SIX SIGMA AND ITS APPLICATION TO HEALTHCARE

A CASE STUDY

The Application of Six Sigma Strategies to Medication Administration.

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NB: Before beginning - many of the examples here could have been improved with a modern information technology systems. At the time of the project that option was not available. Indeed, the IT human habit interface is proving to be a major barrier to deploying strategies such as computerized physician order entry systems. Many hospital systems have repeatedly delayed their deployment and some have temporarily stopped their deployment. The purpose of the example is to show the tools of Six Sigma can be used.

INTRODUCTORY COMMENTS

It is hardly news to anyone that the healthcare system in the U.S. is a mess. Consumers complain about the lack of choice, payers about high cost and a stream of horror stories about medical errors in the national and local media have made everyone anxious about safety.

Hospitals as Systems: Systems always produce results that are consistent with their underlying structure not with the expectations we have for a system. On close inspection hospitals as systems are woefully inefficient and inadequate relative to what we expect from them and they are unlikely to met community expectations until at lease four fundamental changes occur.

First, hospitals must become more visible and understandable to the community to create public accountability. Hospitals and medical groups performance has been cloaked in secrecy rendering performance invisible to outsiders.   Current consumers have much more access to cost, performance and reliability data on automobiles, computers and home appliance than they do the healthcare services.

Second, hospitals and physicians must use the latest scientific evidence as the basis of their practices. This may sound strange as we think of medicine as a science, but studies not that long ago show that 80% of what is done in medicine is done out of tradition not science. (1,2,3)

Third, hospitals and physician groups must use up-to-date quality improvement and error reduction methods.   Hospitals and physicians often see themselves on the cutting edge of science in the application of technology but, in fact, they have been consistently a full ten years behind manufacturing in adopting the tools for quality and error reduction. (4)

Finally, consumers of healthcare services must share in more of the initial financial risk in order to have a greater economic voice in the marketplace. Consumers need to be able to reward and penalize sellers of insurance and healthcare services based on what they offer and what they deliver in a way that matters to sellers, in dollars.

The Path: The path out of the current crises that affect hospitals is pretty clear.

- The technical know-how to deal effectively with the crises affecting hospitals today already exist in other social spaces
- The major barrier to incorporating that know-how is our own biology – our individual and collective inertias and mental maps which are inconsistent with how our brains work
- Catalysts (quality tools and information technology processes) to overcome this inertia have already evolved in other industries
- The path will require the application of science and the use of the tools and information technology to design hospital processes that are customer-focused for the delivery of services and management practices that are systems-based.

Some people in healthcare might say you do not understand, "Hospitals and healthcare are much more complex than making widgets." The strategies used in manufacturing do not apply to hospitals.   Yes and no. Yes in that hospital

services are very complex and involve life and death matters. No in that even the most complex properties of human social organizations are generated and ordered by the communication and the coordination of actions on a person-to-person level.

In medicine we typically characterize the body as a system by its structural components (anatomy), the relation of the parts (physiology), the generation and exchange of energy and value (biochemistry) and it relation to the environment (ecology). It is true that we may not be able to anticipate the future structure of the hospital nor its ecological relationship to its community, however, the relations of its parts and the generation and exchange of value will be the same as those in manufacturing just as they are similar between man and other mammals. We share 99% of our DNA in common with the mouse yet our anatomical structure and our social capacities are quite different.

It is exactly because healthcare is complex that tools and processes are required. This particular project applied the strategies, tools and statistical methods of Six Sigma to improve the medication administration process.

INTRODUCTION AND DEFINE

Problem Identification: Ongoing quality monitoring indicated several functions in the medication administration process were not conforming to specifications. First, verbal medication orders were not being signed by the prescribing physician within 48 hours as required by regulation.

Second, the number of adverse drug events identified was several-fold lower than what is in the literature suggesting that the system to identify adverse drug events and the errors that lead to them was ineffective.

Third, there was incomplete documentation of pre-and post-pain levels by the nursing staff when administering pain-relieving medications. Fourth, key vital signs were not routinely documented before administering a powerful cardiovascular medication is a standard practice in hospitals.

Fifth, a two-week event that encouraged all employees to identify breakdowns or concerns encountered in services that, if addressed, would improve hospital and

staff performance identified problems in the medication delivery system as one of the top three problem-plagued processes.

Finally, as everyone is now aware, the Institute of Medicine report suggested hospital errors may kill 98,000 people per year and 25% of those that are preventable are related to medication administration.

Scope: The project included the medication administration system from the time an order was written by the physician through the patient's response to the administration of the medication. Sub-processes included ordering, filling, delivery, dispensing, evaluation of the patient's response and evaluation of organizational effectiveness in monitoring the process.

Goals and Measures: The project would evaluate the six measures suggested by the Institute of Medicine, timeliness, effectiveness, efficacy, safety, patient satisfaction and equitable distribution of resources with the goal of reducing cost and improving reliability.

Project Team: The project team included the CEO, the Medical Director, a staff pharmacist, the Director of Quality Management, two registered nurses, the Admissions Manager, the Accounting Manager, the Director of Clinical Services and a Registered Dietitian.

Training: During the previous six months the members of the team had been trained along with all department managers and supervisors in the use of the basic quality tools, definitions of errors and principles of Lean manufacturing and Six Sigma. In addition, all had been engaged in a process improvement project using DMAIC. This team was given additional "just in time" training preceding each step of the process.

DEFINE (continued)

A SIPOC map (suppliers, inputs, processes, outputs and customers) was completed to identify customers, stakeholders, key inputs, processes and key outputs (Figure 1). The primary purpose of the system is to translate physician orders into therapeutic interventions in a safe and effective way.

Medication Administration System

System Scope: Medication selection through patient response to medications

SIPOC PROCESS MAP:

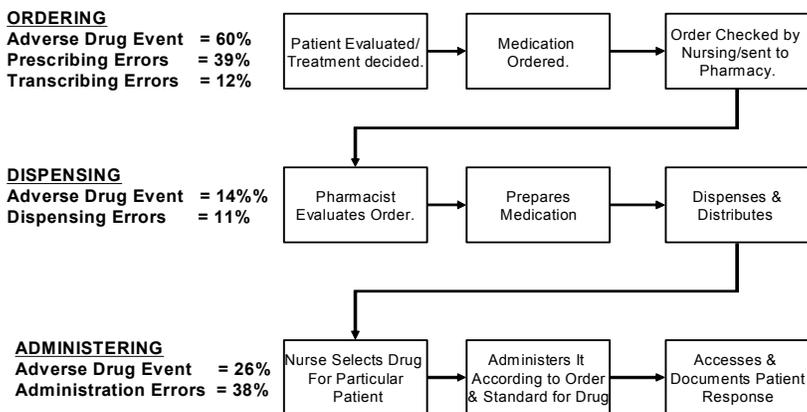| SUPPLIERS	INPUTS	PROCESS	OUTPUTS	CUSTOMERS
•Sun Script	•Patients	•Selecting	•Relive of symptoms	•Compliance agencies
•Referring	•Completed order	•Ordering	•treatment of condition	•Physicians
Hospitals	•Medication	•Filling	•error free	•Patients
•MDs		•Delivering		•Insurers
•Insurers		•Dispensing		•Referring facilities
		•Evaluating		
		•		

Know Problems

**High cost etc pharmacy costs plus costs of labor – nursing, unit
   secretary, night supervisors & Pharmacy $ - 23% non fixed costs
Lack of effective ADE reporting system (regulatory requirement)
Incomplete narcotic medication and delivery and response documentation
   (regularity requirement, previously cited deficiency)
Inadequate documentation of patient parameters with critical medications
Failure to get all phone orders signed by MD with 48% hours**

Figure 5 (M105)

A detailed process map was developed by the team and identified 67 unique steps
with a minimum of 35 steps needed from the time the order was written to the
evaluation of the patient's response to the medication.

MEDICATION ADMINISTRATION

ORDERING
Adverse Drug Event = 60%
Prescribing Errors = 39%
Transcribing Errors = 12%

Patient Evaluated/ Treatment decided. → Medication Ordered. → Order Checked by Nursing/sent to Pharmacy.

DISPENSING
Adverse Drug Event = 14%%
Dispensing Errors = 11%

Pharmacist Evaluates Order. → Prepares Medication → Dispenses & Distributes

ADMINISTERING
Adverse Drug Event = 26%
Administration Errors = 38%

Nurse Selects Drug For Particular Patient → Administers It According to Order & Standard for Drug → Accesses & Documents Patient Response

Bates et al., JAMA 1995;274:29-34
Leape et al., JAMA 1995
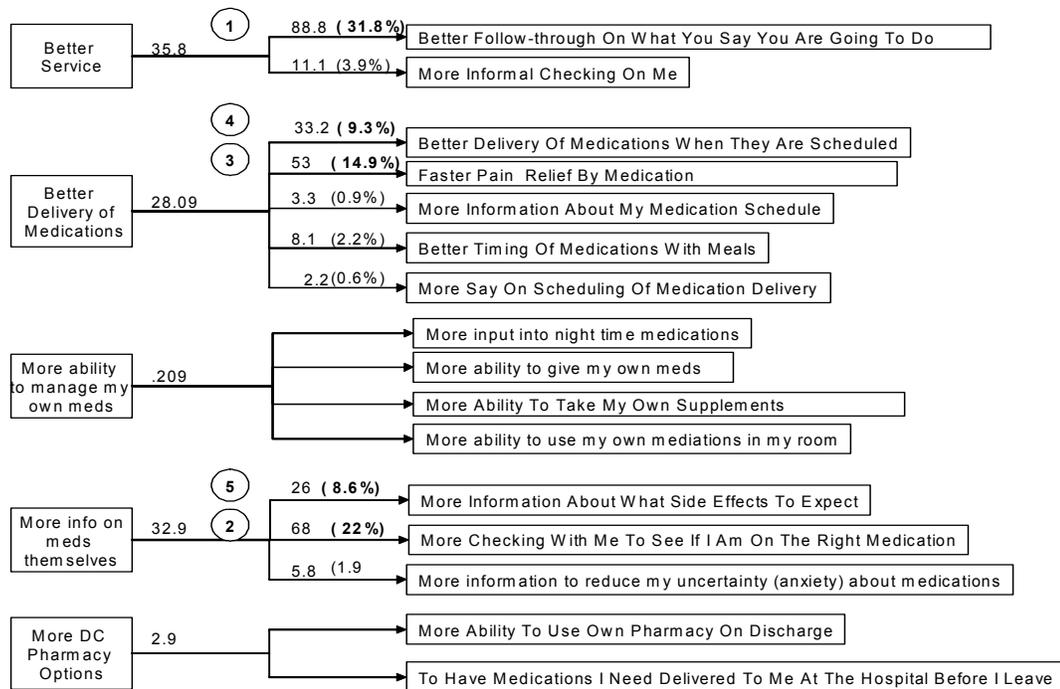*Classen et al JAMA 1997*

Figure 9 M105

The detailed steps were grouped into categories of prescribing, transcribing, dispensing, administration and follow-up (Figure 2). The percentage of medication errors and adverse drug events from three major articles in the literature for each of these segments was collated and reviewed by the team.

A time study was carried out and it indicated that 23-25% of non-fixed operating costs were related to medication administration.

The define phase included capturing the Voice of the Customer. The Voice of the Customer and the tools of Quality Function Deployment (see Reference 4, Chaplin and Terninko).

To capture the Voice of the Customer, six patients were interviewed. Sixteen unique items or demanded qualities were identified . We then had the patients, using affinity process, group these.   They grouped them into three major categories. The patients then ranked these using the Analytical Hierarchy Process (AHP – a pairwise comparison method) and the relative weights of the sixteen demanded qualities were determined (4).

