Quality Improvement Methods
For use in QUERI research proposals and grant projects
Second Edition

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I. Preface

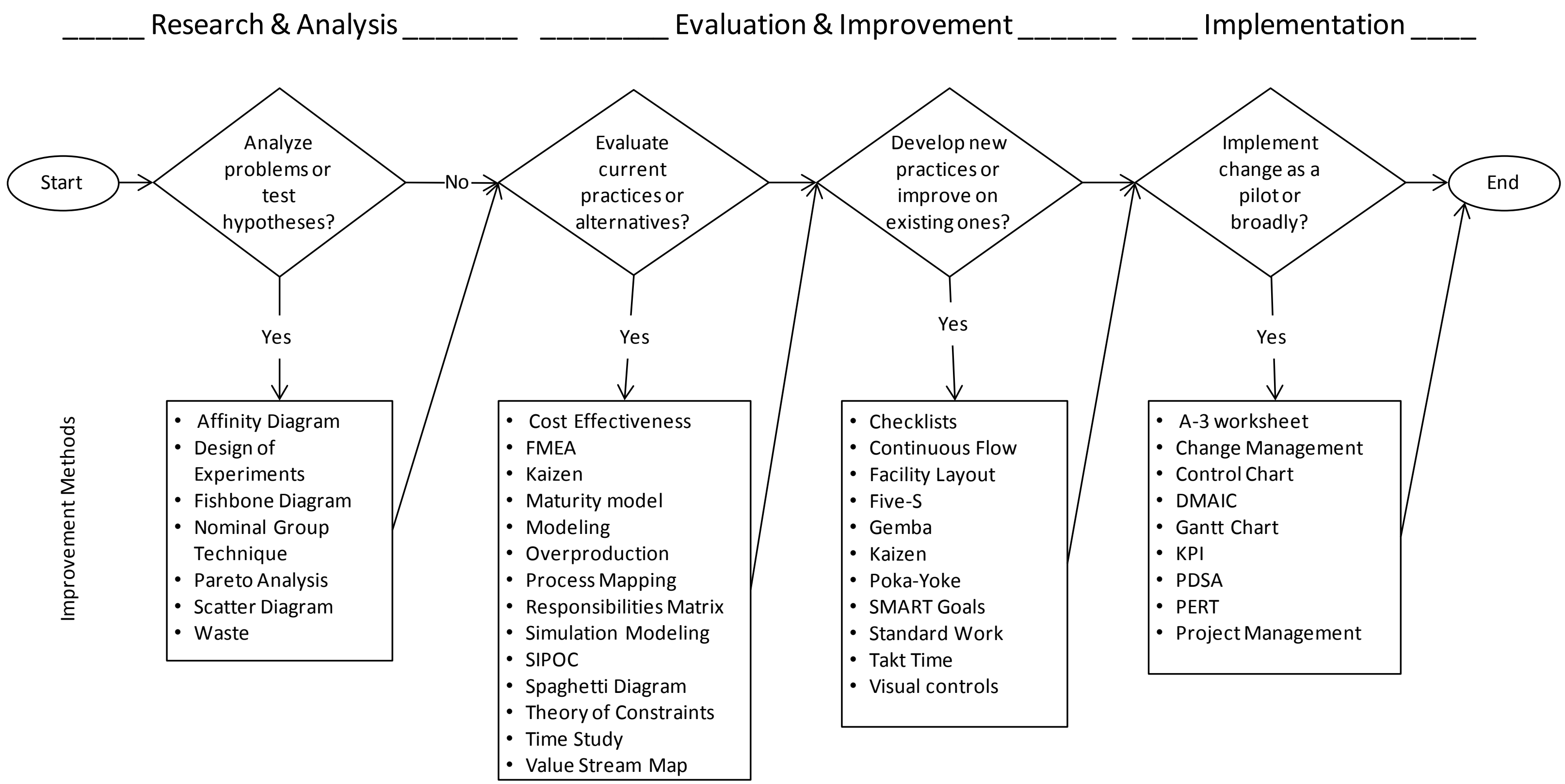
Research in healthcare involves changing processes and creating better ones. There has been much developed on how to assure quality and effectiveness when making changes in clinical and non-clinical settings. This handbook presents to researchers, in a condensed and digestible way, the most helpful improvement methods available. A broad variety of such methods exist. Described here are those which are most widely used and relevant to the QUERI researcher. Each method is described briefly so that the reader can decide what seems most useful. Further information will be needed to implement any of these methods but this handbook provides a starting point.

II. Introduction

When planning a research project, there are always opportunities to improve the results. Targets for improvement include quality, productivity, costs, and other aspects of a project. In some cases, it may be possible to improve the conduct of the research itself as well as the effectiveness of the clinical practice addressed. Fortunately, there are many methods for making such improvements. Some of these were initially developed by industries other than healthcare, but are applicable to healthcare nonetheless. Interestingly, some of these methods seem to work better in healthcare than they do in the industry in which they were initially used.

This document provides a set of improvement methods or tools that the QUERI researcher might find useful. Depending on the particular research proposed, the most useful set of methods will vary. Figure 1 shows these improvement methods categorized by phase of research where they are likely to be a good fit. In Section III an example of selecting methods for a particular proposal is presented. In Section IV the full set of methods is described in alphabetical order.

Figure 1. Project Steps and Methods



While QUERI research projects may encompass all possible phases of research, most are of a more limited nature and address primarily one of the following questions from Figure 1:

- Analyze problems or test hypotheses? These are projects that are more fundamental in nature. The researcher hopes to learn about current issues and their causes. Or, there is some idea about a problem and more work is needed to understand it.
- Evaluate current practices or alternatives? There may be better practices to be investigated and compared to current ones in order to better understand opportunities and challenges.
- Develop new practices or improve on existing ones? In this case, the researcher hopes to improve on current practices, with the goal of maximizing their effectiveness.
- Implement change as a pilot or broadly? This sort of project involves having a change take place, understanding the impact, and spreading and sustaining the change.

This paper describes 43 useful methods – actually more since there are several versions of some methods. Also some methods are referred to by more than one name. In order to identify which method is best for your particular situation a web site is available for assistance at http://www.queri.research.va.gov/implementation/quality_improvement/. The web site asks for the attributes of your research project and based on that response it presents the methods which offer the most capabilities relevant to the research. Of course, the researcher is free to peruse all the methods because unique aspects of certain situations may be helped by any of these methods.

The entire set of methods possibly used by a QUERI researcher is more than those described in Section IV. Not included in this handbook are:

- Statistical analysis of data and testing of hypotheses. These are the methods needed by the clinical researcher when comparing outcomes of an intervention.
- Clinical research issues and specific clinical practice methods
- Finding available best clinical practices

Most of the improvement methods described in this paper have a long history of their development and their literature. A degree of variability in their implementation exists depending on the practitioner. Thus, some authors may describe a method differently from others. It is not possible in this paper to provide training in each method or list all the literature and resources for each method. Many of these methods are individually covered in a college course or a separate textbook. Rather, the intent here is to give the researcher the basic idea and common uses of these methods as a starting point. If the method seems applicable, then further information can be easily found. None of these methods should be considered esoteric or unusual. All are in use at many healthcare institutions. For each improvement method the following is described:

a. Brief definition and when it might be helpful for QUERI research
b. Literature & resources (a limited sample)
c. Examples of use, particularly in a healthcare or research setting
d. Steps or brief directions to use the method

One aspect of these methods is that the exact approach varies by the practitioner using them or the institution where they are used. Moreover, some of them are referred to by more than one name and, in some cases; different methods share the same label. The most common names used in healthcare are used here.

General literature which provides details on many of the methods described in Section IV includes:

- Graban, Mark. Lean Hospitals: Improving Quality, Patient Safety, and Employee Engagement. Productivity Press, 2011.
- McLaughlin, Daniel B., and John R. Olson. Healthcare operations management. AUPHA Press, 2012.
- Ozcan, Yasar A. Quantitative methods in health care management: techniques and applications. Vol. 4. Jossey-Bass, 2005.
- Hall, Randolph W. Patient flow: reducing delay in healthcare delivery. Vol. 91. Springer Science+ Business Media, 2006.
- The Toyota Way to Healthcare Excellence: Increase Efficiency and Improve Quality with Lean (ACHE Management) by John R. Black (May 1, 2008)
- Gawande, Atul. Complications: A surgeon's notes on an imperfect science. Profile Books, 2010.

A number of organizations provide training, literature and web sites with information on these methods. These include:

- American Society for Quality http://asq.org
- The Institute of Industrial Engineers and its Society for Healthcare Systems http://www.iienet2.org and http://www.iienet2.org/shs
- The Institute for Operations Research and the Management Sciences. https://www.informs.org
- Society for Healthcare Improvement Professionals http://www.shipus.org
- VA Quality Enhancement Research Initiative (QUERI) http://www.queri.research.va.gov/
- VA Office of Systems Redesign https://srd.vssc.med.va.gov (VA Intranet only)
- VA Veterans Engineering Resource Centers https://srd.vssc.med.va.gov/Committee/verc (VA Intranet Only)

Other clinical, engineering, consulting and management organizations and publications also provide information on these methods.

It is strongly suggested that the researcher consider these methods as part of a QUERI research proposal. This is necessary to assure that interventions achieve maximum beneficial impact and that research is done in an efficient manner.

