three days with the old tool. Testing will start the following Monday and run for two cycles for a total of twelve days. A count of daily assessments will be plotted over time on a run chart and comments by staff will also be recorded.

Do:

The test cycle was completed; the run chart and comments are shown below:

Comments from staff captured during the test:

- The new form seemed much easier to use;
- I liked the new form as it took less time to complete;
- I think the check boxes should be larger on the new form.

PDSA Cycle #1 - Completed Assessments

Study:

The run chart data appear to support our prediction that the new form increased the number of completed assessments. Qualitative feedback from staff also appears to support this idea.

Act:

For our next cycle, we will ask new employees to test the form. Our prediction is that they will be able to complete assessments at the same rate as experienced employees.

Figure 8: Sequential Building of Knowledge -Multiple PDSA's

Cycle #4 – Abandon twice daily huddles. Continue with once daily. Test huddles on weekend shift. Test huddle with residents.

Cycle #3 –Change time of safety huddle and add two huddles per day. Test huddles on night shift.

Cycle #2 – Modify questions in safety huddles. Test 2 days with 2 more physicians and 2 more nurses. Ask for feedback.

Cycle #1 – Test huddles one day with one physician and one nurse with one group of patients

Concept:
Safety Huddles

The example above describes multiple PDSA cycles which a team ran in sequence, incorporating what they had learned into each subsequent cycle. The concept of 'safety huddles' remained the same, but varying the conditions under test created knowledge in addition to what may have been learned by a single iteration.

Implementing a Change

Teams are ready to implement changes when their degree of belief is high that the change is an improvement in their system. While testing involves trying and adapting different ideas for change, implementation means that a change now becomes a permanent and integral part of the day-to-day operation of the system. Implementation is similar to testing in the following ways:

- PDSA Cycles are used to build knowledge of the implementation process and translate that learning into action;

- Predictions are made;

- Data are collected;

- Unexpected and unplanned impacts are documented and studied;

- New knowledge is built into subsequent plans.

Implementation and testing are different in the following ways.

Table: Testing Versus Implementation[27]

	Testing	Implementation
Expectations of Failure	**25-50% of tests should fail** Failed tests are critical to learning and building knowledge. They help teams understand under what conditions their ideas will not work and why. Failed test are gifts that every team should cherish.	**No implementation should fail** With an appropriate amount and scale of testing under multiple conditions, few or no implementations should fail to achieve expected results.
Support Processes (Training, documentation such as job aids and flowcharts, standardization)	**Less important** Changes are not permanent and will be refined as testing continues.	**Very important** Training and documentation provide a consistent view and help others understand the new process. Standardization is a helpful method to reduce variation and assure results.
Resistance to Change	**Less important** Communication of the aim is critical. Engaging staff in testing of changes is one strategy to mitigate resistance and build commitment. Because changes are not permanent, people can provide feedback. Ongoing measures provide evidence of whether the changes are resulting in improvement.	**Very important** With appropriate testing resistance to change is mitigated. All change has social and emotional aspects to it. As changes become permanent, recognize the human impact of the change. Communicate why the changes are required. Results from testing can be used to show how the change will be an improvement.
Measures	**Focus on outcome measures and include balancing** The focus is on outcome measures of the immediate process. Some balancing measures are needed to ensure that the changes do not have a negative impact on other areas.	**Focus more on balancing measures** Balancing measures become more important. Additional upstream and downstream measures of the system may be needed. Outcome measures are still used to ensure that changes have the intended impact and to hold gains developed in testing.

Holding the Gains

Once changes are tested and implemented, teams are challenged to hold the initial gains, to ensure that improvements are permanent and the system does not revert back to its previous performance. Holding the gains starts in the testing stage of improvement and continues through implementation.

Figure 9: Holding the Gains
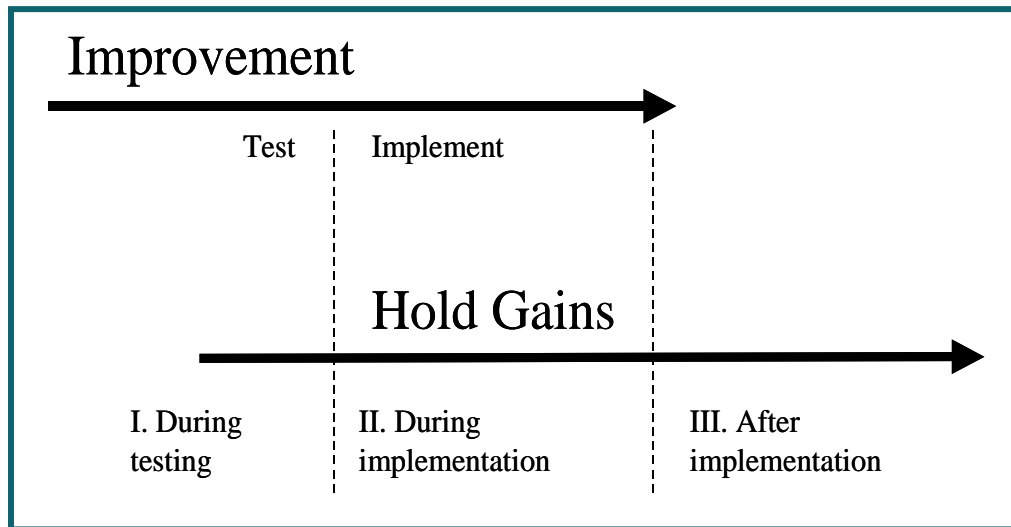
During the **testing** stage, teams will want to test changes under a wide range of conditions and force the changes to fail in order to understand limitations of the idea. This is called "robust design." Planned groupings, especially with extremes, can help the team understand how the changes work in the local system. Measurement for learning during testing is used to understand which ideas have the most power to accomplish the aims and outcomes set out in the original Improvement Charter. Failure during the testing phases can be expected and desirable. Designing a "robust" process should allow for successful implementation. For example, creating a new checklist which can be easily completed by both experienced and new staff would be an example of a "robust" change.

When **implemented**, changes can be described as being permanent, integrated in the daily work and "the way we now do business." Teams can continue to use multiple PDSA cycles to organize and manage implementation and assist the team in learning. During implementation, it is important to seek and use inputs from people who may be affected. Address the social aspects of the change with frequent, interactive communications. Explain the "why" of the change, how it may affect people and understand and address the causes of resistance. Publicize results and show appreciation for the team's efforts. Support mechanisms often need to be updated to reflect the new process. It may be helpful to map the flow of the new process, provide training to those affected and document learning to be used in subsequent projects. It is helpful to design the new system to make it as difficult as possible to return to the previous system.

After changes have been implemented, there is a natural tendency for teams to want to move on too soon to other priorities. Assumptions like "we met our goals and assumed the improvement would hold" and "this is an isolated project with a start and finish" often prevent the long-term realization of goals. As a result, the improved system can revert to the previous system. **After implementation**, it is suggested that teams continue monitoring key outcome measures (less frequently) and integrate the process into the normal everyday workings of the system; for example, by reviewing results at senior leadership meetings and comparing results to expected standards. Build the changes into the infrastructure of the organization. For example, job descriptions, policies and legal documents may require review and modification. It also helps to assign ownership to a senior leader for holding the gains, to provide recognition to team efforts and to celebrate successes along the way.

Spreading Successes[28]

Spread means disseminating the changes beyond the scope of the original aim as often described in an improvement charter. A team is ready to spread their ideas and successes to other parts of the system when:

- They have been successful at testing, implementing, and holding the gains in their own environment and can demonstrate their **results** through their data and stories;

- There is **will** among senior leaders and sponsors to spread the changes developed in the Collaborative;

- The topic is an important **priority** for the organization and explicitly communicated in strategic and business plans;

- A senior **leader** has been assigned to spread the changes.