Better Service	35.8	① 88.8 (31.8 %)	Better Follow-through On What You Say You Are Going To Do
		11.1 (3.9%)	More Informal Checking On Me
Better Delivery of Medications	28.09	④ 33.2 (9.3 %)	Better Delivery Of Medications When They Are Scheduled
		③ 53 (14.9 %)	Faster Pain Relief By Medication
		3.3 (0.9%)	More Information About My Medication Schedule
		8.1 (2.2%)	Better Timing Of Medications With Meals
		2.2(0.6%)	More Say On Scheduling Of Medication Delivery
More ability to manage my own meds	.209		More input into night time medications
			More ability to give my own meds
			More Ability To Take My Own Supplements
			More ability to use my own mediations in my room
More info on meds themselves	32.9	⑤ 26 (8.6 %)	More Information About What Side Effects To Expect
		② 68 (22 %)	More Checking With Me To See If I Am On The Right Medication
		5.8 (1.9	More information to reduce my uncertainty (anxiety) about medications
More DC Pharmacy Options	2.9		More Ability To Use Own Pharmacy On Discharge
			To Have Medications I Need Delivered To Me At The Hospital Before I Leave

Based on these results, five were selected for further evaluation.

1. Better follow-through on what you say you are going to do (41.8% of weight)
2. More checking with patient to see if they are on the right medication (22% of weight)
3. Faster pain relief (14.9% of weight)
4. Better delivery of medications when they are scheduled (9.3% of weight)
5. More information about what the side effects are of medications (8.6% of weight)

These five demanded qualities and their relative weights were entered them into a Demanded Qualities/Performance Measure Matrix (aka the House of Quality). The team then brainstormed a number of potential performance measures that could be used to determine whether we were meeting these demanded qualities. The team then ranked each performance measure relative to Demanded Qualities by asking the question, "If you knew the results of this performance measure, how accurately would it predict patient satisfaction for a given demanded quality?" The weight of individual cells was then determined and the columns and the relative weights of the columns determined as described by Chaplin and Terninko in Customer Driven Healthcare, ASQ Press.   An abbreviated Demanded Qualities Performance matrix is shown below.
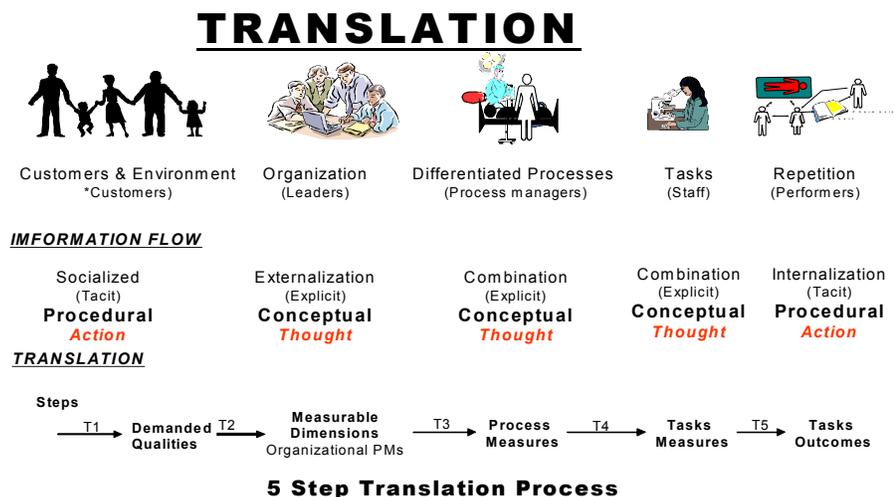
PERFORMANCE MEASURES

Legend:
- ● Strong
- ◑ Medium
- ○ Weak
- . None

DEMANDED QUALITIES	AHP WEIGHT	1. Time between request and response	2. Time to get a medication changed - patient request	3. # of routine meds missed on admission	4. % of pain medications delivered on time	5. % of pain resolved	6. Difference between medications due (schedule) and received	7. % of patients that know side effects all their meds	8. % of patient that know the side effects of new meds
A Better Follow-through On What You Say You Are Going To Do	31.8	○	●	◑	●	●	◑	○	◑
B More Checking With Me To See If I Am On The Right Medication	22			●					
C Faster Pain Relief By Medication	14.9	●	●	●	●	●	◑		◑
D Better Delivery Of Medications	9.3			◑	●	◑	●		
E More Information About What Side Effects To Expect	8.6							●	●
Column Weight	86.6	176	438	384	531	469	239	41.8	155	2434
% column weight		6.7	16.9	14.8	20.4	18.1	9.9	1.6	5.97	

The four most highly weighted measures were selected. These were:
1. Time go get a medication change (from patient request to receiving medication) (cycle time)
2. Number of routine medications missed on admission
3. Percentage of pain medications delivered on time
4. Percent of pain resolved

Many hospitals conduct patient satisfaction surveys. Yet on close inspection these are surveys about dissatisfaction with existing services. They are analytic in nature and refer to a performance gap in existing intentions. More recently leading hospitals have begun using focus groups and other strategies for identifying what customers want. However, the results have been meager. Why?

Do you remember as a child sitting in circle and one person whispers a sentence into the ear of the next person, and that person the next and so on? What was the result?   When this example of human-to-human communication is used in presentations to groups, many in the group invariably laugh as they recall such experiences. Yet this same phenomenon happens in hospitals every day. Translating what customers tell you in focus groups or incorporating the technical know-how from another social space into routine hospital practices is more easily conceptualized than actualized.

TRANSLATION

| Customers & Environment *Customers) | Organization (Leaders) | Differentiated Processes (Process managers) | Tasks (Staff) | Repetition (Performers) |

IMFORMATION FLOW

| Socialized (Tacit) **Procedural** *Action* | Externalization (Explicit) **Conceptual** *Thought* | Combination (Explicit) **Conceptual** *Thought* | Combination (Explicit) **Conceptual** *Thought* | Internalization (Tacit) **Procedural** *Action* |

TRANSLATION

Steps

T1 → Demanded Qualities → T2 → Measurable Dimensions / Organizational PMs → T3 → Process Measures → T4 → Tasks Measures → T5 → Tasks Outcomes

5 Step Translation Process

From Chaplin and Akao Quality progress; In Press

Capturing and translating either the voice of the customer or the lead user know-how and translating that knowledge into actions of individual hospital staff is a five-step translation process (4-7):

> T1   Tacit knowledge – the Voice of the Customer (or know-how from another industry) is translated into an explicit form – organizational targets.
>
> T2   The explicit voice of the customer is translated into an explicit voice of the organization – targets with measurable dimensions of targets – organizational performance measures.
>
> T3   Organizational performance measures are translated into targets and measures for key processes – process measures.
>
> T4   Processes measures are translated into explicit targets and measurements for critical tasks by staff – staff actions.
>
> T5   Staff targets – know-what – must be embodied into the day to day automatic behaviors of staff – become new tacit know-how – new habits.

Practices such as Quality Function Deployment and Lean User Strategies can identify and harvest tacit knowledge from customers or within existing social systems, externalize it and make it explicit (4-8). The new explicit knowledge is combined with knowledge within the existing organization and then re-internalized as tacit know-how that shows up in the day-to-day actions of people (6,9). Just like the game of telephone, each step is an opportunity for a breakdown in translation, a loss of voice, introduction of inefficiencies and unnecessary cost, and a chance for adverse outcomes and injury.

The whole process – from Voice of the Customer (or knowledge from another industry) through the necessary repetition to encode new habits - is only hypothesis about what is needed. Results must be monitored, the hypothesis confirmed, rejected or modified by sampling the effectiveness of the results – relative to patient/customer concerns.

MEASURES

In addition to the measures for patient demanded qualities noted above, eight additional process measures thought important to understand the current level of process function were identified:

1.   Number of night/weekend pharmacy entries (a regulatory issue)
2.   Number of adverse drug events
3.   Number of medication errors
4.   Frequency of incomplete documentation on necessary parameters (for all narcotics)
5.   Frequency of incomplete documentation for cardiovascular medications
6.   Frequency of delayed signing, dating and timing of verbal medication orders within 48 hours by prescribing physician
7.   Pre- and post-pain level checks

We separated the 11 measures into those that were Key Input Variables and those that were Key Output Variables.

Key Input Variables   Key Output Variables

Cycle time – for change medication
 # medication errors
Rate correct documentation
    Narcotics
    Cardiac medications
Pre & Post pain level checks
Rate of routine meds missed
Rate of pain meds on time

Process
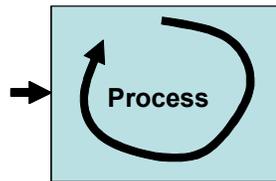
Rate Adverse Drug Events
% patients reporting
    adequate pain relief
 # night weekend pharmacy
    entries
Verbal meds orders time
    & dated within 48 hours

Data available to the team was reviewed. Findings included:

1.   40 % of the time either pre-pain medication administration levels or post-pain level checks were not present and there was wide variation – process was out of control
2.   There were almost daily discrepancies between the medication administration record that a narcotic was given and the narcotic sheet that a narcotic was dispensed – not compliant with regulations
3.   Verbal medication orders were dated and timed by the ordering physician within 48 hours only 40% of the time and there was wide variation – not conforming to regulations and process was out of control.

4. The number of adverse drug events being captured were far below that reported in the literature suggesting poor reporting methods (1/10,000 vs 1-2/1000)
5. Unnecessary night and weekend entries into the pharmacy by non-pharmacy personnel occurred on a daily basis.

Data was then prospectively collected over a 24 hour period for the 6 additional measures and the following was noted:

1. Key parameters were not routinely documented before giving cardiovascular medications
2. Cycle time from the time an order was written to delivered was an average 60 minutes – there was one outlier at 240 minutes, however, on further checking it became clear that the medication was ordered to be given at a later time – no further action was deemed necessary on this measure
3. During the sample time fifteen new medication orders were written, two of these had a potential for error, one the name of the order sheet was different from the chart and on the other the dose could possibly have been misinterpreted; the main discrepancy was caught before the order went to the pharmacy and the nurse called to clarify the dose before sending it to the pharmacy
4. Number of routine medications missed on admission. The team interviewed ten patients and in 3 routine medications they had been on at home had been missed on admission the acute hospital or transfer to our facility. When transferred to us from the acute hospital they were not ordered (95% of our patients are referred from other hospitals). In neither case were they on the transfer sheet. In both cases they had been overlooked on admission to the acute hospital.
5. Number of patients reporting satisfactory pain relief (pain $\leq$ 2 on a 10-point VAS). These were not recorded post-medication on 3 of 10 charts.
6. Pain medications prescribed to be given regularly were all given within 20 minutes of the time ordered (no further intervention).

Based on these observations, we decided to focus on six of the eleven measures. These included:

1. the percentage of verbal orders not signed and dated by the prescribing physician within 48 hours verbal medication orders (a regulatory requirement)
2. frequency of inadequate documentation of necessary vital signs before administering cardiovascular parameters (key input variable)
3. frequency of discrepancy between medication administration record and narcotics sheet (regulatory requirement)
4. number incomplete documentation pre- and post-pain levels
5. percentage of patients not reporting adequate relief after administering pain medication (key output variable)
6. frequency of adverse drug events (key output variable)
7. Frequency of night and weekend entries to Pharmacy (a regulatory requirement)

ANALYZE

Background: Reports about hospital errors have become all too familiar to us because they are not rare. They will continue to occur until we truly understand how the human brain works. Why? Because the source of hospital errors is the human being, they are human errors, and our beliefs about how we do what we do are the biggest barrier to preventing them.

Hospitals rarely evaluate the limitations of the most important component of their processes – the human beings who carry them out. This chapter addresses this oversight by identifying some of the capacities and limitations of the human brain (For more extensive reading, see Chapter 2, and the Epilogue in Chaplin and Terninko, Reference 4).