III. An example of an application of these methods

1. Proposal: A Multi-VISN Implementation of a Program to Improve HIV Screening and Testing[1]

Screening for HIV infection offers significant clinical benefits and is cost-effective. However, historically, at many VA facilities such screening was not consistent, even though HIV identification and treatment provides substantial clinical benefits to the population receiving the screening. Screening results in more timely medications, immunizations, and prophylactic treatments that reduce mortality, prevent hospitalizations and turn HIV into a chronic disease, avoiding the high cost of treatment and the mortality of more advanced cases. Screening appears to improve patients' outcomes, particularly quality of life after treatment. However, at one point in time such screening was not deployed commensurate with the benefits and was not well understood at many VA provider locations. The facilities that were currently using the screening procedures differed in terms of how it was deployed. There are multiple ways in which HIV testing can be encouraged, results audited, providers reminded and the program organized.

An initial limited program was successfully implemented resulting in a significant increase in testing rates and as well as an improvement in outcomes. Based on this success, the researchers proposed to extend this program to more sites and VISNs with eventual goal of a national roll-out.

Let's now imagine that we are the researchers preparing the proposal. The proposed research project must answer pressing questions as to how best to deploy limited resources for this program with the best design in order to achieve the desired results. Thus, proposed objectives are to:

- Evaluate alternative refined versions of the intervention to be done at multiple sites. This will utilize of a study in which implementations will be done at a randomized set of sites to apply differing designs of the program. It will allow the researchers to determine the effectiveness of alternative designs for applying local resources.
- Identify situational variations as well as systematically neglected populations and identify strategies to reduce these issues. Particular attention will be paid to the needs of veterans who are at highest risk. The project plans to design clinical testing and reminders.
- Further evaluate implementation costs, generalizing the business case model developed for the prior deployment so that the full rollout of the program can be justified based on its economics.
- Identify organizational requisites (e.g., staffing, infrastructure and training) for the success of this intervention.

[1] This example is loosely based on an actual set of projects conducted by Matthew B. Goetz, MD and colleagues. See Goetz et al. "A system-wide intervention to improve HIV testing in the Veterans Health Administration." Journal of General Internal Medicine 23.8 (2008): 1200-1207 and Goetz et al. "Central Implementation Strategies Outperform Local Ones in Improving HIV Testing in Veterans Healthcare Administration Facilities." Journal of General Internal Medicine 28.10 (2013): 1311-1317. The example has been adapted to illustrate the various methods in this handbook.

Accomplishment of these objectives is expected to provide a strong foundation for the roll out this intervention to the entire VA. Thus, at the end of the proposed project, which is based on current knowledge and some preliminary data, the researchers expect to know if their proposed screening plans are effective and how best to change provider behavior appropriately and sufficiently. The researchers hope to extend a pilot intervention, improve upon it and to extend it to a wide set of providers.
What QI methods should be included in such a proposal?

2. Selecting the right QI methods

Certain of the QI improvement methods presented in this handbook will strengthen the proposal in significant ways. Success requires selecting the most relevant methods and having the necessary training and experience in their use. The proposal will be enhanced by having staff with relevant QI expertise as part of the team and in a meaningful role.

First, the researchers must understand the environment they hope to impact and that there are proven QI methods to improve upon that understanding. Researchers are expert practitioners in their particular clinical field but they must understand the specific sequence of work processes they plan to impact and constraints on making sustained changes. There may be an organizational culture that will delay or reduce the effectiveness of the proposed intervention, there may be unanticipated costs and there could be many factors not experienced in the researchers' earlier studies. Cost is always a constraint and efficient use of resources requires an efficient design as well as a measurement of outcomes and resulting costs.

Before making a significant change it is important to understand the existing processes and opportunities for improvement. The following methods are particularly applicable for the above proposal:

- Understanding existing processes - A good way to understand current screening processes is documentation through mapping the process and reviewing the map with the staff (see Section 28). It may be useful to compare a map of the processes at the initial study site versus a map at other sites doing similar screening to identify relevant differences. To the extent certain individuals will need to change practices, the development of a responsibility matrix would be helpful (see Section 30). That would indicate which types of individuals must be included and where duplication should be avoided. Also the receptivity of the local organization to the new practices could be considered. A Maturity Model (see Section 15) is one way to do that as assuring proper goals are understood as well as a plan to communicate new objectives (see Hoshin Kanri Section 24).
- Planning change to assure success - Implementing change, in order to be effective, should follow a proven technique such as PDSA (see Section 25). This will mean the change process is designed so as to adopt new practices in a manner to assure a high likelihood of being sustained. Since a variety of professional specialties are involved, a Kaizen like team will be useful (see Section 17). Clinical researchers may be familiar with what is to be done in implementing a change, such as new testing and patient education, but there are ways to increase the likelihood of complete and permanent change. Early implementations may not be as efficient as they could be. A value stream map (see Section 41) based on process maps done earlier in the project can be used to

identify waste and opportunities for improvement. The Kaizen team that created the Value Stream Map can use it to identify desirable practical changes. Setting clear goals is also important (see SMART Goals Section 35) so that participants know what is intended and so that leadership can know if it is being achieved.

- Implementation – Often implementation of changes such as new testing and clinical reminders can best be done in an incremental way (See PDSA in Section 25). Consistent implementation is necessary for good quality and maximum effectiveness. That means that it will be very important to document the Standard Work description (See Section 37). By having Standard Work prepared, an ongoing use of the preferred practices is assured. If data is available, a control chart (see Section 6) can be used to verify the outcomes are as desired and to communicate progress to all concerned (See the A-3 form Section 1).
- Evaluation of results and sustaining change – Sustaining a consistent practice may benefit from checklists (see Section 4) and designing work processes so that they must be done one certain way (See Poka Yoke Section 27) and to use visual controls (see Section 42) where possible. The business case will require determination of cost effectiveness (see Section 7) and statistical comparisons to assure support of the change. Cost is always as constraint and determining an economic effectiveness measure for the results of the project is reasonable to expect.

IV. Methods for Improvement

1. A-3 Worksheet

a. Definition: Communication and participation are key elements of quality improvement. Getting the important points of an improvement project across on a single page is a good way to assure needed information is communicated to everyone who needs it. The layout can vary but often a large paper size (hence the A-3 term which is a paper size) is often used. On the page are the goals, current status, role of participants and performance measures. The paper form may be posted in multiple accessible spaces for all to see as well as used as a working document by the team of people most involved. It can also serve as a structure for a quality improvement project since it highlights what aspects of a project must be developed.
Research projects benefit from having all involved knowing what improvements are occurring. Posting A-3 forms in hospital or clinic work areas will increase the likelihood of a new practice being successful.

b. Literature: Design and use of the A3 is generally described in texts on the Lean Method (see Section 19). Also see:
   - Sobek II, Durward K., and Art Smalley. Understanding A3 thinking: a critical component of Toyota's PDCA management system. Productivity Press, 2011.
   - Lee, Te-Shu, and Mu-Hsing Kuo. "Toyota A3 report: a tool for process improvement in healthcare." Stud Health Technol Inform 143 (2009): 235-240.
   - Visich, John K., Angela M. Wicks, and Faiza Zalila. "Practitioner perceptions of the A3 method for process improvement in health care." Decision Sciences Journal of Innovative Education 8.1 (2010): 191-213.

c. Example: A research project developed an intervention that impacted several provider departments in a hospital. The implementation team included people from various areas which were affected by the intervention. It was important that all areas implemented the changes as planned and with coordinated timing. The prior research results provided specific goals and an overall time schedule. As a way to organize the tasks to be done, as well as a way to keep everyone impacted by the project informed, an A-3 form was prepared and updated as the team proceeded with the implementation. The form was posted for view by staff in the Emergency Department as well as in other departments such as radiology and pharmacy, and it was updated weekly as parts of the project were changed or completed. Because everyone was informed, participation was more likely. The A-3 not only included objectives and plans but also responsibilities, results and conclusions or insights. The following is an example of a blank A-3 form.

Title: ____________	Location ____________	Date ______	**A-3**
Team leader ____________	Sponsor ____________	Version: ________	
1. Objectives *Aim:* *Scope:*	4. Current situation	7. Analysis	
2. Background	5. Plan of action		
3. Desired situation	6. PDSA events	8. Findings	
Follow up			

d. Steps:

1) Use of the A-3 requires selection of a consistent format so that readers find it easy to understand. There is no one standard universal format. Available literature presents a variety of possible formats if one format has not already been adopted by the organization.
2) The form is filled in and then used by posting it in work areas for all affected to see. It is also used as a working document for discussion and an organization structure for a Kaizen (see Section 17 in this handbook) or a research group.
3) As the change process proceeds, the A-3 is updated and new versions posted.
4) At the end of the effort, the A-3 provides a historical record of the change process.

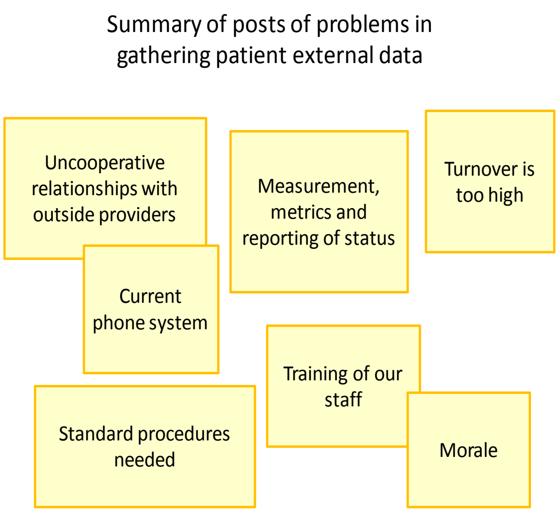
2. Affinity Diagram

a. Definition: An affinity diagram organizes ideas according to their relationships. Notes about similar observations or ideas are posted and then grouped together visually so as to support insights and to promote creativity about them. The affinity diagram was created in the 1960s by the Japanese anthropologist Jiro Kawakita and thus is also referred to as the KJ method. It is helpful when there are many ideas and bits of disjointed information to consider, perhaps in the early stage of a research project.

b. Literature: This is a relatively straightforward idea and not much literature is specific to it. Such diagrams are discussed in much of the literature on quality improvement.