The Institute for Healthcare Improvement has developed "A Framework for Spread."[29] The framework is not meant to be prescriptive or considered as a specific set of interventions. Instead, it is meant to suggest some general areas, based on theory and experience, to consider as a large spread project is undertaken. Factors such as a system's infrastructure, culture, size, and strength of the underlying social and operational systems will influence how the following components of the framework are applied.

Figure 10: A Framework for Spread
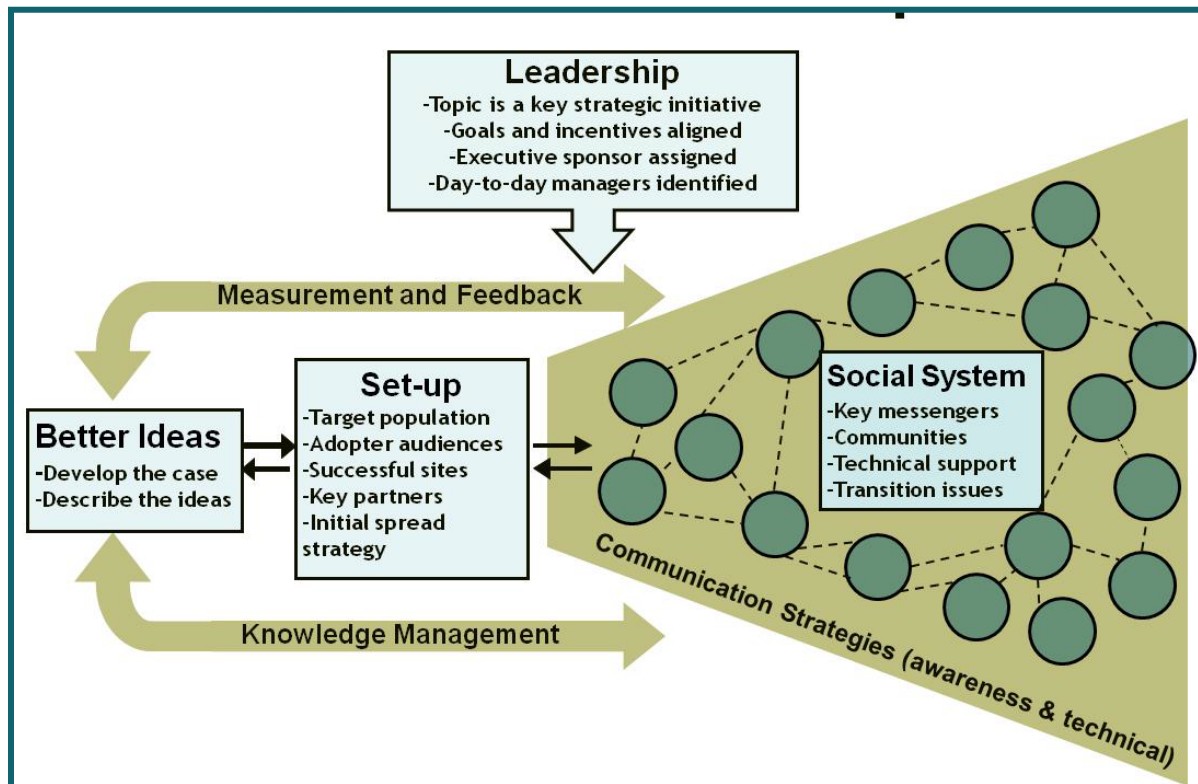
Source: Institute for Healthcare Improvement White Paper "A Framework for Spread."[3]

The framework includes six elements:

- Leadership includes setting the agenda and assigning responsibility for spread;

- Better ideas describes the new ideas and uses evidence to "make the case" to others;

- Set-up for Spread identifies the target population and the initial strategy to reach all potential sites in the target population with the new ideas;

- Social System and Communication builds understanding of the relationships among the people who will be adopting the new ideas and methods to increase awareness and share technical information about the new ideas;

- Knowledge Management includes observing, learning and using the methods for spread as they emerge in the organization;

- Measurement and Feedback means collecting and using data about process and outcomes to better monitor and make adjustments.

As depicted above, spread happens over time and contains multiple feedback loops.

For additional detail on IHI's Framework for Spread, see:
http://www.ihi.org/IHI/Results/WhitePapers/AFrameworkforSpreadWhitePaper.htm

There are a number of potential mistakes that might be made when attempting to spread changes beyond a team's initial scope.

Table: Common Spread Mistakes and Alternatives[28]

Common Mistake	Possible Alternatives
Start with big pilot project, then "roll out"	As one Collaborative team member put it, "rolled out feels rolled over." It is almost impossible to "implement" changes hospital or region-wide. Instead ask, how can we build in learning and feedback to change designs as we go? Another alternative is to plan and sequence the changes using a spread matrix or the idea of "1 to 5 to all."
One person to do it all	Processes that become people dependent are not sustainable. Spread the work around, build ideas into processes that can be repeatable and involve others. Spread efforts will naturally involve others in the target population and those in senior leadership positions.
Work harder	Vigilance and memory are proven to be the weakest parts of any system. Build changes into reliable processes, standardize and make it easy to do the right thing and hard to do the wrong thing. Remove barriers to best practices.
Don't change the changes	It is important to adapt even the best ideas for change to local conditions. Also, people who help design change are more likely to support them. Teach the use of PDSA Cycles.
Use the successful Collaborative team leader as leader for entire spread plan.	Often the reason that local champions are successful is due to relationships and their connections within the local system. For spread, rely more heavily on organizational leadership to support the spread plan, connect to strategic plans of the organization and use their authority to ensure that it happens. Find champions and opinion leaders in the target population.
Use of quarterly data, especially defects	It is essential to have real-time feedback, both qualitative and quantitative for purposes of learning and adapting approaches. Use sampling to reduce the volume of data required and the associated workload.
Expect marked improvement in outcomes without attention to process reliability	Outcomes cannot be expected to change unless processes change and become more reliable. Ensure staff can be responsible for process improvement and reliability.

The concept of spread is best understood as local reinvention, not as implementation of a magic bullet.[8]

- Donald M. Berwick, MD, MPP, former President and CEO
Institute for Healthcare Improvement

Summary

Outlined in this section have been systematic approaches to create, test, implement and spread changes that result in improvements based on the framework of The Model for Improvement. The approaches attempt to combine useful theory with good practice. By following these methods, teams and those who support them can increase their capability to address both existing and future challenges.

Additional Frameworks

Healthcare organizations have used one or more of the following additional approaches to guide improvement in their systems.