Hold the figure below at eye level, close your left eye, and stare at the circle in the middle of the grid with your right eye. Slowly move the paper along the line of your vision, until the star vanishes (about ten to fifteen inches in front of you). The star disappears when it is in your blind spot. If we have a blind spot, how is it we do not go around with a hole in our vision? Now open your left eye, close your right eye, and stare at the star. Move the figure until the circle in the middle of the grid vanishes. When it does, notice that the lines of the grid remain intact.

a

b   c
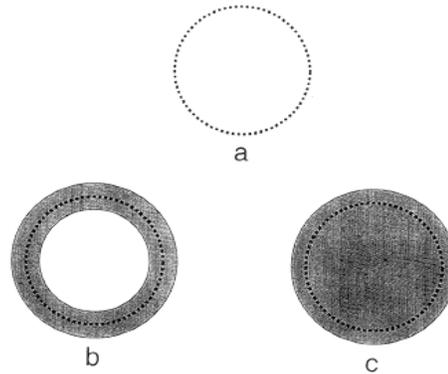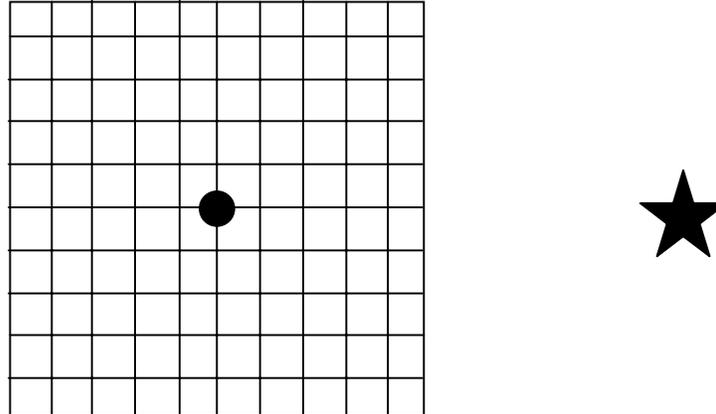
Our brains fill in the blind spot. To prove this point, experimenters (10) had subjects with one eye open and one closed locate the blind spot and outline it ("a" in Figure 2.a). They then used a thick, colored ring ("b") sufficient in size to stimulate the reception around the margins of the blind spot but not the blind spot itself. When the ring was placed over the area of the blind spot, subjects reported seeing not a ring but a colored dot or disk such as "c." These experiments show that we fill in what our brains expect to be there.

Stimuli captured by the retina of the eye seem to interact upon a background of what we already expect from past experience. Learned expectations affect our perceptions. Look at the figure below. Because we are accustomed to rectangular rooms, we see two people of different sizes, rather than a room with an unusual shape. In reality, the left corner of the far wall is farther away from the observer (as shown in the drawing). These are illusions of perspective. When such illusions are

shown to people who did not grow up with rectangular rooms, e.g., an Australian aborigine, they see the room and the people the way they are (11). Such experiments demonstrate that our past affects how we perceive the present.
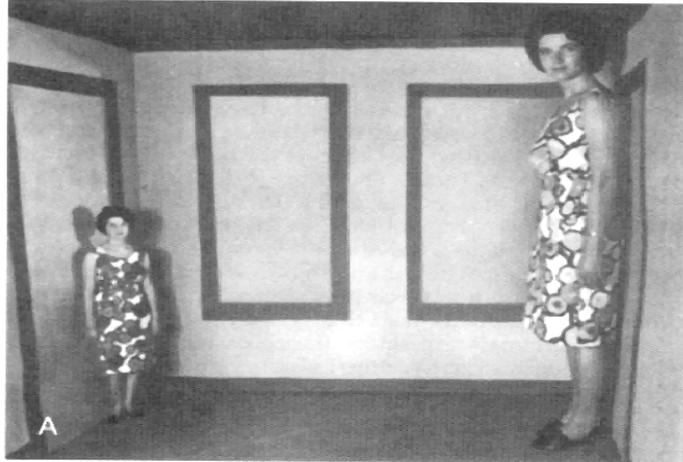
When figures and experiments noted above are taken separately the can be seen as peculiar anomalies, paradoxes. When take together these examples indicate that our experience of the present is influenced by past experiences. They also challenge the assumption that we see reality without distortion. They suggest that the world we perceived as our phenomenal awareness is highly processed. This ordering not only predisposes us to see the world conditioned by our past, it limits our capacity to change.

Such simple tasks, such as reaching out to touch an object or hitting a baseball, illustrate most of the brain activity involved in perception and action is beyond our awareness (see epilogue Chaplin and Terninko reference 4).

A major league baseball player selects his swing within 200 millionths of a second of the pitcher's release of the ball. Two-thirds of the brain activity to initiate his swing occurs before he is even aware he will swing. Furthermore, he does not even "see" an image of a ball until 300 milliseconds after he initiates his swing. His only choice is to reinforce the swing as he becomes aware he is about to swing or abort – to check it. We are no different. The brain pathways that initiate our actions and those that give us images, thought and veto power are

two distinct systems. One operates at the speed a frog zaps a fly or the snake strikes its prey. The other is "slow."

Most of you have probably used a keyboard for a computer. Like most people, if someone asks you where the "U" is on a keyboard, when you are not at the computer, you'll have to stop for a moment and visualize it. Yet, if you spend any time at all at the computer, you instantly move toward the U whenever you need to use it. Someone asks you to spell a word and you take a pen and write it out. Or, you try to recall a phone number for someone but cannot yet you go to the phone and dial it. The first attempt at "knowing" in each example is a conceptual knowing — the latter is a tacit or procedural knowledge. Nonkaka and Takeucho (9) have defined these kinds of knowledge as "know what" (explicit knowledge) and "know how" (tacit knowledge). These two types of knowledge rely upon two distinct memory systems within the brain (12). We encode and access each type of knowledge very differently.

Reach out and touch an object. Can you explain exactly how you did that? Probably not. Nor can the most learned neurophysiologist. However, we can distinguish some key elements. When we reach for an object, a result (a template of the future) is projected ahead in time. This target (an image of what you want to achieve) calls forth and pulls from our past the capacity to act. Biologically speaking, our actions arise within a pull system.

The written request to reach out and touch something is a stimulus that was interpreted by you and a target was selected. The target we formed feeds forward and automatically calls forth a sequence of actions and individual actions unfold. As the arm moves, it creates internal feedback that modifies individual muscle actions as well as the sequence of actions to reach the target. The internal feedback continually self-corrects the movement of the arm to reach the target. The end result of the sequence of actions – the output – is the target is touched.
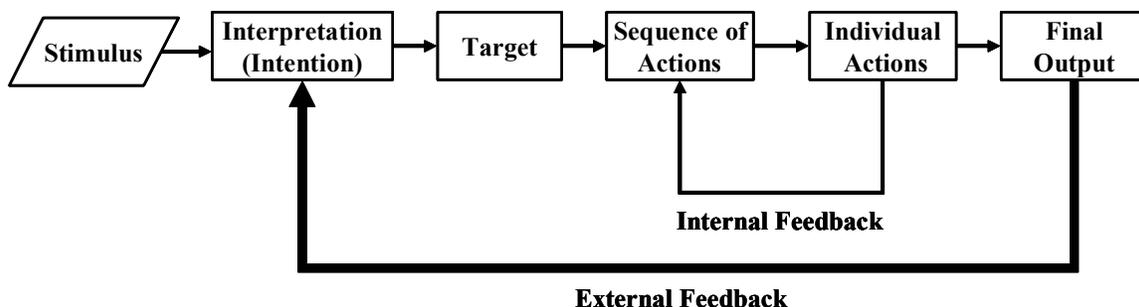
Double Loop Learning

If you were requested to touch a particular target and you unexpectedly found it painfully hot to the touch it, this new stimulus, which is feedback from the environment, would alter how you interpret that set of stimuli in the future - how you select targets - and you would be unlikely to do that again.

Internal feedback is capable of self-correcting toward already selected targets but it is the result the actions have at the environmental interface – the net result - that feeds back and alters future interpretations of the stimulus and target selection.

Steps 2-4 (interpretation, target selection and plan sequences of actions) constitute a hypothesis of how to respond to the stimulus. Steps 5 and 6 (individual actions, adjustments of individual actions via internal feedback) constitute doing the experiment. Step 7 is the data, the result of the experiment, and Step 8 is feedback from the environment that prompts us to accept or reject or modify our original hypothesis. This is the method of science. It is also how we learn collectively and individually.

This fundamental pattern is present in every cell of your body, your brain and within our social units. This will be our working model for human processes. Each of these components is necessary for a living system to effectively function and learn from its experiences.

Gaps in our awareness about how we do what we do have led us to believe that:
- We perceive reality without distortion
- We are rational beings that select our targets and initiate our actions by fore thought based on logic and
- We have a personal self, an agent that initiates our actions

In contrast the visual paradoxes, scientific data and a few common everyday examples show (13):
- We live in a remembered present, our past opens and closes possible futures and colors our present
- Ninety five percent of the time we initiate our actions and then think
- The personal self we think initiates our actions is late. It is feedback that orients us to what we have already selected and are about to do. We, like the major league batter, go with it or check it

Most performance improvement strategies are designed to get people to think before they act because we believe that is how we function. However, the data

and examples presented stands this notion on its head. We initiate our actions "long" before we think based on signals from our environment. It's the hospital environment where actions are triggered and unsafe practices need to be blocked. Currently the hospital environment holds the keys to solving hospital errors.

The implications of these studies and the conclusions they lead to are hard to hear because they fly in the face of common sense. The images we unfold appear so compelling to the eye. The sun does appear to rise and set yet we know we are rotating. Until we experience that the consequences of our past actions past shape how the present appear, create our future expectations and selects our actions, we will remain trapped in historical roles. We will live as prisoners within the beliefs and images programmed into our brains and hospitals will continue to be slow in adopting new strategies and in creating safe environments to deliver care.

Medical errors exist and have persisted because of the gaps in our mental maps. They will not be solved by some simple legislative reform or regulatory oversight. Instead, correcting unsafe conditions in hospitals requires a radical rethinking about the sources of errors at the level of the human brain and innovative responses by hospital leadership.

Once we understand the capacities and limitations of the human brain what needs to occur to improve hospitals and healthcare is conceptually relatively simple, even though at first glance they can seem overwhelming. However just as ice cream, which comes in many flavors is basically different variations of iced milk, many of the current problems in hospitals are different versions of a small number of basic problems. This makes the task simpler. Furthermore standing on science based mental maps and the experiences in other industries; we can see there are a limited number of general interventions available. There are four to be exact – training, rewards and consequences, environmental cues and automatic stops (immediate feedback).

Medical errors exist and have persisted because of the gaps in our mental maps. They will not be solved by some simple legislative reform or regulatory oversight. Instead, correcting unsafe conditions in hospitals requires a radical rethinking about the sources of errors at the level of the human brain and innovative responses by hospital leadership.

Project: In the course of collecting the data, one of the root causes for multiple breakdowns in the medication administration process was a high number new staff and high use of registry. Just prior to the medication administration project, the hospital doubled the acute bed capacity and their census. The acuity of

patients was also high.   Together these necessitated hiring new staff and a higher use of registry.   In the process of collecting data, the higher numbers of deficiencies in documentation of registry and new staff were noted. However, performance on of previously employed staff was not also meeting specifications.
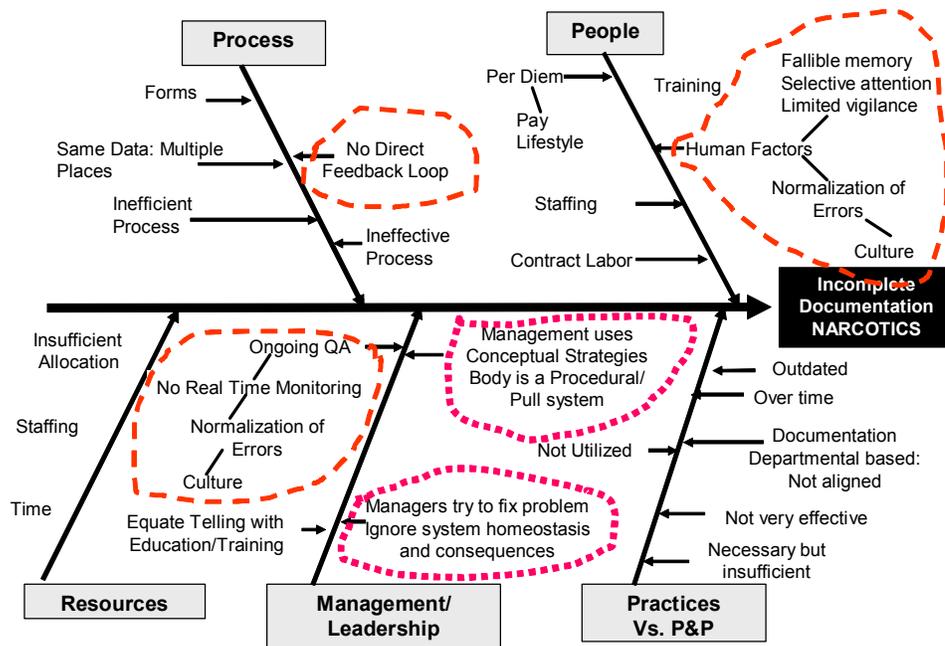
The team used a fishbone diagram to identify the causes of incomplete documentations and the following contributing factors were identified:

1.   Human factors – fallible memory, selective attention and limited vigilance resulted in failure in documentation. Over a period of time incomplete documentation had become an accepted norm (an error of normalization). There was no direct feedback loop to reinforce the expected outcome (feedback control loop within the process) and there was no real time ongoing quality monitoring of the specific problem (i.e., no independent audit – a quality assurance function).