- "Problem-Solving Tools for Analyzing System Problems: The Affinity Map and the Relationship Diagram", Lepley, Cyndi J. PhD, RN, Journal of Nursing Administration: December 1998 - Volume 28 - Issue 12 - pp 44-50

c. Example: Affinity diagrams have been applied in a wide variety of settings, from consumer research to project management. Once a set of ideas or issues are identified they can be grouped by similarities, often graphically, in order to share and discuss the arrangement with a group of people. This graphic becomes a prompt for discussion of insights or possible improvements to an issue. The affinity diagram can be used to develop ideas for an intervention for a given system or setting or to better understand the overall situation. For example, causes for a problem are grouped together. It can be quite informal, such as ideas generated in a group discussion with Post-It notes:



d. Steps:

1) Determine the issue or general topic to be addressed.
2) In a group setting create a comprehensive list of ideas, information, or problems through brainstorming or a non-judgmental open discussion. A high volume of items is preferred without prejudging or eliminating any ideas.

3) Post these items on a sheet of paper or wall as they are identified, perhaps with sticky notes, so that they can be easily moved and rearranged.
4) Move the notes about so as to group together similar or related items. This could involve a hierarchy of groups and subgroups. If this is a team effort, discuss the changes together and collaborate to rearrange it.
5) Add group headings or titles to the groupings.
6) Other graphics can be added such as lines indicating connections between items or subgroups.
7) If appropriate, reduce the diagram to a reproducible document, perhaps as an outline or tree-like diagram. Also use it as a starting point for brainstorming ideas to address the issue or solve problems.

3. Change Management Approach

a. Definition: An approach to assure that an operational or organizational transition takes place successfully. There are a set of ideas and methods that are recommended regardless of the particular change being made. The environment for change is important, including motivation, support, understanding and reinforcement.

Change management principles cover a wide range of items. Generally considered key components are:

- Formalize the change describing precisely and in writing what is to be done, responsibilities, etc.
- Communications to stakeholders so that they are aware of a change including the benefits, responsibilities and other specifics
- Dealing directly with the personal issues of the individuals affected by a change
- Assure that individuals are motivated and sufficiently trained regarding the change
- Monitoring progress (see Section 29 on Project Management)
- Prepare for unexpected events, changes and problems

b. Literature:

- Kotter, John P. Leading change. Harvard Business Press, 1996.
- Bridges, William. Managing transitions: Making the most of change. Da Capo Press, 2009. Scott, W. Richard. Institutional change and healthcare organizations: From professional dominance to managed care. University of Chicago Press, 2000.
- Gill, Roger. "Change management--or change leadership?" Journal of Change Management 3.4 (2002): 307-318. Grol, Richard, and Jeremy Grimshaw. "From best evidence to best practice: effective implementation of change in patients' care." *The Lancet* 362.9391 (2003): 1225-1230. Is “an overview of present knowledge about initiatives to changing medical practice”.
- Anderson, Dean, and Linda Ackerman Anderson. Beyond change management: How to achieve breakthrough results through conscious change leadership. John Wiley & Sons, 2010.

c. Example: Change management means that in order for a change to occur as intended, and for it to be sustained, it must be done in a rational and structured way – more than just project management to track the schedule. By including the basic ideas of change management in the execution of a change, the effort is much more likely to meet with success. Some of these ideas that are not always used in healthcare or research are:

- Assign a Change Management Coordinator, particularly if the change is relatively large.
- Select system owners for each of the areas affected, such as radiology, pharmacy, accounting, etc.

Also, be sure to involve all functional areas affected by the change.

- Set a weekly schedule to review progress against established milestones.
- Make sure that all areas are fully committed and not limiting the responsibility to just management, just nursing, or just IT, etc.

d. Steps:

1) Recognize the changes in the broader business environment
2) Develop the necessary adjustments for the company's needs
3) Train employees on the appropriate changes
4) Win the support of employees with the persuasiveness regarding the appropriate adjustments

The concept of change management may seem simple but successful and sustained change is extremely difficult, particularly in the complex healthcare setting. By developing a good change management plan, success is more likely to occur.

4. Checklists

a. Definition: The idea of a checklist is a rather simple and obvious tool. However, critical quality steps are sometimes overlooked without one in use. Many healthcare functions, such as preparation for surgery and emergency department care, benefit from a checklist which makes explicit the requirements for quality results. A good checklist assures work has been done correctly and completely. It is an important ingredient for other methods in this handbook when improvements must be consistent and sustained.

b. Literature:

- Gawande, Atul. The checklist manifesto: How to get things right. Profile Books, 2010.
- Gawande, Atul. "The checklist." The New Yorker 83.39 (2007): 86-95.
- Øyvind, Thomassen, et al. "Implementation of checklists in healthcare; learning from high-reliability organizations." Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine 19.

c. Example: Checklists are a common practice throughout healthcare (or at least should be). Often they are written as a protocol but not always in familiar use with the staff. A checklist of critical actions is very helpful in many situations such as prior to surgery or checking in a new patient. Their power is often overlooked, but they are a powerful aid to assure ongoing and consistent quality. A checklist may be a way to assure consistent implementation of a change resulting from research.

d. Steps: Beyond the simple list of items, a checklist process can include a description of standard practices to assure the checklist has been properly executed, that a copy has been kept, that the necessary individuals were involved in its creation and the necessary individuals have been trained in its use. It is possible to have a checklist for developing checklists. Like many improvements and changes it will be helpful to make the transition in an incremental and iterative manner (see PDSA, Section 25)

5. Continuous Flow

a. Definition: Continuous flow is the concept that work can be done best where there are no stops and starts but rather a smooth and organized sequence. This reduces waste, such as waiting between steps. Continuous flow improves quality due to ongoing focus on the necessary tasks. Doing work in batches is the opposite of continuous flow and leads to waste (see Section 43). One piece flow is deemed better because it tends to reduce inventory and makes errors more obvious.

b. Literature

The concept of continuous flow comes from the manufacturing and supply chain industries but its benefits are applicable to healthcare work as well.

- Nelson-Peterson, Dana L., and Carol J. Leppa. "Creating an environment for caring using lean principles of the Virginia Mason Production System." Journal of nursing administration 37.6

(2007): 287-294. The Virginia Mason hospital in Seattle has implemented many of the Toyota Production System ideas, including converting batch work to more continuous one piece flow.

- Adapting lean to histology laboratories, René J. Buesa, Annals of Diagnostic Pathology, Volume 13, Issue 5 , Pages 322-333, October 2009. There are many published examples of successfully converting work done in batches to continuous flow. Often this is in a Lab or Pharmacy setting but successful examples occur in emergency departments, surgery, outpatient clinics and others.

c. Example: A hospital pharmacy prepares medications each day and various technicians do the work. It is a part time task for each technician. Previously the technicians would work on a batch of orders but do other tasks between the batches. By creating a workflow, a work layout and staffing that promotes continuous flow, a better quality and productivity results.

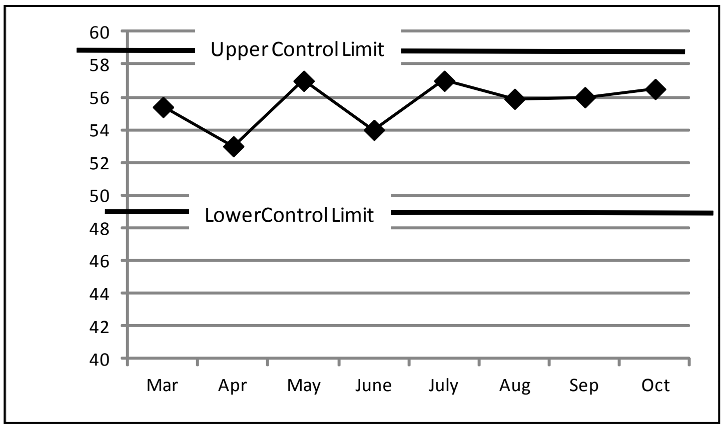
d. Steps

The basic idea of continuous flow is to function with one-piece flow rather than batch flow. Thus providing a service or completing a product is done in a sequence of continuous workflow. Steps include:

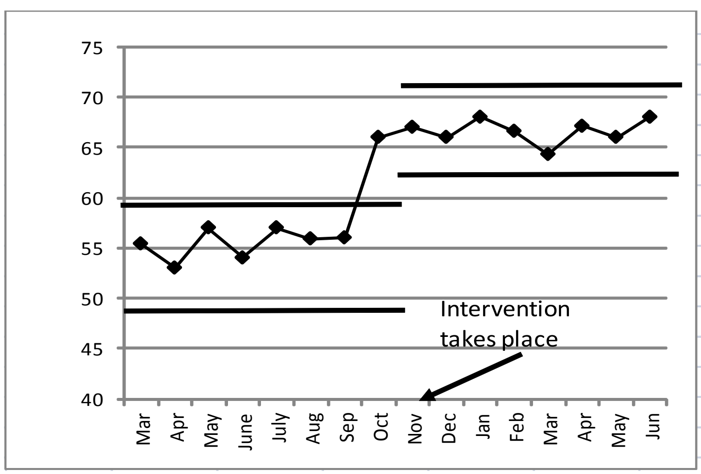
1) Determine where continuous flow is applicable and the steps involved to create it. Continuous flow is useful where there is sufficient work to require ongoing staffing and is often helpful as part of a simplification effort
2) Determine the work, and equipment needed for each step
3) Determine “Takt time” to create a continuous flow (see section 38)
4) Determine the staffing needed to meet the Takt time
5) Balance the work within the cell

6. Control Chart

a. Definition: A way to display and analyze data on a process over time using statistical methods to determine when variation in the data is other than would be expected or if the variation is due to a an undesirable cause. In healthcare, it can be used to determine the effectiveness of an intervention, monitor the consistency of work done or determine if there has been a change in the environment. Since a degree of randomness exists in most healthcare processes, a degree of variability may be acceptable. The control chart is useful in determining when variability exceeds the expected randomness based on upper and lower control limits on the range of likely random fluctuations.