C. Liberating Structures

Liberating Structures are a group of some 33 methods and principles intended to "transform how people interact and work together in order to achieve much better results than what is possible with presentations, reports, and other conventional methods.[30] Liberating Structures are designed to include and engage everybody in a new way. At the core is the idea that "simple shifts in routine patterns of interaction make it possible for everyone to be included, engaged, and unleashed in solving problems, driving innovation, and achieving extraordinary outcomes."[30]

"Instead of oscillating between too much control (Presentation), too little control (Open Discussion), and too centralized control (Managed Discussion), Liberating Structures distribute the control of content among all the participants so that they can shape direction together as the action unfolds. This liberates energy, unleashes participants' contributions, stimulates creativity, and reveals the group's latent intelligence. Liberating Structures are designed to transform the way people collaborate, how they learn, and how they discover solutions together. They support and spark creative adaptability."[30]

Figure 11: Liberating Structures and Conventional Microstructures Differences in Control and Structure
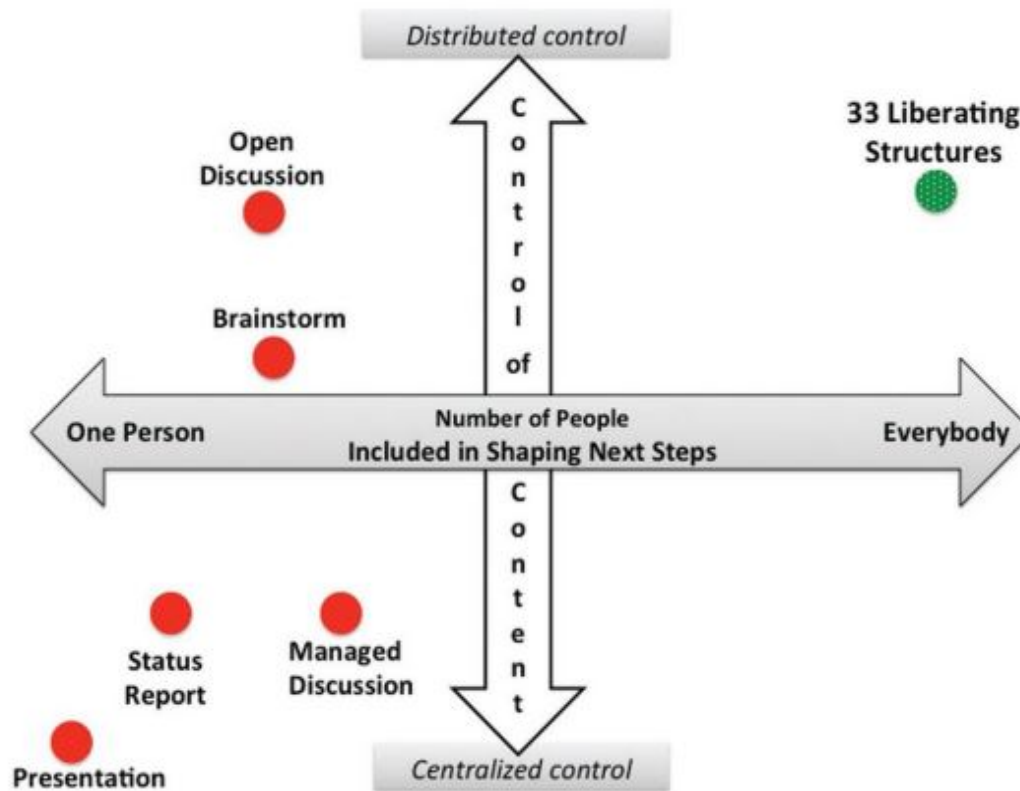
Source: Lipmanowicz, Henri; McCandless, Keith (2014-04-01). The Surprising Power of Liberating Structures: Simple Rules to Unleash A Culture of Innovation. Liberating Structures Press, Seattle, WA.

Figure 12: Menu of the 33 Liberating Structures

Impromptu Networking
Focusing on People, Purpose & the Power of Loose Connections

TRIZ
Designing a Perfectly Adverse System to Make Space for Innovation

What, So What, Now What? W³
Reflecting on Your Progress and Making Adjustments-As-You-Go

Conversation Café
Making Sense of and Forming Consensual Hunches about Challenges

Appreciative Interviews
Discovering & Building On the Roots Causes of Success

1-2-4-All
Conversing in Cycles: Self-Reflection, Pairs, & Small Groups

9 Whys
Becoming Clear About Purpose

15% Solutions
Noticing the Influence & Discretion You Have Now

Ecocycle
Engaging Groups in Growing and Sifting Their Portfolio of Activities

Shift & Share
Spreading Good Ideas from the Grass Roots Up & the Fringe In

25-To-10 Crowd Sourcing
Vetting Powerful Ideas and Igniting Action

Min Specs
Unleashing Innovation by Specifying Only "Must-do's" & "Must-not-do's"

Wise Crowds
Tapping the "Wisdom of Crowds"

Wicked Questions
Framing a Paradoxical Challenge That Engages Everyone's Imagination

Purpose-To-Practice
Designing for Shared Ownership, Adaptability, and Resilience

Improv Prototyping
Developing Inventive Solutions to Chronic Challenges

Agreement-Certainty Matrix
Matching Approaches to Your Different Types of Challenges

What I Need From You
Surfacing Needs and Working Across Silos

Heard, Seen, Respected
Practicing Deeper Listening and Empathy

Social Network Webbing
Drawing Out Informal Connections & Adaptability

Design StoryBoards
Detailing Design Elements for Meetings & Innovation Efforts

Open Space
Liberating Inherent Action & Leadership In Large Groups

Discovery & Action Dialogue (DAD)
Discovering Solutions To Big Challenges In Plain Sight

Integrated~Autonomy
Moving from *Either-Or* to *Both-And* Creative Solutions

Generative Relationships
Understanding Patterns in Relationships that Create Surprising Value

Critical Uncertainties
Preparing and Practicing Strategy-Making for Surprising-Yet-Plausible Futures

User Experience Fishbowl
Sharing Insights Gained from Field Experience with a Larger Community

Drawing Together
Drawing Out Insight that Precedes Logical Understanding

Panarchy
Spreading Your Innovation or Good Idea At Many Levels Simultaneously

Troika Consulting
Guiding Your Next Steps with Colleagues

Celebrity Interview
Exploring Big Challenges with an Expert or Leader

Helping Heuristics
Practicing Progressive Methods for Helping Others and Asking for Help

Simple Ethnography
Making Field Observations of User Experience

Source: Lipmanowicz, Henri; McCandless, Keith (2014-04-01). The Surprising Power of Liberating Structures: Simple Rules to Unleash A Culture of Innovation. Liberating Structures Press, Seattle, WA.

Building on the work of others, Lipmanowicz and McCandless assembled the current list of 33 methods and continue extensive real-world testing and refinement. Additional resources and a user-group can be found at: http://www.liberatingstructures.com/

D. Positive Deviance (PD)

Positive Deviance is based on the observation that in every community there are certain individuals or groups whose uncommon behaviours and strategies enable them to find better solutions to problems than their peers, despite having access to the same resources and facing similar or worse challenges.

The Positive Deviance approach is an asset-based, problem-solving, and community-driven approach that enables the community to discover these successful behaviours and strategies and develop a plan of action to promote their adoption by all concerned.[31] Basically, positive behaviours that are already being practised by some people in the community are shared with others who decide whether to adopt these behaviours. The community thus leads the improvement process using their own ideas.

For example, in healthcare settings, some individuals (so called positive deviants) have successfully developed behaviours that have allowed them to successfully implement 'practice bundles' to decrease infections from mechanical ventilation, surgical procedures or central intravenous catheters. Yet, having other healthcare workers become interested and consistently comply with these interventions has been shown to be remarkably difficult, often because these practice bundles are forced onto staff in a top-down, command-and-control fashion without giving front-line staff the chance to implement their own strategies.[32] Traditional command-and-control strategies in the form of revised policies, step-by-step plans, education, compliance and inspection often fall far short of what is possible to achieve. Rarely knowledge is the issue; rather the prevalent deeply rooted culture tends to discount or push back against ideas and strategies that are foreign. This problem may be best described by the saying that "culture eats strategy for breakfast."