2.   Past management attempts to improve non-conformities used conceptual strategies such as educating the staff. However, the body is a procedural pull system. Training alone is insufficient. The structure of the process needed to be altered to include prompts and feedback.

3.   Any intervention into a system tends to have three effects
     a. intended consequences,
     b. systemic homeostatic responses in the organizational culture -
         culture returning the system to its pre-existing state, and
     c. unintended consequences.
     Previous attempts at fixing the problem had not adequately
     attended to the homeostatic nature of organizations.

Systems always function in perfect alignment with their underlying structure and relations. When we say a system is broken or fails we are making an assessment relative to our expectations of the system – an assessment that often lies outside the system. For example, when a person has a gallstone obstructing the common bile duct, bile cannot flow from the liver to the intestine, the person develops jaundice and a set of characteristic signs and symptoms. We call this abnormal, however, the system is still functioning in perfect alignment with its underlying structure and relations. It's the human expectation that is out of alignment with the biliary system.

Relative to our expectations we can distinguish four categories of systems:
1.   Complete and effective.
2.   Complete and ineffective.
3.   Complete and harmful events.
4.   Incomplete.

The team also carried out a Failure Mode and Effects Analysis(not shown here). The highest ranking failure mode was the lack of direct RN monitoring, i.e., real time process feedback to front line staff and no auditing or control measures were in place. The current system was incomplete and ineffective.

IMPROVE

The process improvement team went to the floor for direct line of sight observation as to how a number of tasks were carried out. It became immediately apparent that the documentation process itself was inefficient. Nurses were required to do double documentation on separate sheets increasing the chance of errors of omission and reducing productivity.

The team employed several Lean strategies to improve the process. These include:

1. Reduce cycle time
2. Visual feedback measures
3. Reduce steps and standardization of workflow
4. Development of Standard Work Instructions

The team also incorporated strategies from human factors and error reduction programs. Most error reduction programs utilize six levels of defense against errors.

There are six levels of barriers to errors
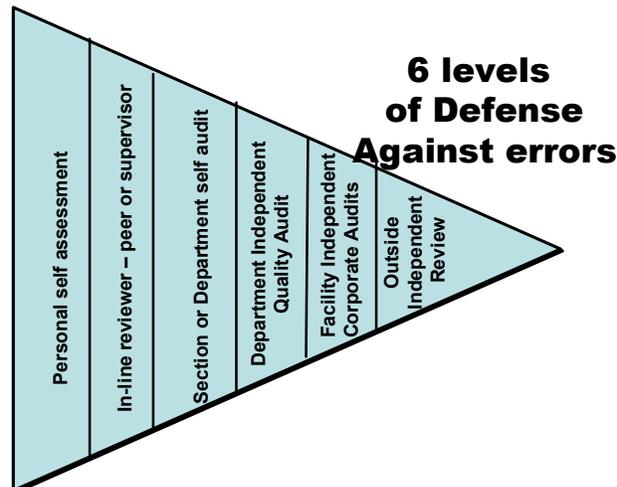
1. Personal self-assessment and self-monitoring by each staff of capacity to meet the standard
2. Review by either a peer or supervisor
3. A department or section periodic audit
4. Independent audit by the quality department
5. Audit independent of the facility, i.e., by corporate
6. Outside independent review, i.e., JCAHO of State of California

Documentation

As noted above, the team identified the lack of real time feedback to the front line staff as a major flaw in the as-is system. This was improved by adding a daily

check for discrepancies between desired targets, for example, concordance of the Medication Administration Record (MAR) and the narcotic sheet, or appropriate documentation of vital signs prior to critical cardiac medications and pain level pre- and post-pain medications. The MARs were already checked on a daily basis to identify errors and this audit just piggybacked upon it.

Pilot: MEDICATION ADMINISTRATION
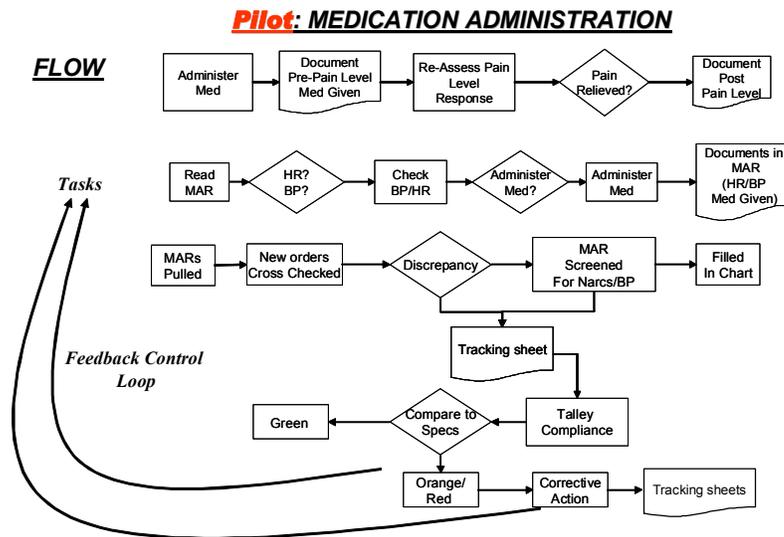
The results of this check were then posted on a visual control board to provide direct feedback to all staff as to how they were doing collectively. Results were displayed daily. If 100% complete (0 defects) was demonstrated, a green dot was placed, if defects were greater than zero but less than 5% a yellow dot and if greater than 5% a red dot. It was then the responsibility of the unit charge nurse and the supervisors of the nursing personnel to take corrective action to improve the process if two yellow dots occurred in a row or one red dot occurred.

Before the process was fully deployed the mean defect rate was 0.12 and the process was not in control.

September 2002 NURSING

Pre & Psot pain Checks Documented
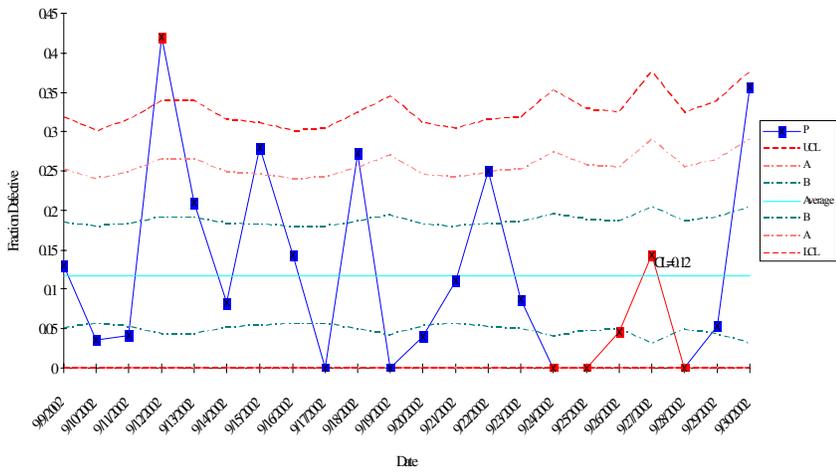
After full deployment and some improvements the defect rate is down and the process over has been in control.

December 2002 NURSING

Pre & Post Pain Med Documentation
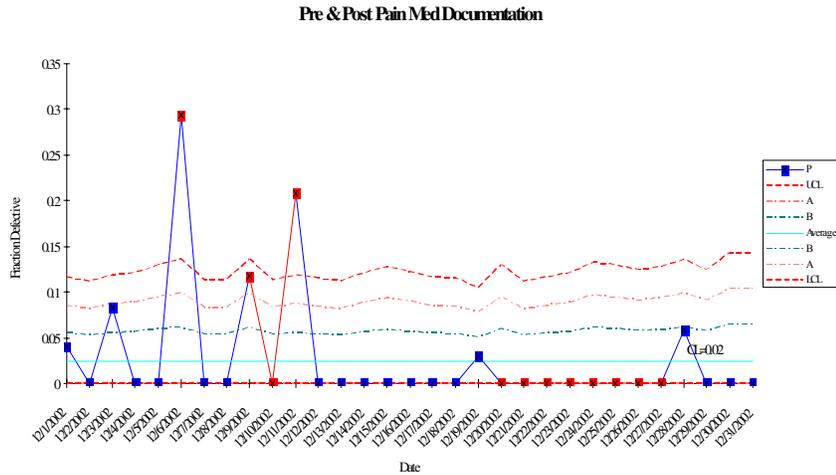
As noted earlier, under Analysis and Human Factors, the high number of new staff and high use of registry were considered contributing causes in breakdowns in medication administration standards. To mitigate this, standardized work instructions were developed for patient medications that identified purpose, key points, what needed to be reported, parameters for notifying physician, etc., tools and forms that were required and the estimated time it would take the patient. Standardized work forms were permanently affixed to the medication cart for just-in-time reference by staff whether they were old staff, new orientees or registry.

SWI: PATIENT MEDICATION ADMINISTRATIONS

What – Safe and adequately documented medication Delivery

Key points

    1. BP and heart rates check on cardiovascular medication form minimum 7 days
   after admission or change in dose
        - Reviewed BP & Heart rate data form within last hour, if none check
        -Is patient symptomatic?
        - If **HR < 60** , Systolic **BP < 100** Or Diastolic **BP < 50** or Drop in Systolic BP or 30 mm or
            Diastolic BP of 30 mm below usual BP and no parameters to hold
            then do not give medication, notify MD and obtain change in order or parameters
        -Depends on Medication and parameters written by MD
        -Depends on Indication of medication
    2. Pain medications
        - Ask premeditation pain level & record on MAR next to medication
        - Obtain post-meditation pain level between 30 - 60 minutes post administration, record on
          MAR next to pain medication
        - Ask if patient is satisfied with pain relief & yes/no on MAR next to pain medication

Tools/Forms

    1. For cardiovascular medications record pre-administration HR & BP on MAR
    2. Record Pre and post pain level on MAR

Estimated time required per patient per dosing time.

    If oral med = 10-15 min.
    If enteral = 20 min.
    If IV = 20 min.

BP & HR with Cardiac Medications
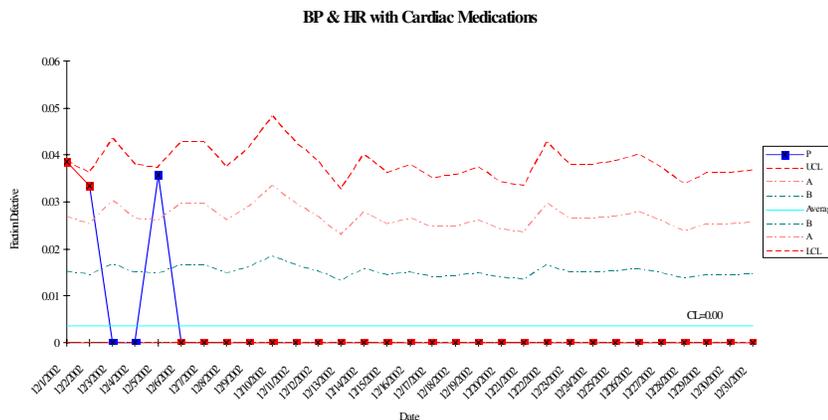
The defect rate fell and the process appears to be in control.