In research there may be a change as a result of an intervention. This may mean a change in the control limits but it would still be necessary to monitor the variability.



b. Literature:

- Woodall, William H. "The use of control charts in health-care and public-health surveillance." Journal of Quality Technology 38.2 (2006): 89-104.
- Carey, Raymond G. Improving healthcare with control charts: basic and advanced SPC methods and case studies. ASQ Quality Press, 2003.

- Control charts 101: a guide to health care applications, Qual Manag Health Care. 2001 Spring; 9 (3):1-27.

c. Example: A hospital's GI department tracks the time taken for a particular procedure. Of course, there is variability in the time for each patient and provider. One statistic they can measure is the average time for all cases of a particular type each month. The hospital has established a range that should be expected for the average amount of time taken. There were enough cases so that the monthly average should not vary a great deal. Control limits were statistically calculated using 99.5% confidence interval. Deviation outside this interval should occur only rarely, not occur more than 0.5% of the months, unless something had changed, which should be investigated. Besides noting if the control limits were breached, it is also relevant to look at trends within the control limits to alert the clinic to something unusual occurring. An unusual occurrence would be a series of points moving in the same direction, for example, or an alternating pattern of data points above and below the midpoint. The control chart limits are supposed to indicate the range of acceptable variability due to the nature of the activity. If the data indicates some pattern or predictability then there may be an undesirable factor occurring. This would indicate a need for further investigation even if the data points are still within the control limits.

d. Steps:
   1) Gather data on the metric or measure to be tracked. This can be a quality measure or other attribute of a system where we want to be alerted if the variation is greater than expected.
   2) Based on the available data, determine the average of the data, as well as the extent to which the measure varies randomly; this random variation is captured in the variance or standard deviation of the measurement.
   3) Determine how sensitive you want to be to detecting changes. For example, we might want the control limits to encompass 95% of the variability and then want to be alerted when the measure breaches these 95% control limits.
   4) Create a graph showing ongoing data as well as the control limits. Consider any value outside these limits to be an indication that the tracked process is "out of control" or something has changed which bears further investigation.

Note: Control charts can be used on individual measures, averages of groups of data, ranges for a group or the variability. A spreadsheet program such as Excel facilitates the calculations as well as drawing of the graph.

7. Cost Effectiveness Analysis

a. Definition: Cost effectiveness analysis (CEA) is the economic evaluation of alternatives by considering both the benefits and the costs. Costs are generally a monetary amount (dollars) and could include the indirect impact of an intervention. The benefits, in a health care setting, are sometimes difficult to put in monetary terms and therefore are measured as an improvement in health outcomes such as a reduction in morbidity or reduced hospital readmissions. Benefits may include an improvement in so-called quality-adjusted life years (QALY). The results are reported as the cost divided by the benefit, such as $500 per readmission avoided. Cost effectiveness should be considered on an incremental basis as the change in cost divided by the change in the outcome in comparison to other alternatives or to the current situation.

While CEA is important, it is sometimes difficult to quantify the full benefits of an intervention resulting from research into economic terms.

One of the alternatives considered is often the status quo or no change. Future costs and benefits should be reduced (discounted) at a percentage annual rate. Satisfactory cost effectiveness may be compared to a predetermined minimum amount. Below that minimum may not be satisfactory. Economic evaluation can also use the percentage rate at which benefits are received for a particular cost, sometimes referred to a return on investment (ROI). The resulting rate is then compared to some minimally acceptable rate.

b. Literature:

- Drummond, Michael F., Mark J. Sculpher, and George W. Torrance. Methods for the economic evaluation of health care programs. Oxford university press, 2005.
- Gold, Marthe R., et al., eds. Cost-effectiveness in health and medicine. Oxford University Press, USA, 1996.
- Weinstein, Milton C., and William B. Stason. "Foundations of cost-effectiveness analysis for health and medical practices." The New England journal of medicine 296.13 (1977): 716.
- World Health Organization - CHOICE Choosing Interventions that are Cost Effective, http://www.who.int/choice/en/
- Information, guidelines and additional references about cost effectiveness analysis specific to VHA are at http://www.herc.research.va.gov/methods/cea.asp A discussion of QALY is provided.

c. Example: A project to change current clinical procedures in order to reduce emergency room visits is being considered. There is a forecast of the cost of the changes and their expected impact on health outcomes. Incremental (added) costs can be estimated as well as the economic benefits of reduced utilization of health services. Cost effectiveness can be calculated using the expected benefit of $400 per emergency room visit avoided with 20 visits a year avoided for 5 years, a $20,000 initial project cost and additional costs of $1,000 per year due to the changes. (These numbers are for example purposes only.) Thus, costs over 5 years would be $25,000 (or $20000 + $1000*5) and benefits $40,000 (or $400*20*5). A return on investment can be calculated based on the rate at which savings result from the initial cost. In this case there is a return on the investment of 35% per year (or ($400*20 - $1000)/$20000).[2] Also, a consideration should be the uncertainty in the costs and benefits, what time horizon to use, and what investment alternatives are available.

d. Steps: The particular steps will depend on if cost effectiveness is being determined prospectively (to decide whether to proceed with a particular intervention) or retrospectively to evaluate the results in economic terms. If prospective, there will be uncertainty regarding both costs and benefits, and modeling or simulation may be required. If retrospective, it may be difficult to determine actual costs and dollar benefits but the impact on outcomes will more likely be known.

[2] More precisely a return on investment should consider the exact timing of the cash flows. Here most of the outflow is at the start and the returns are later and limited to 5 years. An economist would calculate an internal rate of return or the rate at which the discounted present value of all cash flows is zero. In this case the rate of return is 22%. Calculators are available and references in Engineering Economics. In MS Excel the @IRR function calculates this value.

8. Design of Experiments Statistical Approach

a. Definition: Design of Experiments (DOE) is a statistical approach to efficiently plan tests so that when changes are made, such as clinical interventions in existing processes, the effect on individual factors associated with changes can be determined. This approach to gain knowledge from the outcome of tests or experiments is to plan tests in such a way that information can be gathered with a minimum number of trials.

b. Literature:

- Telford, Jacqueline K. "A brief introduction to design of experiments." Johns Hopkins apl technical digest 27.3 (2007): 224-232.
- Neuhauser, Duncan. "Why design of experiments just may transform health care." Quality Management in Healthcare 14.4 (2005): 217-218.
- Cox, David Roxbee, and Nancy Reid. The theory of the design of experiments. Vol. 86. Chapman and Hall/CRC, 2002.
- Fisher, Ronald A. (1971) [1935]. The Design of Experiments (9th ed.). Macmillan. ISBN 0-02-844690-9. (Fisher is generally considered a founder of DOE)
- Barrentine, Larry B. An introduction to design of experiments: a simplified approach. ASQ Press, 1999.

c. Example: A hospital system was considering changes to a current clinical function. The changes were an increased use of a particular medication and also the reduced use of a certain therapy, which could both be done to varying degrees. Thus they were faced with a number of trials of possible change combinations. The hospital has various outcome measures with regards to evaluating the procedure. They want to determine a minimal set of trials. DOE provided a way to minimize the necessary set of trials (or experiments) so they could determine the best procedure as quickly as possible.

d. Steps: The use of the DOE idea is to determine what outcome you are interested in, what changes are to be tested and then to use DOE algorithms to determine an efficient plan to determine the best combination of changes.

9. DMAIC (Define, Measure, Analyze, Improve, Control)

a. Definition: The improvement process is often cyclic and it is useful to define the sequence of steps involved. DMAIC represents improvement as five steps: Define, Measure, Analyze, Improve and Control. Pronounced De-MAY-ick. By considering all these steps clearly and in sequence, the success of an intervention or quality improvement project is more likely. DMAIC becomes the project structure for a Six-Sigma improvement effort (see Section 34).

b. Literature: Most books on Six-Sigma have at least one chapter on DMAIC. Also see:
- Shankar, Rama. Process Improvement Using Six Sigma: A DMAIC Guide. ASQ Quality Press, 2009.
- Kumar, Sameer, and Kory M. Thomas. "Utilizing DMAIC six sigma and evidence-based medicine to streamline diagnosis in chest pain." Quality Management in Healthcare 19.2 (2010): 107-116.

c. Example: A hospital unit was concerned about the quality indicators they had recorded for a particular diagnosis. These quality indicators demonstrated a quality gap that needed to be closed. Recent research indicated that the hospital unit should add a step to their current procedures for these patients. In using the DMAIC approach, a first step would be to clearly identify the current state and to quantify current performance. Also, the hospital unit would need to determine output variables to analyze and set a target for these which they would like to achieve. These are the “define” and the “measure” steps, respectively. Next would be an analysis of the factors that might cause the problem and implementation of tests of changes to determine their impact on the output variables. Finally, the unit had to put in place procedures to be certain that the changes were consistently followed and for ongoing measurement of the results.

d. Steps: DMAIC is itself a set of steps regarding a quality (or other) improvement project.
1) **Define** the key metrics for measuring success and achieving goals of the effort, perhaps a certain quality level. It is important to write down these objectives for later reference, thereby creating a charter for the effort.
2) **Measure**: Implement a measurement of the key elements, determine past levels which become a baseline to determine if a significant improvement has occurred
3) **Analyze**: Identify the opportunities for improvement of each metric. This may include determination of the root causes of problems in quality or other aspects
4) **Improve**: Identify creative solutions, redesign the relevant processes so as to achieve the goals, and implement the change.
5) **Control**: Measure the improvement and report the results so as to sustain success. Ideally the change created by DMAIC is self-sustaining and no monitoring is necessary.