PD relies on a number of tools and approaches to help identify and spread positive behaviours. The tools often include those listed in Liberating Structures. In common use are discovery and action dialogues (DADs), improvisational acting (improv) and theory of inventive problem solving (TRIZ).

DADs are short, 15-20 minute facilitated discussions that provide involved staff a way to identify and act on their ideas, which fosters ownership of both the problem and the solution. Improv can be used to re-enact situations and behaviours that allow an audience to experience the situations and behaviours and learn from them in a safe environment. For example, staff can use improv to work through how to have difficult conversations regarding lack of compliance with isolation precautions. TRIZ requires staff to design a system to achieve the exact opposite of what they hope to achieve. For example, if the group is trying to control the spread of superbugs, they are asked to list the ways that they could spread superbugs to all patients. This typically proves that the group knows exactly how superbugs are spread and hence knowledge is not the issue; and it allows them to see that many of their current actions actually contribute to bad outcomes.

Other PD tools include appreciative inquiry, focus groups and social network mapping.   In keeping with PD's underlying theory of complex adaptive systems, tools and approaches are applied based on 'emergent design.' That is, choices are made along the way to use certain tools in certain ways based on local conditions, not according to a pre-set plan.

The improvement work is "characterized by individuals who can learn, interconnect, self-organize, and co-evolve with their environment in non-linear and dynamic ways."[33] The fact that there is no pre-conceived implementation "road map" is often challenging for new teams that are used to more traditional best-practice approaches.

While PD in healthcare is somewhat new, there are positive results shown in reducing methicillin resistant staphylococcus aureus (MRSA) and other hospital-acquired infections (HAIs), improving smoking cessation, and improving hand hygiene for example. PD appears best applied to complex, hard-to-solve problems that are deeply rooted in culture.[34] Emerging evidence suggests "PD is a powerful technique that can help change healthcare worker actions and, later, the prevalent culture… Likely a key factor contributing to success is that the ideas and actions come from the people who are touching the problem."[35]

> "PD is messy, relationship focused and, on the surface, appears uncontrolled; but this is what one would expect of an effective strategy for a complex problem."[35]

E. Seven (to Eleven) Step Problem Solving Models

Particularly with the advent of Total Quality Management (TQM) a number of problem-solving frameworks have been developed and deployed. Some models focus more on removing problems, while others concentrate on improving design or re-design of products or services. While they differ in detail, in general these frameworks include a logical progression of steps including:

1. **Define problem, purpose, goals or scope**
   This step helps to establish the 'target,' in what way it may be important to the organization, what boundaries will define the effort, and may include improvement goals, team selection and initial plans;

2. **Review current situation**
   This step is to establish current knowledge – what is known about the problem or effort. Often includes history, contextual issues and data on current performance;

3. **Analyze causes**
   This is the study part of the model. May include root-cause-analysis, cause-and-effect diagrams or other tools to help identify the source of current problems or the causes thought to influence design or re-design;

4. **Develop potential solutions**

   This is the design phase, where potential solutions are developed for future testing and implementation. Often, creativity tools, change concepts or known solutions from other environments are applied;

5. **Apply solutions**

   This is the "do" step where potential solutions are tested and then implemented. The step may include the use of prototypes, simulations or other test methods and various deployment, communication and engagement methods;

6. **Measure results**

   This check is to see if expected results are occurring;

7. **Adjust**

   This is to make changes to the solution in order that it better resolve the problem or accomplish the goal;

8. **Standardize**

   This is to establish permanency of the solution. This may include more formal documentation, training, communication and standard setting as appropriate;

9. **Continue to improve**

   This step suggests continued monitoring of outcomes with an aim to improve in the future.

While the steps are listed in sequence, in practice there are often iterations between steps to reflect what is being learned with adjustments along the way as required. Step-model frameworks attempt to balance the need for structure with action.

F. Lean Improvement

Lean is the practical application of systems thinking to the improvement of production or productive processes. It combines this thinking with a set of principles, tools and techniques focused on reducing complexity in the production stream. Activities that don't add value are eliminated. Bottlenecks and other constraints on process flow are likewise taken out of the process to produce a smooth process flow. The result is reduced cycles times, increased inventory turns, simplified and streamlined processes that work faster.

Lean was first defined by James Womack and Daniel Jones in their landmark study describing the Toyota Production System (TPS), the model for Lean.[36] Since then, Lean has been extended to Lean Enterprise that applies Lean to all areas of organizational functioning from accounting to manufacturing to shipping and from the factory floor to the head-office boardroom. More recently it has been applied in service industries and healthcare.

Lean has evolved to become a comprehensive management system and philosophy. It is perhaps most easily understood as a rigorous effort at eliminating all forms of waste in the enterprise.[36]

There are five key focus areas identified in Lean: [37]

- Value – defined from the customer's perspective;

- Value streams – activities to provide customers a product or service;

- Flow – making the value added steps flow smoothly;

- Pull – having customers 'pull' the product or service when needed;

- Perfection – everyone in the organization is pursuing perfection.

There are a number of tools and techniques associated with these activities, including value-stream mapping, Just-In-Time (JIT) production, Kanban (signal card) system, Five S's approach (sort, straighten, sweep/shine, standardize, sustain) and the Eight Forms of Waste (overproduction, waiting, transportation, non-value-added processing, inventory, underutilizing people, defects and motion). A helpful resource with additional information about the "Top 25 Lean Tools" is available at: http://www.leanproduction.com/top-25-lean-tools.html

A challenge in healthcare is to understand under what conditions these helpful tools and practices from manufacturing may be successfully applied. A pre-requisite is to understand the change required to a 'systems-thinking' perspective. This foundation helped lead to the initial development of Lean tools and approaches. Within Canada the jurisdiction with the broadest application of Lean tools looks to be the Saskatchewan healthcare system. Further information about these efforts is available at: http://hqc.sk.ca/improve-health-care-quality/lean/

The Lean framework appears to be helpful in healthcare when the focus is on removing the causes of waste in all its forms and adding valuing from the patient's perspective. It is not as effective when used as a framework aimed at simply cutting cost or to increase standardization in a command and control management system.

For a further perspective about the Model for Improvement and Lean see *Comparing Lean and Quality Improvement. IHI Whitepaper, 2014.* [38]

G. Six-Sigma (DMAIC, DFSS and Lean Six-Sigma)

Six-Sigma is a framework originating in North American industry (Motorola) and was built with a focus to reduce variation using statistical approaches. The framework itself varies somewhat although usually it is characterized by five steps: define, measure, analyze, improve, and control (DMAIC). More recently it has included design for six-sigma (DFSS). A popular variant of this approach is define, measure, analyze, design, verify (DMADV). [22]

Six-Sigma has "moved from a statistical measure to a management system" in the form of *managing for Six Sigma* (MFSS). [18] Six-sigma now may now also include Lean tools within the Six-Sigma framework (Lean Six-Sigma). The aim is to include tools to reduce variation and add value to customers (Lean) within a project structure (Six-Sigma; most often within the DMAIC model).

Six-Sigma uses a variety of statistical tools, nearly always enumerative in design,[39] to describe process performance with a focus on the reduction of defects. There is an underlying assumption of "we can't improve what we don't measure".[4] Tools may include histograms, capability indices, and defects per million (DPM) or defects per million opportunity (DPMO) measures. Six-Sigma may also include the use of other quality approaches; quality function deployment (QFD), failure modes and effects analysis (FMEA), benchmarking and design of experiments (DOE), for example.