The visual triggers were used as a strategy to reduce the number of verbal medication orders not signed within 48 hours as required by regulations. This improvement added real-time feedback into the process.

MD Order Sign & Date
Visual Color Flag System

Eight physicians were responsible for almost 90% of the verbal medication orders. On each unit a rack of colored folders was placed. The colors corresponded to the color-coded patient name on charts that were unique to each physician. Above the rack are color-coded flags which, when opened, alerted the physician there were items that needed to be signed in the folder. The unit clerk, who performed a daily check of the charts as part of ongoing quality monitoring, made a photocopy of any verbal medication orders that were unsigned and placed them in the folder. After the physician signed them, they were placed back into the chart. The defect rate has been falling.

Verbal Med Odered Timed & Dates 48 Hours
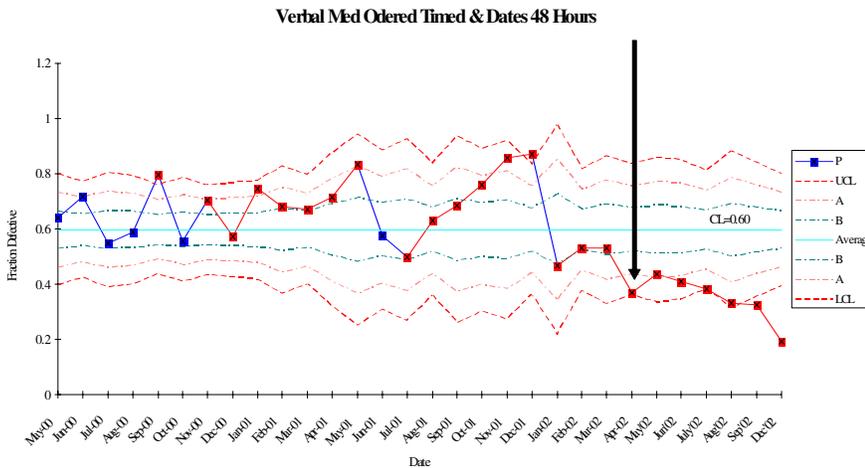
As part of the improvement process, the project team actually had carried out a line-of-sight observation study and observed the passing of medications and the documentation. It became clear that nurses were being required to do double documentation on two different sheets – double charting. Based on this observation, the sheets were redesigned such that all the activity around medications, including vital signs, time administered, response to pain, etc., were documented in one place.

Data from the literature were reviewed on the frequency of adverse drug events. Those that were preventable occurred most frequently with analgesics, antibiotics, particularly aminoglycosides, sedatives, cardiovascular medications, anti-coagulants, anti-psychotics and insulin.

ADVERSE DRUG EVENTS

Class	ADE %	Preventable %	
Analgesics	30	29	
Antibiotics *	24	9	
Sedatives	8	10	
Cardiovascular	9	4	
Anticoagulants *	3	4	
Antipsychotics	2	7	
Diabetes *	2	6	

Bates et al JAMA 274:29-34 1995

Pharmacists were already dosing antibiotics and prior to this time hospital pharmacists had been managing approximately 50% of the anti-coagulation medications. Studies in the literature show having the pharmacist as the point of control resulted in less adverse events. The project team recommended to the Medical Executive Committee that the pharmacist should manage all anti-coagulants. They agreed. In addition, a standard sliding scale insulin was agreed upon for new admissions and patients being tapered off insulin. This reduced variation in the sliding scale in the facility from approximately ten to two.

IMPROVE CONTINUED

FMEA: Before full deployment of the redesign process occurred, its strengths and weaknesses were explored using Failure Mode and Effects Analysis (Design FMEA. See chapter 10, Chaplin and Terninko, Reference 4). The team identified three areas with high risk priority numbers.

1. Lack of timely in-process feedback to staff by peers or nursing supervision.
2. Poor reliability for self-reporting of medication errors and adverse drug events.
3. Lack of direct feedback to physicians on adverse drug events and no accountability for their participation in efforts to reduce ADRs that resulted from medication errors.

Lack of Timely and Immediate Feedback to Nursing Staff: The nursing staff was not getting any direct real time feedback from either their peers or supervisors and the nursing department was not doing any departmental audit. This failure mode led to the development of the visual feedback board discussed above.

Ineffective Feedback Loop to Staff

Product or Process	Failure Mode	Failure Effects	SEV	Causes	OCC	Controls	DET	RPN
Pain Level Monitored	Not Assessed	Regulatory Non-Compliant	7	Not Asked	10	Visual Control system	5	350
		Customer Dissatisfaction	6	Not Documented	5	Press Gainy Survey	7	210
		No Feed Back Data	3	Poor System	5	Visual Control system	4	60
Heart Medication Monitored	Not Assessed	Regulatory Non-Compliant	7	Not Asked	10	Visual Control system	5	350
		Customer Dissatisfaction	4	Not Documented	5	Press Gainy Survey	5	100
		No Feed Back Data	3	Poor System	10	Visual Control system	5	150
		Adverse Pt. Outcome	8	Poor System	10	New SOP & VCS	5	400
Tracking Sheet	Not Done	No Feed Back Data	7	Not trained	5	Management	5	175
		No Feed Back Data	7	Registry	5	Tracking sheet	5	175
		No Feed Back Data	7	Not Important	1	Management	3	21
		No Feed Back Data	7	Not my Job	1	Management	3	21
		No Feed Back Data	7	Over looked	2	QA system	3	42
RN Supervisor	Not Done	Process Out of Control	9	To Much to do	10	Nothing	10	900

As noted above, systems always produce results consistent with their underlying structures. The structure for process and systems of the Toyota Production Systems (Lean Manufacturing) are built on three rules of design and one rule of improvement (14).

- Rule #1 – All work shall be highly specified as to content, sequence, timing and outcome.
- Rule #2 – Every human-to-human connection (customer-supplier) must be direct and there must be an unambiguous yes-or-no way to send requests and receive responses.
- Rule #3 – The pathway for every product and service must be simple and direct.
- Rule #4 – Any improvement must be made in accordance with the scientific method, under the guidance of a teacher, at the lowest possible level in the organization (the application of the principles of science).

The analysis phase of this project noted the workflow was not highly specified as to content, sequence and outcome and there were no specific guidelines for peer-to-peer non-supervisory feedback. The monitoring system was incomplete and ineffective. More highly specified workflows were developed, standard work instructions were deployed and ongoing monitoring was put in place. Actions were also taken to reduce errors.

Error-proofing: Experience for industries with a longer history of error reduction programs have identified causes for error include:

1. error-producing conditions
2. barriers with holes
3. non-conservative decision.

Care reports also indicated injury to a patient is very unlikely to be the result of a single error but rather usually a chain of errors. Therefore, the team employed a strategy of six levels of defenses to reduce errors or identify errors when they occur and mitigate their effects. These were discussed above and included:

1. personal self-assessment
2. in-line review – peer or supervisor
3. section or departmental self-audit
4. department independent quality audit
5. facility independent corporate audit
6. outside independent review

In order to enhance the robustness of the defenses for medication administration, front-line nursing staff themselves started self audits at the end of shift. This data would go to the supervisors and the unit's performance as a whole was posted on the visual feedback board (see above). During the initial deployment period, a weekly department independent audit was carried out by pharmacy on nursing documentation of narcotics, parameters of cardiovascular medication and post-pain medication levels. These audits continue on a daily basis.   A process control plan was developed to deploy a more complete and more effective monitoring process. The plan included daily auditing by peers with daily feedback on results to all staff and corrective actions by supervisors if specifications were not being met (P1 and P2). The remainder of the control plan will be discussed in the next section.

Process Description	Process Customer(s)			Customer Requirements		Outcome Quality Indicators				
Medication Documentation	Patients/Quality Council			Pain Relief/ Safety/ Regulations		Documentation Pain & CV Meds Pain Relief				
Process Flowchart				Indicators		Checking				Misc.
Tasks	RN	Night Shift	Supervisors	Pharmacy	Control Charts Quality Indicators	Control Limits Specs/ Targets	Checking Item What to Check	Frequency When to Checking	Respon- sibility Who Checks	Control Plan Action for Nonconforming	
When										
Immediately	Medication Administered									
Immediately	Medication Documentation P1				P1 Completed Documentation	0-5%	MAR	daily	RN Decrrpancy checks		
End of Day	Audit Completed	Corrective Action								
	Tracking sheet completed	Yes								
End of Day		Discrepancy?								
	No				P2 Visual Board Up to Date	0%	Visual Boards	Daily	Supervisor	Direct Feed Back	
	Visual Board Updated P2		P3							
Daily			Internal Audit		P3 Completed Documentation	0-5%	MAR	Weekly then monthly	Pharmacy	DQM MEC	
			DQM							
monthly)										
	P4 Corrective Action	Yes Discrepancy?			P4 Corrective Action Log	0%	Pharmacy Audit	Monthly the Qtr.	DQM	MEC QC	
		No								
Monthly		Quality Council								
					Rev #	Date		Revision Control		By

The results of both the departmental self-audit and the pharmacy audit would be reported to the Department of Quality Management and reviewed by the Quality Council.

Reliability of Self-Reporting: As noted above, the team designed improvements for the use of anti-coagulants and insulin. The risk priority numbers were high for both severity of occurrence and detection for the use of analgesics, sedatives and anti-psychotics. But what about other medications?

Look at Figure 9 (M105) on page 6. Using the model for action and of a self-correcting, self-learning system on page 6, what is missing?   There is no feedback loop from patient response to ordering physicians where 39% of errors and 60% of Adverse Drug Reactions (ADR) are initiated.   In day-to-day care of patients, physicians do see signs and symptoms of ADRs and make adjustments but the organization has not collected aggregate data to identify patterns in physician prescribing habits.

A presentation by David Clausen, formerly of Latter Day Saints, Inter-Mountain Health, indicated that self-reporting was not effective in capturing adverse events. In a study carried out to test an automated computerized detection system, an extremely detailed analysis identified 731 adverse drug events. The computerized system identified 88% of these as opposed to 9 which had been captured historically in that facility by traditional self-reporting. In order to enhance self-reporting, a special key on the keyboard had designated such that a provider who suspected the possibility of a medication error had only push it. The rest of the evaluation was carried out by other personnel.   This simple "automated" self-reporting only captured 12% of the errors. This suggests that self-reporting by nurses or physicians will not create robust, error nor adverse drug event reporting systems.

Because the Inter-Mountain Health experience, the team concluded it was unlikely self-reporting would not be a reliable way of monitoring ADRs. Instead, it was agreed that the hospital would implement a trigger tool developed by Institute of Healthcare Improvement (IHI www.IHI.org) which included randomly sample of a minimum of ten charts per month. This trigger tool was designed to identify adverse drug events by identifying abrupt stoppage of a medication, over-sedation, use of anti-emetics, high INR, high PTT, development of abnormal renal studies and a number of other events for a total of 25. These would be identified and then a search would occur for contribution to medical errors to identify preventable adverse drug events. Together they would be trended and adjustments to improve the system made accordingly.

25% of the charts triggered using the tool actually identified ADRs.   Abruption stops in medications, use of anti-emetics, signs of over-sedation and the use of a

benadryl were the four most common factors that triggered finding an adverse drug reaction.