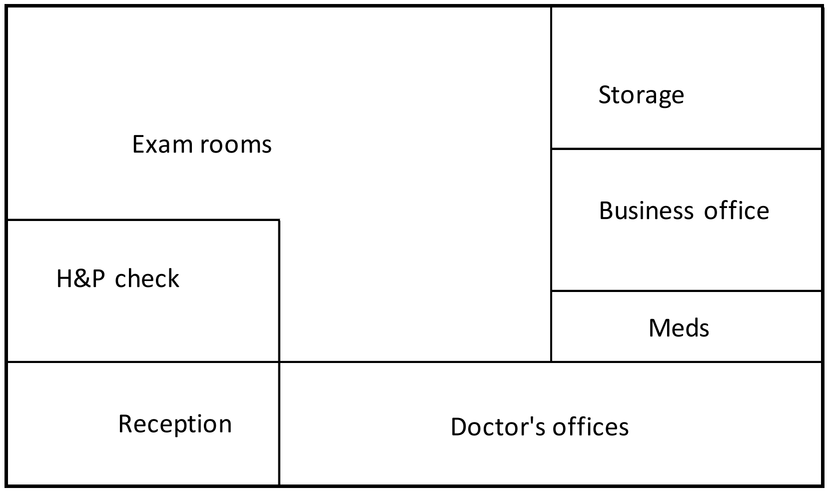
10. Facility Layout Assessment

a. <u>Definition</u>: The physical arrangement of a workspace, such as a healthcare clinic, has a significant impact on productivity and quality. Methods exist for arranging workspaces to minimize distances the staff and patients must move, and to optimize visibility, sound, safety and other aspects of a facility's layout. These operational considerations may be ignored by architects or plant operations but considering the needs of the clinician or operations management can have a long term beneficial impact. When a new process or intervention is considered, the facility layout often should be studied as well because it can influence the effectiveness of such a change. Also, similar to layout decisions, the subject of facility location can be addressed in an analytic manner.

b. <u>Literature</u>:
- Tompkins, James A. Facilities planning. Wiley, 2010.
- Muther, Richard. "Systematic layout planning." (1973). (contains many practical and easy to use tools but may be difficult to find)
- Miller, Richard Lyle, and Earl S. Swensson. Hospital and healthcare facility design. WW Norton & Company, 2002.
- Joseph, Thomas P. "Design a lean laboratory layout." Medical Laboratory Observer 38.2 (2006): 24. The principles of Lean and efficiency apply to facility layout as well.

c. <u>Example</u>: In the initial planning of changes to a clinic, changes to various functions were needed: reception, business office, phone system, exam rooms, doctor's offices, medication storage, and others. The organization knew how big a space it could afford and had a site which required a certain exterior configuration. As a first step, the organization had to determine how much space was required for each function and then where each function should be located within the building walls. Through an analysis of various adjacency factors, an optimum basic configuration was developed. This reduced future operating costs, and assured patient satisfaction and clinical quality.

d. <u>Steps</u>: There is a wide range of issues which might be involved in facility layout; what area should be near what (adjacency), size of workspace, configuration/shape of a workspace, layout of workstations for safety and convenience, etc. Depending on the objective, different steps will be required. If a basic block plan is needed, the following are the basic steps:
   1) Identify areas requiring space, factors affecting their size, and determine total square feet required for each.
   2) Determine size of building space to be occupied.
   3) Move about blocks with relative size to determine what spaces are best near (or far from) others.
   4) Adjust blocks to fit into available building space and shape.
   5) Finalize block plan, resulting in a basic configuration, such as below, and then continue to add details within it.



Clinic Block Plan

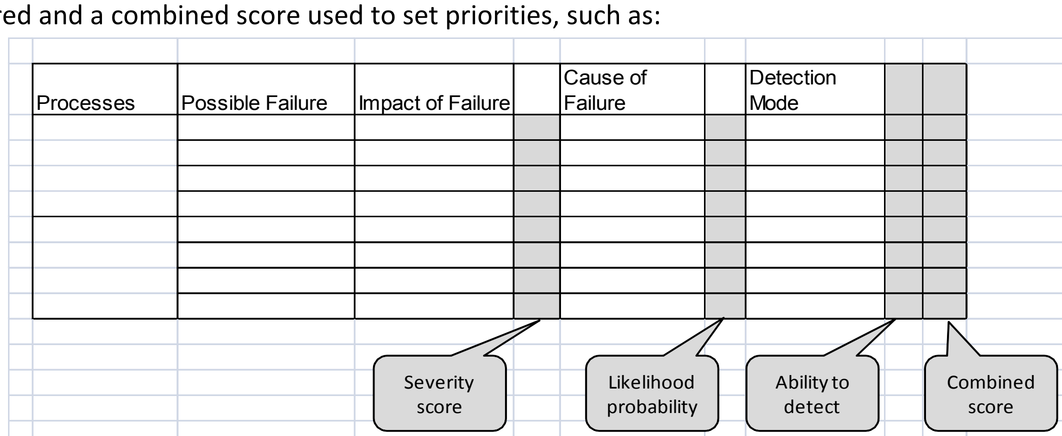
11. Failure Mode and Effects Analysis

a. Definition: This method considers the ways or modes in which something might fail and then doing a structured study of the effects of the failure. By breaking down the causes and relationships, this method results in a better understanding of the processes involved and where best to prevent future failures or reduce risk. It identifies actions to reduce or eliminate errors and documents the entire process. It was initially developed in the 1950s for the analysis of military equipment malfunctions. Where clinical quality is concerned, FMEA can be used to develop an improved design. In planning a QUERI research intervention, it could be used to reduce the chances of adverse results. Worksheets and software exist to manage the information and present it in a standardized way.

b. Literature:

- Brooks, Frederick P. The mythical man-month. Vol. 1995. Reading: Addison-Wesley, 1975. (Not about FMEA expressly but this popular book provides a foundation for it.)
- Stamatis, Dean H. Failure mode effect analysis: FMEA from theory to execution. ASQ Quality Press, 2003.
- DeRosier, Joseph, et al. "Using health care Failure Mode and Effect Analysis: the VA National Center for Patient Safety's prospective risk analysis system." Joint Commission Journal on Quality and Patient Safety 28.5 (2002): 248-267.
- Spath, Patrice L. "Using failure mode and effects analysis to improve patient safety." AORN journal 78.1 (2003): 15-37.
- Reiling, John G., Barbara L. Knutzen, and Mike Stoecklein. "FMEA–the cure for medical errors." Quality Progress 36.8 (2003): 67-71.

c. Example: A hospital performed a FMEA on its electronic health record system. The hospital identified the various scenarios which could result in wrong information being stored in a patient's records. This analysis identified what specific actions the hospital should take in the near term in order to reduce the likelihood of the most important problems related to its quality of care. The cross-functional team used their experience and judgment to determine appropriate priorities for action based on a study of the possible failures, impacts, causes and ability to detect each failure. These factors can be scored and a combined score used to set priorities, such as:



d. <u>Steps</u>:

1) Define the objective and scope of the FMEA.
2) For each function involved, identify the ways in which failure could occur.
3) Determine how serious each failure mode impact is and its likelihood. Often these are given a numerical value.
4) For each failure mode define the detection mode and how likely it is to detect a failure.
5) Determine priorities based on the aforementioned impact, likelihood and detection scores.
6) Develop a mitigation plan based on the information from the analysis.