Six-Sigma is based on the aim of achieving 3.4 DPMO – also known as Six-Sigma quality or Six-Sigma capable. This DPMO rate is based on 4.5 sigma with a drift in the process mean of 1.5 sigma. Interestingly, a process with a shifting mean is said to be unstable (unpredictable) and therefore to have no measureable capability.[19] Additionally, Six-Sigma fails to differentiate between enumerative studies and analytic studies. [40, 41]

Six-Sigma has been an effective approach for engaging senior leadership support and is often led from the 'top' of the organization with substantial resources assigned to the effort. While it is somewhat limited by being a specification driven approach to improvement[4] there are numerous examples of success by organizations that have relied on a Six-Sigma framework.

H. Quality Function Deployment (QFD)

QFD is a comprehensive quality system that systematically links the needs of the customer with various business functions and organizational processes, aligning the entire organization toward achieving a common goal. It does so by seeking both spoken and unspoken needs, identifying positive quality and business opportunities, and translating these into actions and designs by using transparent analytic and prioritization methods, empowering organizations to exceed normal expectations and provide a level of unanticipated excitement that generates value.[42]

Supporting theory and practices:

- Understanding customer requirements;

- Quality systems thinking, psychology and knowledge/epistemology;

- Maximizing positive quality that adds value;

- Comprehensive quality system for customer satisfaction;

- Strategy to stay ahead of the game.

QFD has its roots in manufacturing although there are numerous examples of its successful application in service industries and healthcare.

I. Social Marketing

Social marketing is the use of marketing principles and techniques to influence a target audience to voluntarily accept, reject, modify, or abandon behaviour for the benefit of individuals, groups, or society as a whole.[43] Much of what is called "social marketing" by practitioners and academics is not marketing, however, because neither products nor services are developed, distributed, or promoted. Rather, most of what is referred to as social marketing in public health involves exclusively the provision of information, and is therefore more correctly characterized as communication.[44]

Some key concepts of social marketing include design or redesign of products, services or programs, behaviour change, audience and market segmentation, analysis of competition, using a mix of deployment methods and the principles of diffusion of innovation. It is suggested the following actions should be included in the framework for social marketing:[45]

- Establish specific (end-state) behavioural objectives;

- Conduct formative research (benefits, barriers, key influencers, etc.);

- Employ segmentation and targeting;

- Consider competition;

- Employ product, price, place strategies (to increase benefits and reduce barriers);

- Refer to formative research to position the behaviour, craft simple and relevant messages, and select channels;

- Ensure frequency (e.g., prompts) and duration of message delivery;

- Establish partnerships;

- Monitor and evaluate (adjust accordingly);

- Be in it for the long run.

A number of studies show that behaviour change rarely occurs as a result of simply providing information. Behaviour change is most effectively achieved through initiatives which focus on removing barriers to an activity while simultaneously enhancing the activities benefits.[46] Social marketing has been shown to be an effective framework to support these tasks. [47]

J. Highly Adoptable Improvement (HAI)

Highly Adoptable Improvement (HAI)[48] is a new framework developed by Dr. Chris Hayes during his fellowship year at the Institute for Healthcare Improvement (IHI). Its intent is to help assure that any initially selected improvement initiative will have a high chance of success.

The approach is to carefully assess the overall **time demands** and **complexity** of changes to work processes created because of a proposed improvement initiative. Then the changes in

total demand and the **perceived value** of the change are reviewed in combination to determine which improvement initiatives may be considered for action.

The aim is to make explicit the potential increased work demands and the value an individual/organization may gain as a result of a proposed improvement.

Change initiatives that don't add to the workload and have high perceived value are more likely to be adopted, cause less workplace burnout, and achieve the intended outcomes. That's the hypothesis behind "highly adoptable improvement."[49]

Figure 13: Workload and Perceived Value


Source: http://www.highlyadoptableqi.com/background.html
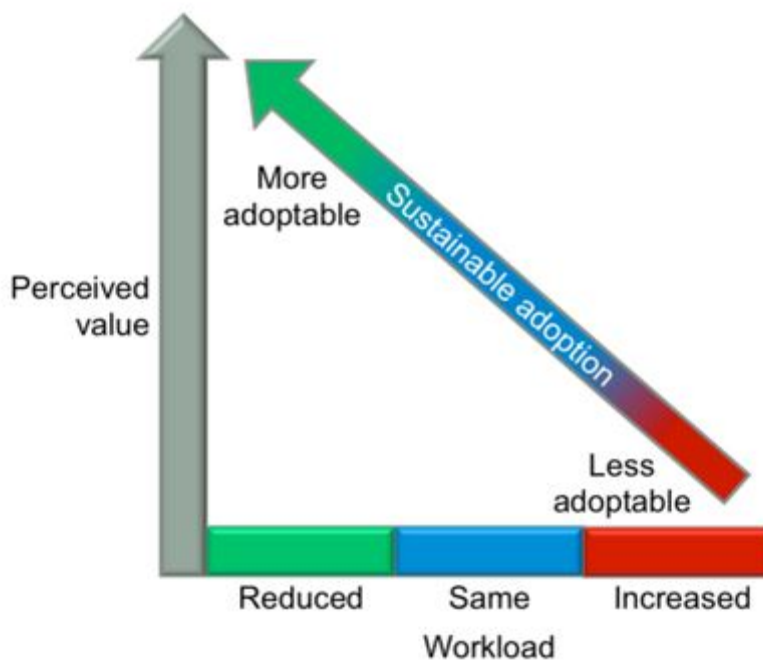
"The diagram depicts that the design of the intervention and the mechanisms by which it is implemented directly contribute to the balance between workload/ capacity and perceived value. If the balance equates to more workload/ less capacity and less perceived value [red path] then the results are more likely to favor burnout, cynicism and workarounds, and less likely to produce the intended results. This will create a negative feedback on the recipients of change and result in decreased perceived value and capacity that will create resistance to ongoing change. If the balance favors less workload/ more capacity and higher perceived value [green path] then the likelihood of adoption and incorporation is greater as is the achievement of the intended outcomes. This creates positive feedback that increases perceived value and capacity and decreases resistance to further change.

The model is not aimed to diminish the importance of or replace other known contextual success factors (supportive leadership, positive culture, data systems etc.) The model is intended to place greater emphasis on the impact of change initiatives on the recipients of change."[48]