The retrospective analysis identified the ADR rate was 0.8 per 1000 doses versus a rate of 2.6 per thousand doses for acute hospitals. The retrospective rate of ADRs was 28% of all admissions versus 24.9% for acute hospitals. The drug classes most likely to cause adverse drug reactions were analgesics, anti-coagulants and psychotropic agents in that order. The next question becomes, "So what?" Retrospective studies, as noted earlier, are too late. How is this analysis actually going to improve patient care in real time? The team is now reviewing these retrospectively identified charts for potential medical errors to see if there is a common pattern that can be identified, communicated, modified or blocked. Second, the data for frequency of particular drug classes, specific drug profiles and symptoms are being incorporated into ongoing education of nurses and physicians. Over the six months term of the project, the rate of self-reporting of medical errors has tripled and the rate of self-reporting of self-reporting of adverse drug events has more than doubled. In recent months, the rate of self-reported ADRs reached 25% of that expected based on the sample of retrospective chart review for that month. Implicit in this approach is the belief that, like the airline experience, increasing safety awareness in general and increasing awareness of specific events can create a sense of a safer environment and a path to continual improvement.

CONTROL

Three forces current shape and are likely to continue to shape the future of the healthcare space near term. These include:

1. Choice – consumers are demanding more input into their care
2. Cost – payors are demanding reduced costs
3. Safety – consumers, payors and society are demanding increased safety.

Earlier in this paper I introduced the tools of Quality Function Deployment which can be used to capture 95% of customer wants and I commented on the studies of Altshuller which indicated 95% of the technical know-how to solve the problems of choice, cost and safety are likely to already exist in other social spaces.

I also pointed out that translating new technical know-how, "mental concepts" (targets and measurable goals) or customer wants into embodied practices so that they show up as habits and culture (task and process outcomes) involves a five-step translation process. (Figure Page 9) I suggest translation effects often fail

because of two sets of factors. One set I call horizontal or local factors. They address the immediate working environment of the staff. They include clear targets with measurable dimensions, appropriate tools and job aides, necessary information and direct and immediate feedback. This paper, like most improvement efforts, has focused on these.

The other set of factors I will call organizational or vertical. They involve generating the organization alignment necessary for appropriate resource allocation, service realization, ongoing measurement and analysis, management involvement and the continued improvement necessary to translate customer wants or to successfully adopt new technical knowledge into the day-to-day actions of staff. They create space the for the local environment and the organizational accountability necessary to successfully translate the goals into daily habits and culture.

The intention to either satisfy new customer wants, new customer segments or to adopt new technology is often addressed in strategic planning. Successful implementation, however, requires a systems approach – a management system. This task usually falls to a quality management strategy. Organizational wide quality management systems are necessary to create both the vertical alignment necessary for success and to expand adoption horizontally across the organization to include other departments, suppliers, etc.

This section of the paper will focus on vertical or organizational issues. Many industries have adopted ISO standards as a basis for the quality management system. Recently these have been adopted for healthcare. IWA 1: Quality Management Systems – Guidelines for Process Improvements in Health Organizations. ISO standards and IWA define a set of standards but they do not prescribe a system to implement them. Proponents for using ISO/IWA 1 guidelines in healthcare face a major challenge in getting healthcare organizations to adopt the standards. Many people in the industry do not have good working mental models for robust quality management systems. IWA 1 or even that matter, many of the JCAHO standards can appear fragmented and are commonly approached in a piecemeal fashion.

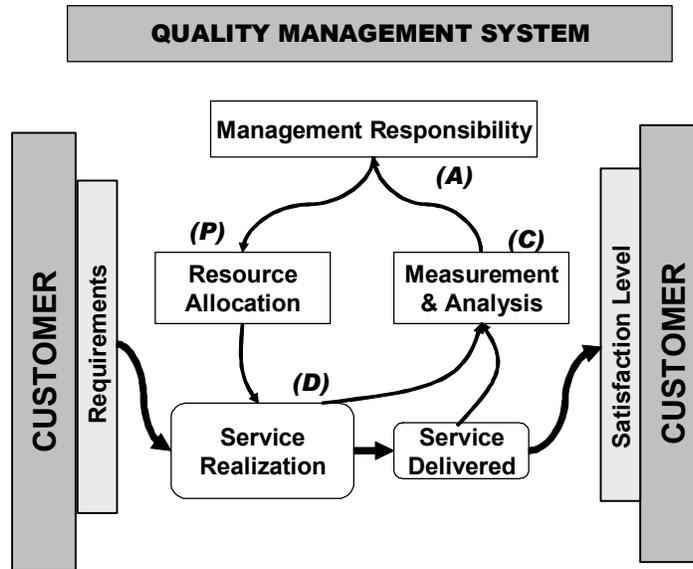The ISO 9000 standards and IWA 1 contains eight sections. The following are key operational sections:

   4.0 Quality Management System
   5.0 Management Responsibility

6.0 Resource Management
7.0 Product/Service Realization
8.0 Measurement, Analysis and Improvement

ISO/IWA 1 embody eight management principles.

1. **Customer Focus** – companies must focus their resources on customer satisfaction.
2. **Leadership** - Good leadership increase a company's effectiveness
3. **Involvement of People** – People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.
4. **Process Approach** – A desired result is achieved more efficiently when activities and related resources are managed as a process.
5. **System Approach to Management** – Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.
6. **Continual Improvement** – Continual improvement of the organization's overall performance should be a permanent objective of the organization.
7. **Factual Approach to Decision Making** – Effective decisions are based on the analysis of data and information.
8. **Mutually Beneficial Supplier Relationships** – An organization and its suppliers are interdependent, therefore, a mutually beneficial relationship enhances the ability of both to create values.

The goal is to develop a quality management system to assure the organization is customer driven, process focused and continually improves, uses a systematic approach by management and leadership which is mutually beneficial to suppliers as well as customers.   The interrelationships between the sections can be displayed as shown in the following figure.

QUALITY MANAGEMENT SYSTEM

```
                    ┌─────────────────────────────┐
                    │  Management Responsibility   │
                    └─────────────────────────────┘
                                 (A)

              (P)                              (C)
         ┌──────────┐                    ┌──────────────┐
CUSTOMER │ Resource │                    │ Measurement  │  CUSTOMER
(Require-│Allocation│                    │  & Analysis  │  (Satis-
ments)   └──────────┘                    └──────────────┘  faction
                          (D)                               Level)
            ┌──────────┐       ┌──────────┐
            │ Service  │──────▶│ Service  │
            │Realization│      │Delivered │
            └──────────┘       └──────────┘
```

A quality management system starts by identifying customer requirements, allocating appropriate resources to realize the service. To continually improve service realize requires ongoing measurement, analysis and assessment of final outcomes (customer satisfaction).

The relationship between management, resource allocation, service realization, measurement and analysis is essentially plan, do, check, act cycle.

Six core functions are identified to coordinate the quality management system and the standards require policies and procedures for each of them.

> Control of Documentation
> Control of Records
> Internal Audit
> Control of Non-conforming Product
> Corrective Action
> Preventive Action

Juran spoke of the Quality Trilogy – Quality Planning, Quality Improvement and Quality Control. These are core principles in any quality management strategy. These and other elements are shown in the figure below.
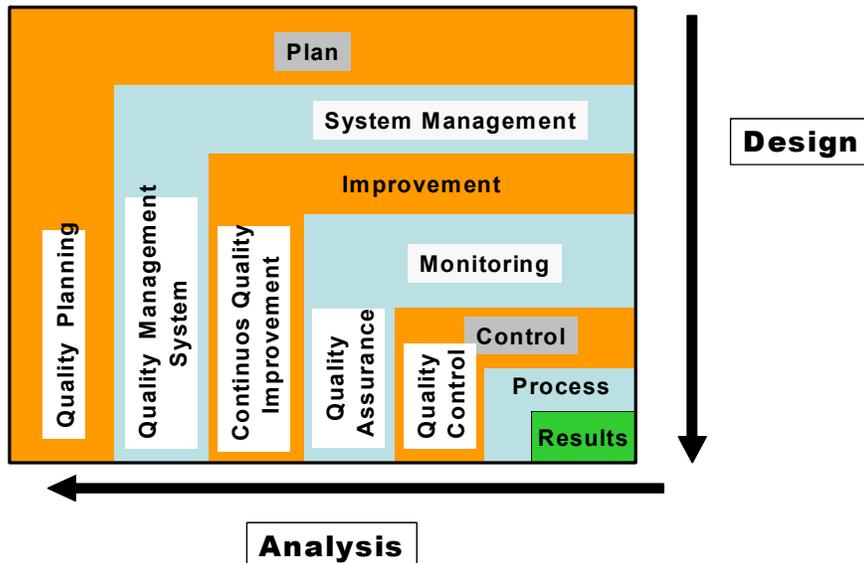
The capacity of every process is a function of its underlying structure and sets of relations. Strong and robust processes have feedback or control loops. They are the basis of Quality Control. Periodic monitoring (internal auditing) of processes is required to assure they are functioning appropriately (Quality Assurance). If they are not, their structures need to be improved (Quality Improvement). The organization needs and overall system to manage quality improvement and monitoring processes (Quality Management). This requires a plan, a design (Quality Planning). Evaluating the system from results up involves analysis. Deploying changes from planning down involves design.

How did this project meet some of the standards for ISO/IWA?

- Customer requirements for satisfaction around medication administration were identified and satisfaction with the output was assessed.
- Leadership as well as frontline staff were involved.
- To achieve the desired result, a more efficient, effective and safer delivery process was deployed.
- Leadership committed pharmacy resources to conduct internal audits of the process.
- Measurements and monitoring were in place to identify not only results but also non-conformance to standards. A process corrective action was present both at the local and the organizational level.
- A number of key process measures were improved and continue to improve - the journey continues

- The organization has been working with pharmaceutical suppliers in a mutually beneficial way to reduce the number of medications (reduce variation) which results in a reduction of the knowledge base needed as well as the cost savings and efficiencies to both the organization and improved safety for patients.
- Standard items such as process summary sheets, process control charts and standard reporting formats were used.

Fundamental to the philosophy of Six Sigma is that:

1. Every product or service can be improved.
2. People in the organization can do more than we ask or allow them to do.
3. Perfection is possible.

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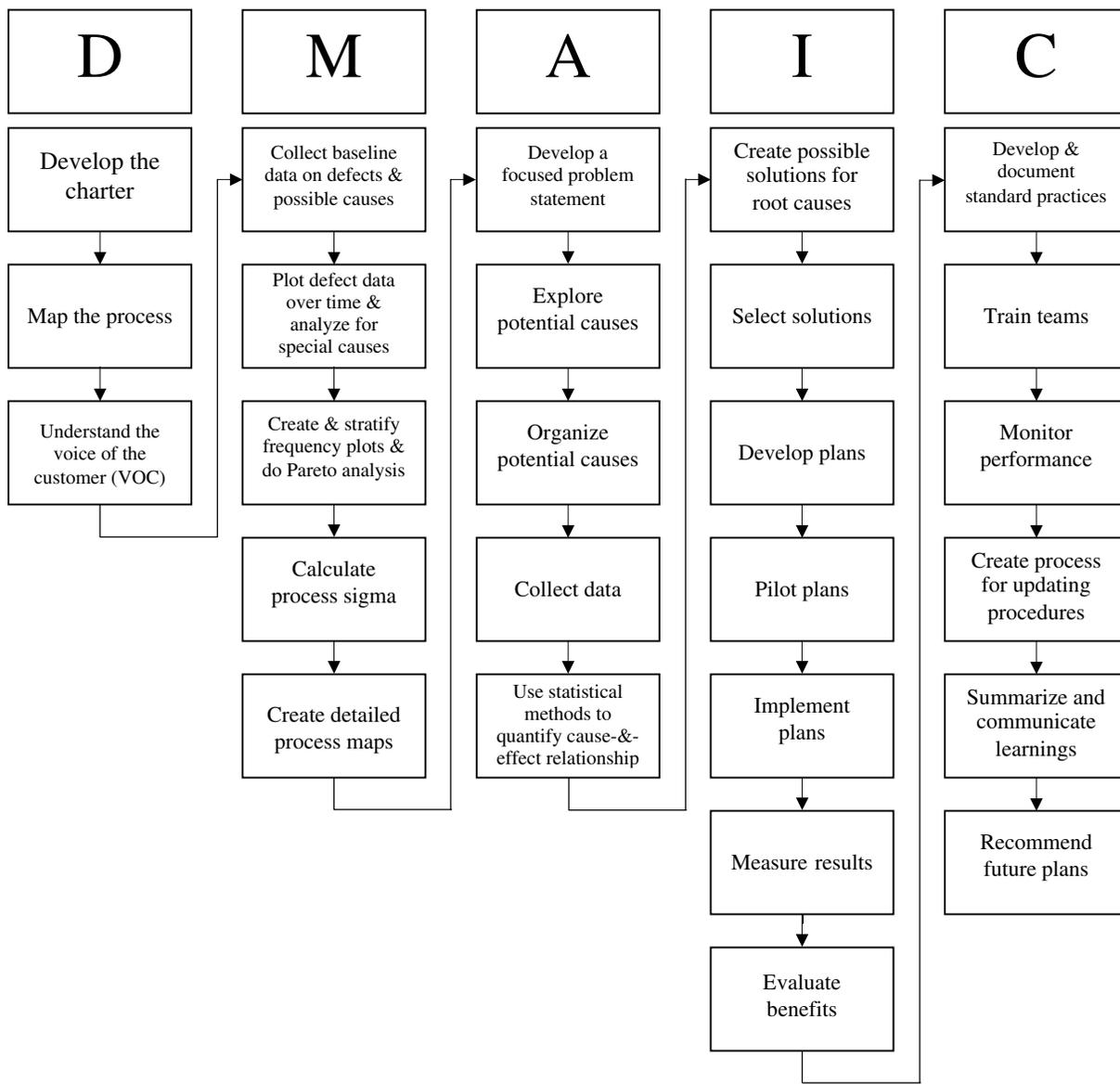
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SIX SIGMA AND ITS APPLICATION IN HEALTHCARE
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SUMMARY