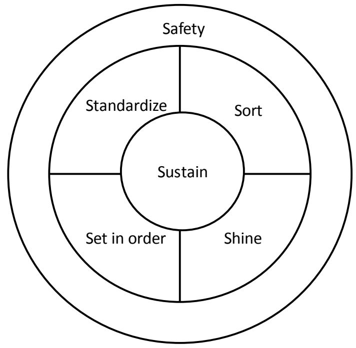
12. Five-S Exercise

a. Definition: A workplace organization scheme with a focus on neatness to support efficiency. It originated in the Toyota (Lean) method with its Japanese terms transliterated into English. It consists of five Japanese words beginning in "S": Seiri, Seiton, Seiso, Seiketsu and Shitsuke, which means tidiness, orderliness, cleanliness, standardization and discipline and sometimes referred to as sorting, set in order, systematic cleaning, standardizing, and sustaining. Often significant improvements occur when a "5-S" exercise is done beyond just simple neatness. Some healthcare organizations refer to 6-S where the concept of Safety & Security is added. The 5-S method is useful when an area should perform better and the idea can be used in conjunction with other interventions to assure maximum improvement. An existing lack of order in the workplace can constrain improvements of any type and harm quality.

b. Literature:
- 5-S is described in most Lean and Six Sigma literature and various books on good management.
- 5-S for Healthcare (Lean Tools for Healthcare Series), Thomas L. Jackson, Productivity Press, 2009
- Clinical 5-S For Healthcare [Paperback] Akio Takahara (Author), Enna; (September 15, 2010)

c. Example: Staff is trained in what sort of workspace problems should be identified from a 5-S standpoint. A nursing station is reviewed, for example, in 5-S terms and the staff observes instruments not as orderly as they could be, supplies not stored in a standardized way and procedures not in place to assure that once the workplace becomes more neat that the change will be sustained.

d. Steps:
1) Train individuals who will conduct the 5-S exercise in the principles and example of 5-S. They need to understand and be sensitive to the 5 (or 6) aspects which are necessary for a neat and hence productive workplace and that it is not intended to blame or penalize anyone.
2) Select a work area to be studied. This would likely start with areas expected to have poor productivity or quality but nearly all areas have potential improvements.
3) Observe the area to be "5-S'ed" and write up the problems observed.
4) Sort the results themselves. Often it is a useful practice, particularly when a team of observers is involved, to do the observation and then reconvene the team away from the area studied. Some use the "waste wheel" idea on a wall where the observers post sticky-notes with each note holding a single issue. The notes are the result of when everyone from a group goes to visit an area and finds cases of waste or lack of neatness.



Waste Wheel   Waste wheel with notes posted

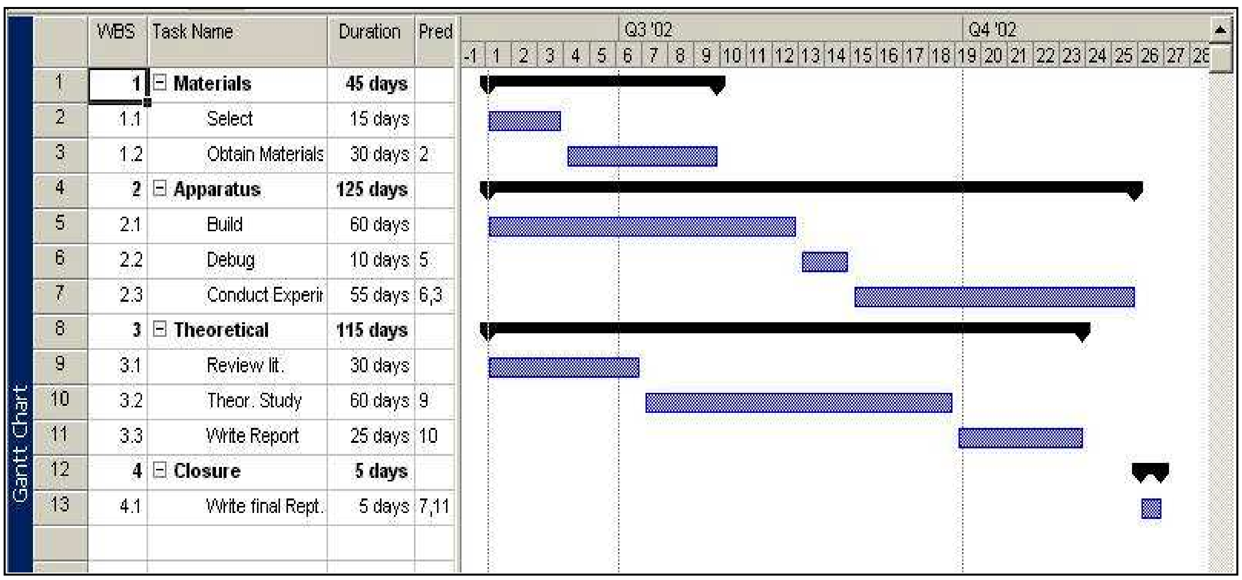
5) Review the results with the staff and management responsible for the area observed. The area's staff and management may act as observers themselves.
6) Set in place standard practices so that the improved operation is sustained.

13. Gantt Chart

a. Definition: The sequence of tasks in a project is represented by a series of horizontal bars. The bars represent the beginning and ending of each task in the project. Other aspects of the sequence of tasks can be included such as the dependency of one task on another task. The chart can also include a graphic display of progress on each task once a project has begun. The Gantt Chart facilitates understanding of the timing and parallel nature of these tasks.

b. Literature: See Project Management references in Section 29.

c. Example:
Nearly all research projects can have their workplan described by a series of tasks with a beginning time and an ending time. Each task involves an expected amount of elapsed time, is sequential in nature and has various attributes such as resources required conducting them. An example of research project's workplan as a computerized Gantt chart is shown below.



d. Steps:
1) Define project's objectives and scope.
2) Identify individual tasks, elapsed time requirements and necessary sequence of the tasks. Some tasks may only be possible to begin, for example, once another task has been completed.
3) List the tasks on the left and draw bars to the right representing the start time and relative length of time required for each task.
4) Additional information can be added to the chart such as resources required, and an outline format of tasks and sub-tasks.

Several types of computer software products are available to help organize a project plan in Gantt chart form as well as track project progress, delays and budgeting.

14. Gemba and Genchi Genbutsu Exercises

a. Definition: A principle developed in the Toyota/Lean method is to "go and see" or be a direct observer of actual operations ("Gemba" is Japanese for "the real place" and "Genchi Genbutsu" means "go and see"). Only by standing at the workplace and walking among the people doing the work can one really understand a process. This is a necessary and early step in the improvement process. It refers to an attitude of not merely relying on reports and the opinion of others but making direct observations of the work being studied.

b. Literature:
   - Womack, James P. Gemba Walks. Lean Enterprise Institute, 2011.
   - Imai, Masaaki. Gemba Kaizen: A Commonsense, Low-Cost Approach to Management McGraw-Hill, 1997.

c. Example: A hospital decided it needed to improve a particular ancillary department. A team of people from various departments were gathered to address the problem. At the first meeting of the team the leader said, "We must do a Gemba Walk." This meant all the team members were to spend several hours standing in and walking about the department being studied. It was done to observe the equipment, the workspace, how the staff functioned, as well as to build relationships for further work on the project. Prior to the Gemba Walk, the team members all had opinions about the department being studied but it was helpful to see firsthand any problems, hazards, wastes as well as opportunities for improvement. This step may seem obvious but it is not always employed when people feel they already know the issues.

d. Steps: A Gemba Walk involves being in the workplace. This could be a onetime visit or a series of visits on different days or time of the day. The Gemba may be more effective if the observer is assigned a task such as finding one or more of the specific types of waste as defined by the Lean method (see Section 42). Moreover, the Gemba may be more effective if the observer is trained in how best to do observing and what to look for; for example, training to identify the various types of waste may be helpful. Toyota employed the idea of drawing a chalk circle on the floor and telling the observer to stand inside the circle while doing the observing to assure that the observation was done in the proper place.

15. Hoshin Kanri Structure

a. Definition: This concept is using collective thinking to develop shared goals in order to improve the likelihood of success in a quality improvement effort. By following the structure developed as Hoshin Kanri there is a way to keep all the people involved at all levels of the organization focused on common long term goals. ("Hoshin" is Japanese for "compass" or "direction" and "Kanri" means "management" or "control.") It is also a particularly effective way to do policy deployment. Management sets overall goals for the organization and determines what gaps are particularly evident. These generate priorities (Hoshin) that become projects to deploy and measure against the overall goals.

b. Literature:
- Jackson, Thomas Lindsay. Hoshin Kanri for the lean enterprise: developing competitive capabilities and managing profit. Productivity Press, 2006.
- Withy, Kelley, et al. "Assessing health disparities in rural Hawaii using the Hoshin facilitation method." The Journal of Rural Health 23.1 (2007): 84-88.
- Hoshin Handbook, Third Edition by Pete Babich (2006)

c. Example: A health care agency responsible for a hospital uses Hoshin Kanri to plan and deliver health care in a more coordinated way across its service area. The agency found that it could do more to improve care by planning and working in a more coordinated way. At part of their Hoshin Kanri, they designed a web site to give everyone – public, providers and managers -- information on current quality results and their plans for further improvement.
In a second example, a hospital decided that it needed to create a culture whereby all parts of the organization were following the same vision. Otherwise, they were going to fall behind competitors. Not that everyone had to act in an identical manner, but more teamwork would lead to better results. The Hoshin Kanri approach was begun in a meeting of key leaders discussing their challenges and opportunities. Once it was clear where they wanted to go it was then possible to define everyone's role in achieving that vision and a way to measure how well they were succeeding. For this particular hospital they felt they must become more successful in performance improvement, among other things, and embarked on a long term plan of hiring and training in performance improvement methods.

d. Steps
The specific implementation approach varies by organization but there should be a focus on goals, good communications and recognition of the effort and time needed for successful policy deployment.
1) Define the organization's vision or goals
2) Define near term objectives; for next year and for further out, perhaps 3 to 5 years
3) Determine priorities and needed improvement
4) Brainstorm possible solutions and prioritize them
5) Communicate and implement the suggestions
6) Review the results