Figure 14: Highly Adoptable Improvement Model

Source: http://www.highlyadoptableqi.com/model.html
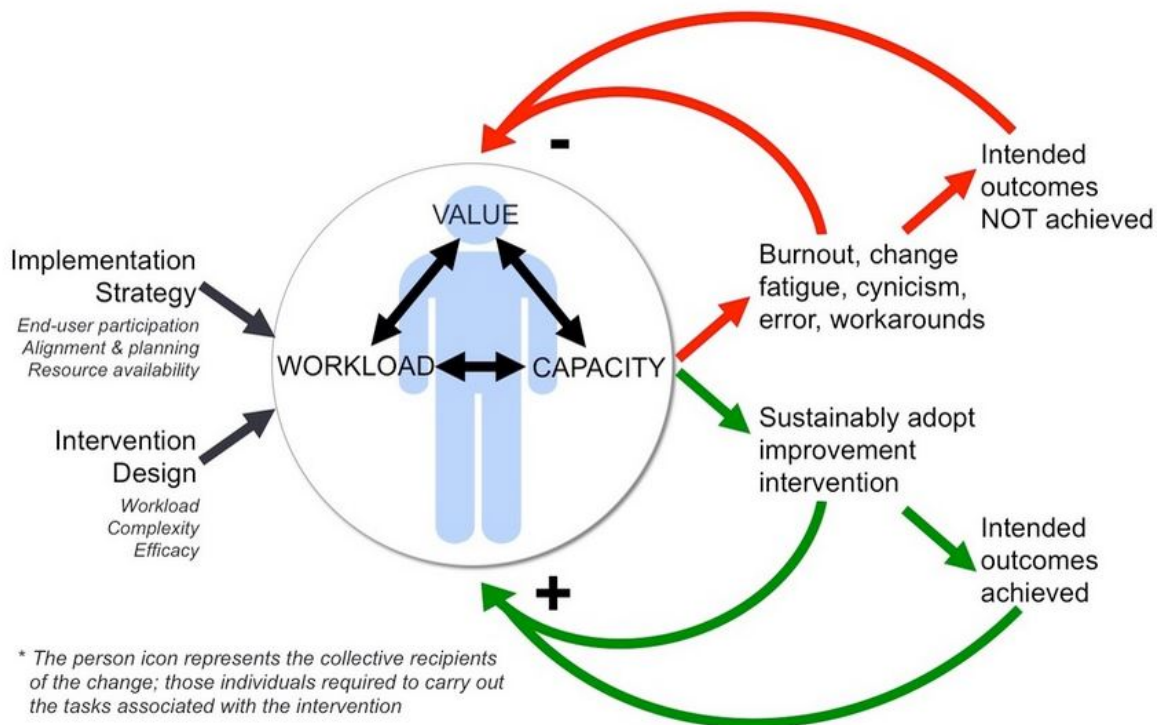
"… given the importance of workload and perceived value, improvement initiatives that do not add additional workload (or reduce workload) and have high perceived value are more likely to be sustainably adopted, cause less workplace burden and, achieve the intended outcomes."[48]

The model is intended "to help guide the development and implementation of an improvement initiative."[48] HAI may be used in conjunction with any of the well-known frameworks described previously in this Guide.

The model includes well-developed support tools including an Assessment Guide and Worksheets, Suggested Actions and Tools, and a Case Study. These are available at: http://www.highlyadoptableqi.com/guide.html

Improvement Frameworks – Conclusion

Back to the beginning - the primary framework which is followed within the *Safer Healthcare Now!* interventions is the Model for Improvement.[2] It has proven to be an extremely effective approach and is robust under a variety of conditions. It is grounded in the scientific method, provides a basis for real-world learning by doing, and is readily accessible to most who seek improvement.

Additional improvement frameworks have also proven to be effective under a variety of circumstances.

In all cases, there remains opportunity to continue to improve the frameworks themselves through thoughtful action guided by knowledge. The journey continues.

> "You cannot cross the sea merely by standing and staring at the water."
>
> *- R. Tagore*

Appendices

Appendix A – Enumerative and Analytic Studies

The important distinction between Enumerative and Analytic Studies is paramount in the science of improvement. For this reason a substantive quote from Lloyd Provost's excellent paper entitled "Analytical studies: a framework for quality improvement design and analysis" follows.[50]

The full paper is available at: Provost - Analytical Studies - BMJ 2011

Abstract

Conducting studies for learning is fundamental to improvement. Deming emphasised that the reason for conducting a study is to provide a basis for action on the system of interest. He classified studies into two types depending on the intended target for action. An enumerative study is one in which action will be taken on the universe that was studied. An analytical study is one in which action will be taken on a cause system to improve the future performance of the system of interest. The aim of an enumerative study is estimation, while an analytical study focuses on prediction. Because of the temporal nature of improvement, the theory and methods for analytical studies are a critical component of the science of improvement.

## Introduction: enumerative and analytical studies

Designing studies that make it possible to learn from experience and take action to improve future performance is an essential element of quality improvement. These studies use the now traditional theory established through the work of Fisher,[1] Cox,[2] Campbell and Stanley,[3] and others that is widely used in biomedicine research. These designs are used to discover new phenomena that lead to hypothesis generation, and to explore causal mechanisms,[4] as well as to evaluate efficacy and effectiveness. They include observational, retrospective, prospective, pre-experimental, quasiexperimental, blocking, factorial and time-series designs.

In addition to these classifications of studies, Deming[5] defined a distinction between analytical and enumerative studies which has proven to be fundamental to the science of improvement. Deming based his insight on the distinction between these two approaches that Walter Shewhart had made in 1939 as he helped develop measurement strategies for the then-emerging science of 'quality control.'[6] The difference between the two concepts lies in the extrapolation of the results that is intended, and in the target for action based on the inferences that are drawn.

A useful way to appreciate that difference is to contrast the inferences that can be made about the water sampled from two different natural sources (Figure 13). The enumerative approach is like the study of water from a pond. Because conditions in the bounded universe of the pond are essentially static over time, analyses of random samples taken from the pond at a given time can be used to estimate the makeup of the entire pond.

Statistical methods, such as hypothesis testing and CIs, can be used to make decisions and define the precision of the estimates.

Figure 15: Environment in Enumerative and Analytical Study

Environment in enumerative and analytical study.
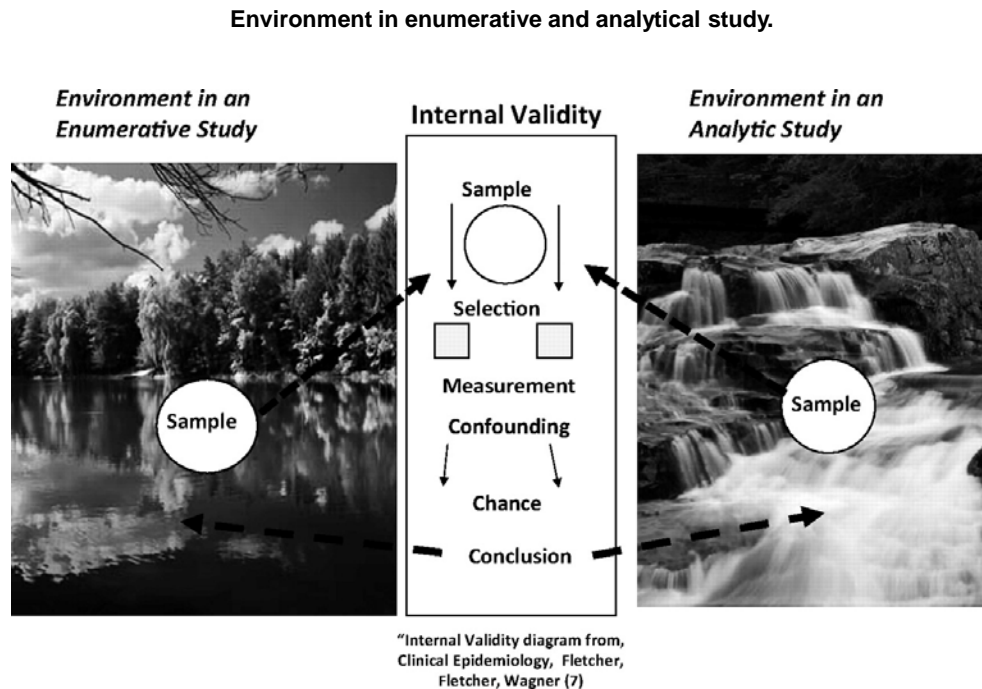
Source: Provost, Lloyd Analytical studies: a framework for quality improvement design and analysis"

The analytical approach, in contrast, is like the study of water from a river. The river is constantly moving, and its physical properties are changing (e.g., due to snow melt, changes in rainfall, dumping of pollutants). The properties of water in a sample from the river at any given time may not describe the river after the samples are taken and analysed. In fact, without repeated sampling over time, it is difficult to make predictions about water quality, since the river will not be the same river in the future as it was at the time of the sampling.