Participants will be supplied with a copy of The Six Sigma Memory Jogger™ II which summarizes how to use each of the tools usually included under the DMAIC (Define, Measure, Analyze, Improve, Control) process of Six Sigma. The following text is adapted with permission from The Six Sigma Memory Jogger™ II © GOAL/QPC.

As a Six Sigma team member, you will most likely work on improvement teams using the DMAIC method. To use this method successfully, you must first be familiar with the goals and outputs of each step, as well as the correct approach to take during each step and the tools necessary to complete your work.

THE DMAIC PROCESS FLOW

D	M	A	I	C
Develop the charter	Collect baseline data on defects & possible causes	Develop a focused problem statement	Create possible solutions for root causes	Develop & document standard practices
Map the process	Plot defect data over time & analyze for special causes	Explore potential causes	Select solutions	Train teams
Understand the voice of the customer (VOC)	Create & stratify frequency plots & do Pareto analysis	Organize potential causes	Develop plans	Monitor performance
	Calculate process sigma	Collect data	Pilot plans	Create process for updating procedures
	Create detailed process maps	Use statistical methods to quantify cause-&-effect relationship	Implement plans	Summarize and communicate learnings
			Measure results	Recommend future plans
			Evaluate benefits	

The goals, outputs, approach, and tools for each step of the DMAIC method are outlined on the next several pages.

THE DEFINE STEP
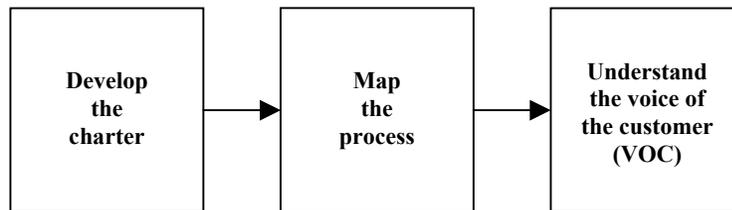**GOALS AND OUTPUTS**

The goal of the Define step is to define the project's purpose and scope and obtain background information about the process and its customers.

The outputs of the Define step consist of the following:
- A clear statement of the intended improvement and how you will measure it.
- A high-level map of the process.
- A translation of the voice of the customer, or VOC, into key quality characteristics.

APPROACH

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┌──────────────┐      ┌──────────────┐      ┌──────────────────┐
│   Develop    │      │     Map      │      │   Understand     │
│     the      │ ───► │     the      │ ───► │ the voice of     │
│   charter    │      │   process    │      │  the customer    │
│              │      │              │      │     (VOC)        │
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To fully define the scope and purpose of your project, you must first understand the boundaries of the process you are trying to improve and the requirements of its customers. You include this information, along with expected resource needs and a projected timeline, in your team charter.

In practice, there is usually some give and take between these activities as you work to define a project that is both important and doable.

The applicable tools for the Define step include the tools found in the table on the following page.

Tool	Description	Page
Affinity Diagram	Enables your team to organize and summarize language based data	38
Charter	Documents what the project is supposed to achieve and what resources are available to your team. A written charter is an important communication and reference tool.	59
Communication Plan	Regular communication with stakeholders (i.e., people who will be affected by the project or can influence it but are not directly involved with doing the project work) can help your team understand its work, identify better solutions to problems, create more buy-in, understand when and how to best involve others, and avoid pitfalls.	70
Control Charts	Focus attention on detecting and monitoring process variation over time.	75
CTQ Tree	Critical to Quality (CTQ) characteristics are features by which customers evaluate the quality of your product or service. The CTQ Tree enables your team to describe your customers' needs and the corresponding measurable characteristics. If a product or service does not meet a CTQ, it is considered to be defective.	91
Data Collection	Data from customers helps your team understand what is important about your product and set priorities if you need to narrow the project's scope. Often the necessary customer data is provided to a team when it is formed.	95
Kano Model	Helps your team understand your customers' requirements, which are sorted into three categories: Must Be, More Is Better, and Delighters.	158
Pareto Chart	Helps your team focus itself on the problems that are causing the most trouble. This helps you identify the areas where your efforts will have the biggest payback.	178
Run Chart	Enables your team to study baseline process performance to identify trends or patterns over time.	221
SIPOC	A SIPOC (Suppliers, Inputs, Process, Outputs, and Customers) analysis helps your team understand the key elements of your process and define the boundaries and scope of your project.	235
Tolgate Review	A formal review process that helps keep the project on track and helps promote successful results.	247
y= (x) Formula	Allows your team to structure the relationship among the Y's (the CTQs) and the y's (the process output directly affecting the Y's), and the x's (the causal factors directly affecting the y's).	263

THE MEASURE STEP
GOALS AND OUTPUTS

The goal of the Measure step is to focus your improvement effort by gathering information about the current situation.

The outputs of the Measure step include the following:
- Data that pinpoints the problem's location or rate of occurrence.
- Baseline data on how well the process meets customer needs (to determine the current process sigma).
- An understanding of how the current process operates.
- A more focused problem statement.

| Collect baseline data on defects and their possible causes | → | Plot defect data over time and analyze for special causes | → | Create and stratify frequency plots and do Pareto analysis | → | Calculate process sigma | → | Create detailed process maps |
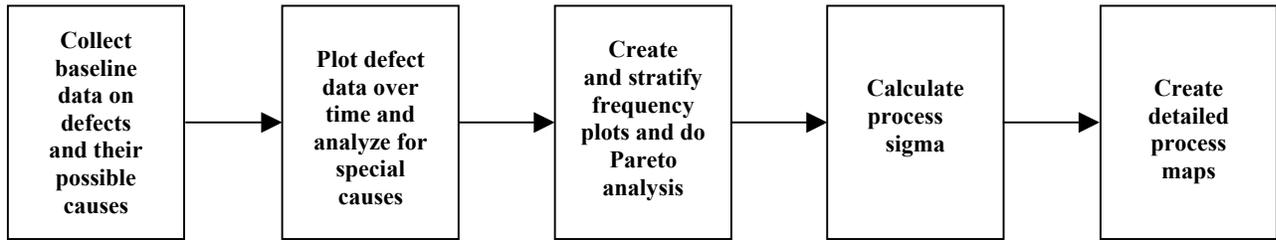
During the Measure step, you investigate the problem you are studying in detail—what specifically is happening, when it is happening, and where it is happening. You also collect data to create a performance baseline to which you can compare the process performance after you work on the Improve step.
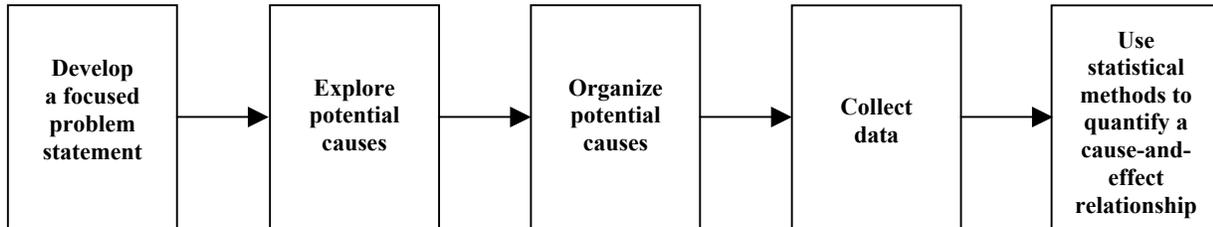
The applicable tools for the Measure step include the following:

Tool	Description	Page
Control Charts	Help you look for patterns over time in process variation, quantify the current capability of your process, and identify when special events interrupt normal operations.	75
Data Collection	Helps you systematically collect baseline data.	95
Data Points/ Data Types	The type of data you have will determine which tool(s) to use.	101
Flowchart	Pinpoints steps in the process that don't add value and helps you identify problems in the process that contribute to waste and defects.	116
Histogram	Reveals how often a problem occurs in different settings. A stratified Histogram helps you identify process characteristics that might provide clues about the potential causes of problems.	129
Measurement Systems Analysis (MSA)	Helps you understand measurement variation.	168
Operational Definitions	Precise descriptions that describe how to get a value for each characteristic you are trying to measure.	176
Pareto Chart	Displays the relative importance of problems. As in the Define step, it helps you focus your attention and develop a detailed problem statement.	178
Process Sigma	Calculations that describe the current process capability. Calculating a baseline process-sigma level provides a gauge for you to evaluate your progress.	204
Run Chart	Plots data from Check Sheets and other sources and helps you look for patterns over time in process variation.	221
Taguchi Loss Function	Defines the loss associated with variation around a customer-specification target.	244
Tollgate Review	A formal review process that helps keep the project on track and helps promote successful results.	247

THE ANALYZE STEP
GOALS AND OUTPUTS

The goal of the Analyze step is to identify root causes and confirm them with data. The output of this step is a theory that you have tested and confirmed.

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┌──────────────┐   ┌──────────────┐   ┌──────────────┐   ┌──────────────┐   ┌──────────────┐
│  Develop     │   │              │   │              │   │              │   │    Use       │
│  a focused   │   │  Explore     │   │  Organize    │   │  Collect     │   │  statistical │
│  problem     │──▶│  potential   │──▶│  potential   │──▶│  data        │──▶│  methods to  │
│  statement   │   │  causes      │   │  causes      │   │              │   │  quantify a  │
│              │   │              │   │              │   │              │   │  cause-and-  │
│              │   │              │   │              │   │              │   │  effect      │
│              │   │              │   │              │   │              │   │ relationship │
└──────────────┘   └──────────────┘   └──────────────┘   └──────────────┘   └──────────────┘
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The Analyze step pinpoints the specific cause(s) of the focused problem statement you will develop as a result of the Measure step. You can then address the root cause(s) through solutions you implement in the Improve step.