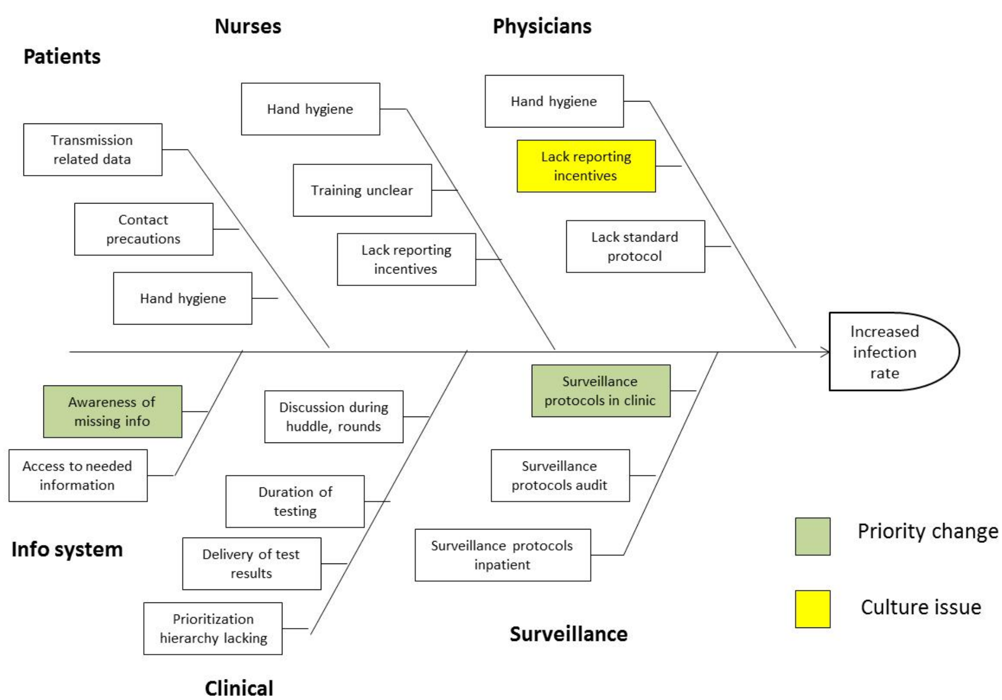
16. Ishikawa/Fishbone Diagram

a. Definition: A graphic representation of the inputs or ingredients to a particular issue or problem. Also sometimes known as, or equivalent to, root cause analysis. The diagram starts with an issue or problem and lines connect to it representing possible causes. Each cause is then broken out further with lines representing possible causes for each cause. The result looks similar to a fishbone.

b. Literature:
- Ishikawa, Kaoru. What is Total Quality Control? The Japanese Way (1985)
- Taner, M. T., Sezen, B., & Antony, J. (2007). An overview of six sigma applications in healthcare industry. International Journal of Health Care Quality Assurance, 20(4), 329-340.

c. Example: Research indicated a higher incidence of stroke in a certain patient population. There were a number of factors which might contribute to the occurrence of strokes. The basic issue was "higher stroke incidence;" this became the "head of the fish" in the diagram. Then the risk factors were developed from several discussion groups and the risk factors were grouped into about six different categories. The structure became a basis for formulating research priorities.

In another example of the fishbone diagram, a hospital was trying to identify factors contributing to an increased infection rate. Interviews and discussions resulted in a variety of causes which were organized into the diagram below. Colors were added to indicate the highest priority items.



d. Steps:
1) Identify the key single problem or issue to be addressed.

2) Identify factors causing or influencing the initial problem; these may themselves be problems which have their own causes. This process often works well in a group setting where the members offer additional causes and problems. This collaboration then builds an accurate and complete picture that might be difficult for a single individual to come up with.
3) Continue to build the sequence of problems and causes and put into a diagram form, such as is shown above. It is unusual to go beyond three levels but it may be necessary in some cases.
4) The resulting diagram then becomes a starting point for improvements or determination of ways to address the sources of the initial problem. By deconstructing problems in this diagram the organization often better understands what is needed and where changes must take place. This is an example of a way to break down a problem into more manageable parts.

17. Kaizen Events

a. Definition: Kaizen is Japanese word that means “improvement” or “change for the good” and it refers to improvement that is a cultural change and not just mechanical or limited adjustment. A Kaizen Event is a focused group working for a limited time on a specific improvement while following various Lean precepts. As a philosophy, Kaizen refers to continuous ongoing improvement involving all staff. An environment is intended which supports innovation and participation in change. Part of the idea of a Kaizen Event is to gather together a group of people who are familiar with a process area and an issue and then use the group to develop improvements to quality. They may be in a position to implement the change as well. Various successful formats have been developed and applied in healthcare. It is sometimes equivalent to Brainstorming, idea generation, Nominal Group Technique (see Section 22), or the Delphi method. The group’s organization is designed to assure full participation and use of the group member’s capabilities.

The Kaizen Event‘s duration should depend on the complexity and importance of the issue being addressed. In some cases it could involve only 2 or 3 people and be done in a few hours. In other cases a Kaizen can involved many more people and held for a full day or a week and repeated for several months. The Kaizen can be on site, at a hospital or a clinic, or off site. An onsite meeting may be more convenient and facilitate observation of current operations. Offsite may create more focus by the participants.

b. Literature:

All the books on Lean include a substantial amount on Kaizen since it is a key element of the Lean method.

- Masaaki, Imai. "Kaizen: The key to Japan's competitive success." New York, McGraw-Hill (1986).
- Jackson, Thomas L. Kaizen Workshops for Lean Healthcare. Vol. 3. Productivity Press, 2012.
- Jacobson, Gregory H., et al. "Kaizen: a method of process improvement in the emergency department." Academic Emergency Medicine 16.12 (2009): 1341-1349. (as an example of Kaizen’s use)

c. Example: A hospital wished to reduce its readmissions for patients with a particular diagnosis. They gathered a team from various areas in the hospital which may be involved with such patients. The team met over 5 full days. The event was led by someone who had led prior Kaizen Events. The leader provided guidance, particularly regarding the attitude and communications necessary for success. The meetings included analysis of the problem, using various Lean tools, developing solutions, picking the best ones and implementing the changes to improve quality. At the end, the team presented its work to management and a large segment of the hospital staff to encourage future Kaizen Events and to assure the recommendations were implemented.

d. Steps:

1) Identify the issue to be addressed and select a cross-functional team to be gathered together in one place. Also identify a “champion” responsible for the results. The team is given goals but also

given the freedom and time to develop its own solutions. The team should include all relevant areas and patients themselves can be very useful participants.

2) In the Kaizen meeting analyze the current state, the goal, and then if onsite observe current operations and quality directly. Often this involves creation of a process map (see #8) describing the existing or current state operations.
3) It is important that each meeting of the group, which could be daily, weekly or monthly, have the proper attitude. Fixed ideas about the past must be avoided and there must be freedom to ask "Why?" by everyone. Kaizen is a way of thinking.
4) Create improvements (which may require encouragement of members) and select preferred solutions. Develop a process map of the desired future state.
5) Identify metrics for success. SMART goals should be used (see Section 35)
6) Plan & implement (repeat if necessary). Get buy-in from parties related to the process. Implementation should be incremental with a "pilot" first step. This should be a change with a high likelihood of success following the PDSA idea.
7) Prepare standard work (see #18) as a way to sustain the change.
8) At the end, conduct a report-out to management or a celebration of the improvement with the entire staff, which helps sustain the results by informing and motivating everyone about the change.

18. Key Performance Indicators

a. Definition: Quantitative measures of performance are considered essential to good quality and meeting an organization's goals. Metrics should include measurement of the important aspects of the healthcare system and various organizations have defined categories and specific measures to be calculated. Ideally any research proposed would be measureable by the KPI's that the organization has defined as important.

b. Literature:

- Parmenter, David. Key performance indicators (KPI): developing, implementing, and using winning KPIs. John Wiley & Sons, 2010. Not specifically about healthcare but covers the KPI topic.
- AHRQ Publication Evaluation of the Use of AHRQ and Other Quality Indicators: Final Contract Report. December 2007. This reports the uses of, market for, and demand for AHRQ and other Quality Indicators. (08-M012-EF)
- Abujudeh, Hani H., et al. "Quality Initiatives: Key Performance Indicators for Measuring and Improving Radiology Department Performance." RadioGraphics 30.3 (2010): 571-580.
- Pro, Douglas Doucette, and Bruce Millin Con. "Should Key Performance Indicators for Clinical Services Be Mandatory?." The Canadian Journal of Hospital Pharmacy 64.1 (2011). Sometimes there are conflicting objectives from various parts of an organization causing disagreement as to what should be measured.

c. Example: A research project envisioned improving patient care for a particular diagnosis. The patient outcomes before and after the intervention were to be measured. The researchers needed to be sure that the outcome measures they tracked, and were trying to improve, included key performance measures the organization currently followed. If the improvement did not impact any of the current KPI then ongoing use of the change may be less likely to be sustained. Some common KPI's are:

- Timely administration and discontinuation of prophylactic antibiotics. As a KPI there would be a measurement of the frequency percentage or the raw quantity. Such a measure is helpful as an indicator of quality.
- Participation in patient care rounds. Some measures are indicators of workload as well as the structure of the work.
- Operational results such as patient throughput and room utilization.

d. Steps: Creation and implementation of Key Performance Indicators could follow the elements of PDSA or DMAIC as described in this handbook.

19. Lean Approach

a. Definition: Lean is an effective and popular approach to improve quality and operations incorporating many methods. It is also referred to as the "Toyota Method," as much of it was initially developed at the Toyota Motor Company (with contributions from other earlier operations improvement efforts by various individuals and organizations). Some refer to Lean as the Toyota Production System or TPS. Many of the components of Lean are referred to by their original Japanese name. Particular hallmarks of these Lean methods are a reduction in waste and focus on value or what is important to the customer or patient.