Deming first discussed these concepts in a 1942 paper,[8] as well as in his 1950 textbook,[9] and in a 1975 paper used the enumerative/analytical terminology to characterise specific study designs.[5] While most books on experimental design describe methods for the design and analysis of enumerative studies, Moen et al[10] describe methods for designing and learning from analytical studies. These methods are graphical and focus on prediction of future performance. The concept of analytical studies became a key element in Deming's 'system of profound knowledge' that serves as the intellectual foundation for improvement science.[11]

The knowledge framework for the science of improvement, which combines elements of psychology, the Shewhart view of variation, the concept of systems, and the theory of knowledge, informs a number of key principles for the design and analysis of improvement studies:

- Knowledge about improvement begins and ends in experimental data but does not end in the data in which it begins.

- Observations, by themselves, do not constitute knowledge.

- Prediction requires theory regarding mechanisms of change and understanding of context.

- Random sampling from a population or universe (assumed by most statistical methods) is not possible when the population of interest is in the future.

- The conditions during studies for improvement will be different from the conditions under which the results will be used. The major source of uncertainty concerning their use is the difficulty of extrapolating study results to different contexts and under different conditions in the future.

- The wider the range of conditions included in an improvement study, the greater the degree of belief in the validity and generalisation of the conclusions.

The classification of studies into enumerative and analytical categories depends on the intended target for action as the result of the study:

- Enumerative studies assume that when actions are taken as the result of a study, they will be taken on the material in the study population or 'frame' that was sampled.

  More specifically, the study universe in an enumerative study is the bounded group of items (e.g., patients, clinics, providers, etc.) possessing certain properties of interest. The universe is defined by a frame, a list of identifiable, tangible units that may be sampled and studied. Random selection methods are assumed in the statistical methods used for estimation, decision-making and drawing inferences in enumerative studies. Their aim is estimation about some aspect of the frame (such as a description, comparison or the existence of a cause–effect relationship) and the resulting actions taken on this particular frame. One feature of an enumerative study is that a 100 per cent sample of the frame provides the complete answer to the questions posed by the study (given the methods of investigation and measurement). Statistical methods such as hypothesis tests, CIs and probability statements are appropriate to analyse and report data from enumerative studies. Estimating the infection rate in an intensive care unit for the last month is an example of a simple enumerative study.

- Analytical studies assume that the actions taken as a result of the study will be on the process or causal system that produced the frame studied, rather than the initial frame itself. The aim is to improve future performance.

In contrast to enumerative studies, an analytical study accepts as a given that when actions are taken on a system based on the results of a study, the conditions in that system will inevitably have changed. The aim of an analytical study is to enable prediction about how a change in a system will affect that system's future performance, or prediction as to which plans or strategies for future action on the system will be superior.

For example, the task may be to choose among several different treatments for future patients, methods of collecting information or procedures for cleaning an operating room. Because the population of interest is open and continually shifts over time, random samples from that population cannot be obtained in analytical studies, and traditional statistical methods are therefore not useful. Rather, graphical methods of analysis and summary of the repeated samples reveal the trajectory of system behaviour over time, making it possible to predict future behaviour. Use of a Shewhart control chart to monitor and create learning to reduce infection rates in an intensive care unit is an example of a simple analytical study.

(Additional examples excluded)

Discussion

Statistical theory in enumerative studies is used to describe the precision of estimates and the validity of hypotheses for the population studied. But since these statistical methods provide no support for extrapolation of the results outside the population that was studied, the subject experts must rely on their understanding of the mechanisms in place to extend results outside the population.

In analytical studies, the standard error of a statistic does not address the most important source of uncertainty, namely, the change in study conditions in the future. Although analytical studies need to take into account the uncertainty due to sampling, as in enumerative studies, the attributes of the study design and analysis of the data primarily deal with the uncertainty resulting from extrapolation to the future (generalisation to the conditions in future time periods). The methods used in analytical studies encourage the exploration of mechanisms through multifactor designs, contextual variables introduced through blocking and replication over time.

Prior stability of a system (as observed in graphic displays of repeated sampling over time, according to Shewhart's methods) increases belief in the results of an analytical study, but stable processes in the past do not guarantee constant system behaviour in the future. The next data point from the future is the most important on a graph of performance. Extrapolation of system behaviour to future times therefore still depends on input from subject experts who are familiar with mechanisms of the system of interest, as well as the important contextual issues. Generalisation is inherently difficult in all studies because 'whereas the problems of internal validity are solvable within the limits of the logic of probability statistics, the problems of external validity are not logically solvable in any neat, conclusive way'[3] (p. 17).

The diverse activities commonly referred to as healthcare improvement[12] are all designed to change the behaviour of systems over time, as reflected in the principle that 'not all change is improvement, but all improvement is change.' The conditions in the unbounded systems into which improvement interventions are introduced will therefore be different in the future from those in effect at the time the intervention is studied. Since the results of improvement studies are used to predict future system behaviour, such studies clearly belong to the Deming category of analytical studies. Quality improvement studies therefore need to incorporate repeated measurements over time, as well as testing under a wide range of conditions (2, 3 and 10). The 'gold standard' of analytical studies is satisfactory prediction over time.

Conclusions and recommendations

In light of these considerations, some important principles for drawing inferences from improvement studies include: [10]

1. The analysis of data, interpretation of that analysis and actions taken as a result of the study should be closely tied to the current knowledge of experts about mechanisms of change in the relevant area. They can often use the study to discover, understand and evaluate the underlying mechanisms.

2. The conditions of the study will be different from the future conditions under which the results will be used. Assessment by experts of the magnitude of this difference and its potential impact on future events should be an integral part of the interpretation of the results of the intervention.

3. Methods for the analysis of data should be almost exclusively graphical, with the aim of partitioning the data visually among the sources of variation present in the study. In reporting the results of an improvement project, authors should consider the following general guidelines for the analysis:

   - Show all the data before aggregation or summary.

   - Plot the outcome data in the order in which the tests of change were conducted and annotate with information on the interventions.

   - Use graphical displays to assess how much of the variation in the data can be explained by factors that were deliberately changed.

   - Rearrange and subgroup the data to study other sources of variation (background and contextual variables).

   - Summarise the results of the study with appropriate graphical displays.

Because these principles reflect the fundamental nature of improvement—taking action to change performance, over time, and under changing conditions—their application helps to bring clarity and rigour to improvement science.

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Appendix B - Improvement Charter[38]

Project Name:

Team Members: _____

_____

_____

Team Sponsor:

WHAT ARE WE TRYING TO ACCOMPLISH?	
	Purpose of Project
	Scope & Boundaries
	Improvement Objectives

	Measures	Current Performance	Goals
HOW WILL WE KNOW A CHANGE IS AN IMPROVEMENT?			

	Change Concepts and Ideas to Test
WHAT CHANGES CAN WE MAKE THAT WILL RESULT IN IMPROVEMENT?	

HOW WILL WE MANAGE THE IMPROVEMENT PROJECT?	Principles for Working Together
	Roles & Responsibilities
	Review Schedule
	Key Dates

Author:

Date:

Improvement Charter – Example

This example is based on an ICU Collaborative team and is modified to illustrate the key components of the Improvement Charter.

Project Name:	Implementing Medical Emergency Team – X Hospital
Team Members:	RN Coordinator, Respiratory Therapist, ICU Team Leader, Critical Care Nurse Manager, Nurse Educator, Intensivist, Ward Nurse, Project Manager, Health Records
Team Sponsor:	Director of Critical Care

> **Include frontline, multidisciplinary team of nurses, physicians, administrators and other allied health**

WHAT ARE WE TRYING TO ACCOMPLISH?