The applicable tools for the Analyze step include the following:

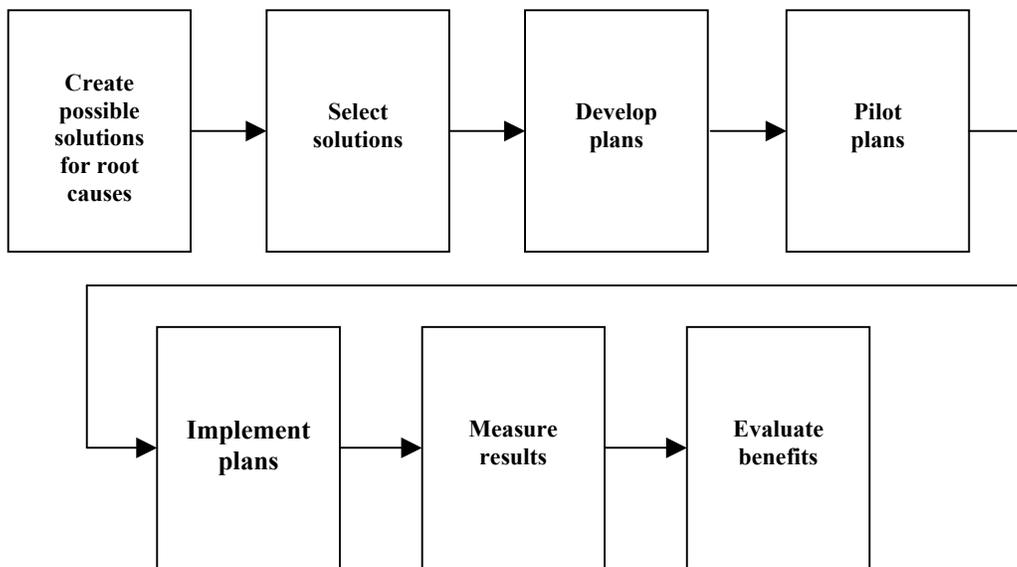| Tool	Description	Page
Brainstorming	Enables your team to creatively and efficiently generate a large number of ideas about causes of error.	45
Cause-and-Effect Diagram	Enables your team to identify, explore, and graphically display, in increasing detail, all the possible causes related to a problem. The deeper you are able to push for causes, the more likely your solutions will be long lasting ones.	49
Design of Experiments (DOE)	Provides a method for testing multiple potential causes of error at the same time, enabling your team to reach conclusions about the primary causes.	105
Focused Problem Statement	Describes specifically what occurs, when or under what circumstances it occurs, and/or who is involved. The goal is to narrow the problem definition so you can use your time and resources most effectively to find a solution.	124
Histogram	Stratified Histograms help you identify process characteristics that might confirm patterns. Like Scatter Diagrams, they help you understand relationships that can confirm an underlying cause of a problem.	129
Hypothesis Testing	Using statistical analysis on a cause-and-effect relationship.	142
Interrelationship Digraph (ID)	Studying cause-and-effect patterns to identify the key drivers and outcomes of critical issues.	147
Scatter Diagram	Used to show the relationship between two variables. It can help your team verify causal relationships.	228
Tollgate Review	A formal review process that helps keep the project on track and helps promote successful results.	247
Tree Diagram	Breaks down the broad categories of causes into increasing levels of detail. Your team can use it to depict the links between root causes and their effects on a problem.	249

THE IMPROVE STEP
GOALS AND OUTPUTS

The goal of the Improve step is to develop, try out, and implement solutions that address root causes and to use data to evaluate the solutions as well as the plans you use to carry them out.
The outputs of the Improve step include the following:
- Planned, tested actions that eliminate or reduce the impact of the identified root cause(s) of a problem.
- "Before" and "after" data analysis that shows how much of the initial gap was closed.
- A comparison of the plan to the actual implementation.

APPROACH

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┌─────────────┐     ┌─────────────┐     ┌─────────────┐     ┌─────────────┐
│   Create    │     │             │     │             │     │             │
│  possible   │ ──▶ │   Select    │ ──▶ │   Develop   │ ──▶ │    Pilot    │
│ solutions   │     │  solutions  │     │    plans    │     │    plans    │
│  for root   │     │             │     │             │     │             │
│   causes    │     │             │     │             │     │             │
└─────────────┘     └─────────────┘     └─────────────┘     └─────────────┘

┌─────────────┐     ┌─────────────┐     ┌─────────────┐
│  Implement  │ ──▶ │   Measure   │ ──▶ │  Evaluate   │
│    plans    │     │   results   │     │  benefits   │
└─────────────┘     └─────────────┘     └─────────────┘
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The Improve step involves not only coming up with solutions but also using the PDCA (Plan-Do-Check-Act) Cycle to evaluate and improve the solutions you want to implement. Preparing people for change is another critical component of this step.

The applicable tools for the Improve step include the tools found in the table on the following page.

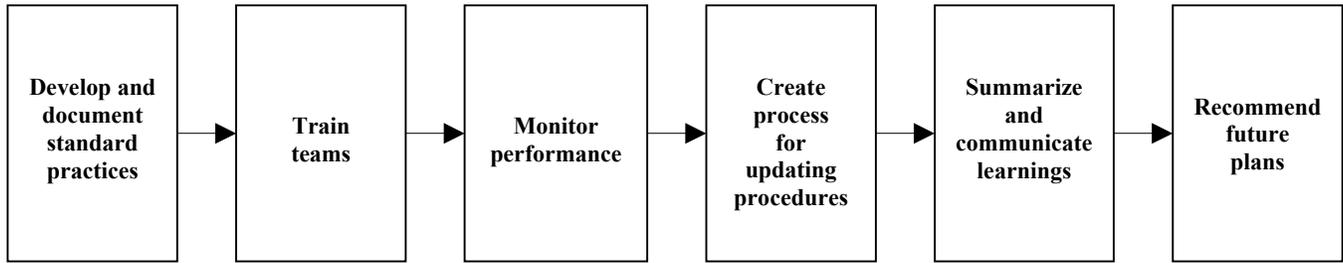| Tool	Description	Page
Activity Network Diagram/Gantt Chart	Helps you keep track of your implementation plans.	27
Brainstorming	Enables your team to creatively and efficiently generate a large number of possible solutions.	45
Commitment Scale	Helps your team understand how much work must be done to achieve desired levels of commitment.	67
Control Charts	In the Improve step, these charts are used to show past and present performance of an indicator. Since Control Charts (and Run Charts) show plots of results as time passes, they are excellent tools for determining whether a solution has any real, lasting effect on your process.	75
Failure Mode and Effects Analysis (FMEA)	Used to anticipate potential problems, allowing your team to take countermeasures to reduce or eliminate risks.	111
Histograms	Comparing "before" and "after" Histograms shows how much progress has been made.	129
Involvement Matrix	Helps your team think about who should be involved in the different steps needed to make change a reality, as well as the level of involvement that is appropriate for each of them.	156
Pareto Chart	As with Histograms, comparing "before" and "after" Pareto Charts is a way to objectively see how much progress has been made.	178
PDCA Cycle/Pilot	The PDCA (Plan-Do-Check-Act) cycle is the basic methodology behind a pilot. A pilot is a test of the whole system on a small scale to evaluate a solution and to make its full-scale implementation more effective.	199
Prioritization Matrix	Helps you objectively evaluate alternative solutions to a problem. The key is reaching consensus on the relative importance of different criteria first and then weighting the alternatives against those criteria.	189
Process Sigma	The true gauge of the effectiveness of any solution will show up in the new process-sigma level.	204
Run Chart	Like a Control Chart, a Run Chart shows whether a solution has any real, lasting effect on your process.	221
Tollgate Review	A formal review process that helps keep the project on track and helps promote successful results.	247

THE CONTROL STEP
GOALS AND OUTPUTS

The goal of the Control step is to maintain the gains you have made by standardizing your work methods or processes, anticipating future improvements, and preserving the lessons you learn from this effort.

The outputs of the Control step include the following:

- Documentation of the new method.
- Training of fellow employees in the new method.
- A system for monitoring the consistent use of the new method and for checking the results.
- Completed documentation and communication of the results, learnings, and recommendations.

| Develop and document standard practices	→	Train teams	→	Monitor performance	→	Create process for updating procedures	→	Summarize and communicate learnings	→	Recommend future plans

Many tools can help you monitor and control processes. Simply thinking in terms of PDCA (Plan-Do-Check-Act) - or, in this case, SDCA (Standardize-Do-Check-Act) - creates a mentality of constantly checking the effectiveness of your current methods. Training ensures consistency of application, as do "conspicuous standards" that make it easy for employees to do the job correctly.

The applicable tools for the Control step include the following:

Tool	Description	Page
Communication Plan	Helps you communicate effectively with the rest of the organization about the project.	70
Control Charts	Monitor progress over time after your project is completed. They can help your team continually quantify the capability of your process and identify when special events interrupt normal operations. It is typically part of the Process Management Chart.	75
PDCA Cycle	Serves as a reminder to think of improvement as being continual: Where can you go next to make the process even better?	199
Process Management Chart	Documents your PDCA – the plan for doing the work, how to check the results, and how to act if something undesirable or unexpected shows up. It also serves as a self-audit tool for checking how well and how consistently the new standards are applied.	199
Run Chart	Monitors progress over time after a project is completed. It is typically part of the Process Management Chart.	221
Six Sigma Storyboard	A pictorial record of your project. Typical documents include a succinct final report and a completed Storyboard that captures the project in graphical form.	239
Tollgate Review	A formal review process that helps keep the project on track and helps promote successful results.	247

DMAIC TEAM STRUCTURE

In most Six Sigma efforts, companies divide the responsibilities for accomplishing the improvement into four major roles: the sponsor; the team coach, typically called the Master Six Sigma Expert; the team leader, typically called the Six Sigma Expert; and the team member.
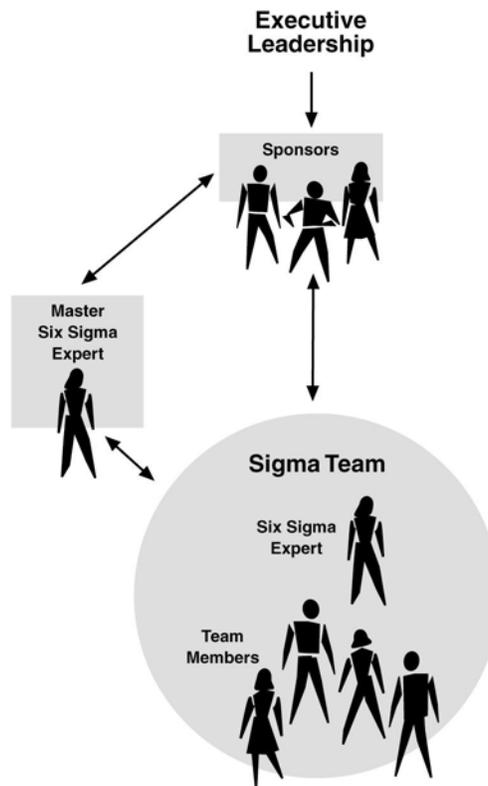
Early on in a Six Sigma project, it's important to clarify your team's relationship with your sponsor(s) - the supervisors, managers, or executives who have the power to allocate resources to the project, provide guidance regarding priorities, and ensure the project fits into your organization's business needs. Ongoing support and review by management are critical for your project's success, so part of the project plan should include activities such as weekly communication between the team leader and sponsors, as well as periodic reviews with the entire team.

You will likely also need technical support from a coach - an expert in Six Sigma improvement who has applied the many tools and concepts in practice. Such a person is often called a Master Six Sigma Expert by companies with a Six Sigma program. An organization typically has a few Master Six Sigma Experts who are called on by all its improvement teams. The Six Sigma Expert leads the improvement team, managing all aspects of the project to meet the goals of the charter. The Six Sigma Expert typically has a strong knowledge of the tools and concepts, as well as some experience in applying them. The Six Sigma Expert might lead one or more teams at any given time, and in many organizations this is a full time role.

Some organizations assign an additional team leader role, which is separate from the Six Sigma Expert role. In these cases, the Six Sigma Expert focuses on specific and more technical Six Sigma concepts, while the other team leader handles the responsibilities of team meetings, managing the project plan, and other less technical issues.

The team members carry out the work of the project. They learn many Six Sigma tools and concepts and apply these throughout the duration of the project. The Six Sigma Memory Jogger II™ is designed to help the team member make a successful contribution to the Six Sigma improvement team.

ACKNOWLEDGMENTS