Purpose of Project

To provide earlier and more definitive management of unstable patients through direct and timely access to critical-care specialists.

Scope & Boundaries

Medical Inpatient Units initially. Expand scope as successes are demonstrated.

Improvement Objectives:

By March 2006:

Decrease cardiac arrests by 60%;

Reduce in-hosptial deaths from cardiac arrests by 10%;

Decrease ICU readmissions from participating units by 60%;

Continually improve MET response times;

Maintain or improve staff satisfaction with MET.

> **These aims are specific, concise and measurable. They include stretch goals and timelines**

HOW WILL WE KNOW A CHANGE IS AN IMPROVEMENT?	Outcome Measures:	Current Performance	Goals
	Codes per 1,000 discharges	20	8 or fewer
	Percentage of patients who died from cardiac arrests	50%	45% or less
	ICU Readmissions	TBD	Decrease
	Process Measures		
	MET response time	TBD	Less than 15 minutes
	MET calls/day	TBD	Increase
	Duration of MET visits	TBD	1 hour or less
	Balancing Measures:		
	Number of ICU bed-days occupied by survivors of cardiac arrests	TBD	Maintain or Improve
	Number of hospital bed-days occupied by survivors of cardiac arrests	TBD	Maintain or improve
	ICU Length of Stay	TBD	Maintain or improve
	Provider satisfaction with MET	TBD	100%

Focus on 2-6 useful measures.

Each aim and goal has an associated outcome measure. Every outcome measure is associated with an aim and goal.

Include balancing measures.

For each measure, make operational definitions explicit, including sampling plans

WHAT CHANGES CAN WE MAKE THAT WILL RESULT IN IMPROVEMENT?

Change Concepts and Ideas to Test

Provide education on MET

Provide MET case studies in easy-to-access manner

Develop educational posters

Develop the team

Draft roles and responsibilities for MET team members

Develop training and orientation manuals

Secure funding

Develop the process

Do mock calls

Create kits

Develop activation "pocket cards"

Test the activation system

Develop relationships

Talk to ward nurses

Talk to attending physicians

Conduct walking rounds on all affected floors to discuss nursing concerns.

List an initial set of ideas and/or change concepts to test.

HOW WILL WE MANAGE THE IMPROVEMENT PROJECT?

Principles for Working Together

Mutual respect

Honesty

Open Communication

Commitment from all team members to do PDSA cycles

Each team member to spend about 1-3 hours per week on testing and implementing changes.

Identify how the team will work together, how the responsibilities are to be divided and how the team will review their work.

Indicate important dates and timelines.

<u>Roles and Responsibilities</u>

Team Recruitment – Director

Data Collection and Run Charts – Project Manager

Communication – Nurse Educator

Documentation – Health Records Clerical Staff

Monthly Reports – Project Manager and entire team to draft, Director to review and sign off

Testing Cycles – All

Participation on Conference Calls – rotated among team members

<u>Review Schedule</u>

"Planning" and "Studying" (PDSA) stand-up meetings every week with core team

Review with project sponsor once a month.

Communicate with Regional Quality Council once a quarter.

Provide ongoing updates to senior management as required.

<u>Key Dates</u>

Conference Calls – every 2 weeks, starting Tuesday March 9th at 1:00 Central Time

Learning Session 2 – June in Winnipeg

Learning Session 3 – October in Ottawa

Author: MY NAME

Date: TODAY

Appendix C - PDSA Cycles[51]

The following worksheets can help improvement teams use the Model for Improvement.

Project Name:	**Cycle #:**

Objective of this Cycle:	

Start Date:	End Date:

PLAN	What change are we testing? What is our prediction and theory? Details of the plan (who, what, where, when and how) including data collection.
DO	Carry out the plan. Record data, observations and modifications to the plan. Use visual descriptions such as run charts.
STUDY	Complete analysis and synthesis. Do the results agree with the predictions? What new questions or issues arose? What are our updated theories? Under what conditions could the results be different? Summarize new knowledge.
ACT	What action are we going to take as a result of this cycle (Adopt, Adapt or Abandon)? Are we ready to implement? What other processes or systems might be affected by this change?
	Objective of Next Cycle(s):

PDSA Cycles – Example

This example is based on an ICU Collaborative team and is modified to illustrate the key components of the PDSA Cycle.

Project Name:	Central Line Infections Team – X Hospital	Cycle #: 1.1

Objective of this Cycle:	Test process and form for implementing daily goals

PLAN	What change are we testing? What is our prediction and theory? Details of the plan (who, what, where, when and how). **Change Concept:** Use daily goals **Specific Idea:** Use a Daily Goals sheet with specific questions **Predict:** ICU team will find the sheet and questions useful. Use of a daily goals sheet and associated questions will improve rounds by providing a consistent, reliable and focused approach. **Theory:** It forms the basis for communication. It is visual and allows all ICU staff to actively participate in rounds. **Details of Plan:** **Who:** MK developed the rounds daily goals sheet test. TM and JP reviewed it and modified (mini-PDSA!) **What:** Sheet and questions **Where:** One patient bedside **When:** Monday morning **How:** MK would lead rounds and use the goals sheet to direct the discussion. For the first PDSA Cycle, the staff would be unaware that we were doing this. Rely on qualitative data to start (ask staff what they thought).

> **Identify specific idea that is being tested.**
>
> **Data collection alone is not a PDSA, but part of DO and STUDY.**

DO	**Carry out the plan**. Record data and observations. The sheet was on top of the rounds cart and individuals were aware that a new sheet was present and somewhat curious. Rounds were conducted in the same format except the random selection of the 6th bedside. At the end of the 6th bedside, several comments were made by the team members to JP who was standing on the periphery recording observations and comments. The flow of rounds was essentially the same but several key areas were reviewed that are not normally part of the rounds process.
STUDY	Complete analysis and synthesis. Do the results agree with the predictions? Under what conditions could the results be different? Summarize new knowledge. The flow was positive with no increase in time. Several key areas were discussed, especially safety, discharge, medications and more detailed goals for the next 24 hours. Two team members noted the difference in the rounds and stated that they wished this could be done at all bedsides. The one resident did not notice a difference and another felt he now knows the details of the plan and what to anticipate for the next 12 hours. This test was made to look very easy as MK was skilled in his delivery and led the elements in a non-irritating manner. A concern was expressed that this could be considered 'just another sheet' and would in fact lengthen rounds. The technique and style could be very different depending on the expertise of the attending physician and the style in which they conduct rounds. There is an added benefit of including a sheet in rounds. It will require team buy-in and could be adapted depending on the attending physician's style. It also posed several more questions: How will we document this? Do we review the list at the end? Is it part of the chart? What is the best way to communicate? Revisions could be made to the initial sheet to simplify it and ask all the questions in the same manner.

> Identify what was learned, especially when results did not agree with predictions. There is no such thing as a "failed test".
>
> Look for additional conditions under which to test the change. Try to make the change fail for

ACT	What action are we going to take as a result of this cycle (Adopt, Adapt or Abandon)? Are we ready to implement? What other processes or systems might be affected by this change? Adapt and continue testing. Consider documentation requirements and follow-up.
	Objective of Next Cycles: **PDSA 1.2** - Revise sheet and questions. Test it again with half of the bedsides with MK on Wednesday. **PDSA 1.3** - Test an educational approach for the sheet for the staff on that shift. **PDSA 1.4** – Test revised sheet with another attending physician next week.

Look a couple of cycles ahead

Connect this cycle with future PDSA Cycles

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