The Lean approach has become popular in the healthcare industry although it was initially developed for manufacturing. Many large healthcare systems employ Lean to some extent. Certification of one's ability to use Lean is given by a number of organizations. However there is no single Lean authority. Depending on the practitioner, one or more of several Lean tools are emphasized. These are described in this handbook and their relevance to Lean is noted in their separate sections.
Lean management implies the broad application of the principles of increasing customer (patient) value by eliminating waste and creating a smoothly flowing experience for the customer. A lean transformation means changing to Lean thinking and not doing just short term changes that may not have a lasting impact.

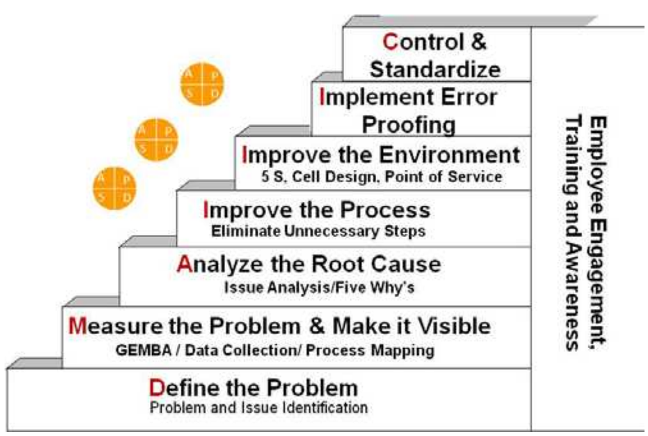
b. Literature: While the Lean or Toyota method was initially developed in the automobile industry in Post-War Japan, it has found much use in healthcare in recent years. There is considerable literature regarding the use of Lean specifically in healthcare. The books on Lean generally provide details on all of the Lean methods although some focus on one particular component of Lean. Literature on Six Sigma (See Section 34) generally covers many these same topics. Some popular Lean books are:

- Womack, James P., and Daniel T. Jones. Lean thinking: banish waste and create wealth in your corporation. Free Press, 2010. Popular reference by one of the early writers about Lean.
- Miller, David. The Toyota way to healthcare excellence: increase efficiency and improve quality with LEAN. Health Administration Press, 2008.

- Graban, Mark. Lean hospitals: improving quality, patient safety, and employee satisfaction. Productivity Press, 2009.
- Hadfield, Debra, et al. The New Lean Healthcare Pocket Guide: Tools for the Elimination of Waste in Hospitals, Clinics, and Other Healthcare Facilities. MCS Media, Incorporated, 2009.
- Sayer, Natalie J., and Bruce Williams. Lean for dummies. For Dummies, 2012.
- Jeffrey, Liker. "The Toyota Way: 14 Management Principles from the World's Greatest Manufacturer." McGraw-Hill, (2004). and Liker, Jeffrey; Meier, David (2006). The Toyota Way Fieldbook. New York: McGraw-Hill
- Kenney, Charles. Transforming health care: Virginia Mason Medical Center's pursuit of the perfect patient experience. Productivity Press, 2010.
- Mazzocato, Pamela, et al. "Lean thinking in healthcare: a realist review of the literature." Quality and Safety in Health Care 19.5 (2010): 376-382.
- Toussaint, John S., and Leonard L. Berry. "The promise of Lean in health care." Mayo Clinic Proceedings. Vol. 88. No. 1. Elsevier, 2013.

c. Example: A group of hospitals wished to reduce readmissions for CHF patients. They initiated a project to do so with a project leader, an owner who was in authority over the functions involved and a multidisciplinary set of staff. Kaizen events (see #17) were held to define the problem, develop solutions and plan implementation of changes. Various methods were employed, such as process mapping and Pareto Charts (see #24), in order to understand the problem. The change was done via PDSA (see #25) cycles and reported via A-3s (see #1) posted in affected areas. At the end of the effort improvements were implemented through checklists (see #4) and written standard work (see #37) . Control charts (see #6) were used to monitor results and to sustain the change.

d. Steps: As noted, Lean can employ a variety of methods. The details and sequence of how it is used it will depend on the particular issues to be addressed. Lean projects to improve a particular function or to address a particular problem should follow a PDSA cycle (Plan, Do, Study, Act) as described in Section 25. The components of Lean are often described as a hierarchy built up from a base as in the figure below.



20. Maturity Model

a. Definition: A study of the capability of an organization's ability to change and improve through the use of methods such as those discussed in this handbook. Some organizations are more developed and able to understand and implement changes. The Maturity Model identifies levels through which an organization can develop or mature. This view helps efforts regarding quality improvement to better understand what is possible and what path is necessary.

b. Literature:
Material on this topic is also referred to as "organizational readiness assessment"

- Kerzner, Harold. Strategic planning for project management using a project management maturity model. Wiley, 2002.
- Gillies, Alan, and John Howard. "Managing change in process and people: Combining a maturity model with a competency-based approach." Total Quality Management and Business Excellence 14.7 (2003): 779-787.

c. Example: Some hospitals have self-evaluated their capabilities regarding their adoption of improvement methods such as Lean and Six-Sigma by considering the matrix of maturity levels and where they currently stand. They would use a matrix such as the one shown below and determine where they stand in terms of evolution of the organization. Without maturity, the full value of the methods is not realized.

ELEMENT	NOVICE	EVOLVING	MATURE
Methodologies Used	Lean tools used consistently by Performance Improvement teams	Lean tools used consistently at all levels of the organization	Lean tools used for enterprise planning & improvement
Leadership Support	Department leaders promote and champion efforts	Leadership across the value stream promotes and champions efforts	Common vision of lean is shared by the extended enterprise
Customer Value Creation	Activities focused on improving process flow , and error reduction	Activities based on understanding the voice of the customer	Able to create value propositions
Breadth of Application	Multi-functional teams include some downstream disciplines and key suppliers	Systems approach to improvement – all stakeholders identified	Downstream stakeholders' values balanced via tradeoffs, as a continuous part of the process
Employee Engagement	Improvement projects led by PI "experts" with multi-functional teams	All employees engaged in planned improvement activities	Employees initiate Kaizen with little to no guidance

Source: Applying the LEAN Maturity Model to the Healthcare Industry, Jennifer Wortham, Dr.PH

d. Steps:

1) Identify elements needed to evaluate the organization's capability for change or improvement, including people who would know the organization sufficiently.
2) Select the applicable matrix and modify as necessary.
3) Survey the appropriate individuals to settle on a consensus of the organization's current level of maturity. This may be different for various aspects of the capabilities.
4) Review the results as a basis for future improvement or completion of the changes desired.

21. Modeling and Optimization

a. Definition: Many processes can be described in mathematical terms using a set of equations, perhaps also with a computer program. These models can be useful to gain insight as to how a process works and can sometimes be used to determine an improvement or optimum design. Such mathematical models are used effectively in many industries, including healthcare and research. The models describe how a process functions, including relationships between its parts and constraints. Some models find an optimum design, whereas others are merely descriptive but provide insights for improvement. Simulation (see Section 32) is an example of a descriptive model which does not necessarily find an optimum. Other popular mathematical modeling strategies used in healthcare include:

- Linear Programming: Attributes of a system are described as a group of variables (numerical values). Linear (straight line) equations describe the relationships and constraints for the variables of the system being modeled. An objective function equation includes the aspects of the system that are desirable and their relative importance. A solution is the point where the variables will produce the optimum result for the objective function.
- Integer Programming: Similar to Linear Programming but where the attributes of the system are integers. Often systems have variables which can only be whole numbers such as a number of appointments or a number of patients.
- Markov Chains: A stochastic model where the future state depends only on the current state. Such a model means that the future does not depend on the past. It makes feasible certain calculations such as weather forecasting or to model a series of clinical decisions.
- Queuing Models: Various aspects of waiting lines can be determined based on elements of a queuing system such as arrival rates, service times and number of servers. These models assume randomness but with definable probability distributions. The time a patient will likely spend in a clinic's waiting room can be calculated, for example.
- Forecasting models: several different mathematical models can be used to extrapolate past history to predict the future or to use a variety of data to forecast events. This can be used for inventory planning or staffing based on expected future demand.

b. Literature: There is considerable literature about each type of modeling approach within the field of applied mathematics as well as computer software to create and analyze such models. Operations Research refers to this field of using advanced analytic methods for decision making and is sometimes referred to as Decision Science or Management Science or Analytics. The professional societies of Operations Research include considerable publications related to healthcare.

- The Institute for Operations Research and the Management Sciences (INFORMS) publishes multiple scholarly journals about operations research. Also, there are a variety of journals on applied mathematics in healthcare, such as Operations Research for Health Care, ISSN: 2211-6923, Elsevier Publishing.
- The Mayo Clinic Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery holds conferences regarding operations research and healthcare and is a source for publications in the field.

- Rais, Abdur, and Ana Viana. "Operations Research in Healthcare: a survey." International Transactions in Operational Research 18.1 (2011): 1-31.

c. Example: A research project is considering multiple patient screening measures of which each measure has differing outcomes and costs. Linear programming can be used to find the optimum mix of measures. The model consists of several equations. The objective function for the model is an equation of the sum of the several outcome measures and their relative importance. There are constraints regarding available funds and constraints regarding outcome measures. A minimum reduction in readmissions and that certain clinical outcomes must exceed specified values are written as constraint equations. The solution of the equations is the point where the net total effect of the outcome measures, which is the objective function, is maximized but the mix of screening measures remains within the constraints. Thus, a research project would seek to determine all the elements of the linear programming model so that the solution can be found and relied upon.

d. Steps:
   1) Develop a detailed understanding of a problem.
   2) Identify the best modeling approach to represent the problem accurately. If a true optimization is needed then a descriptive model will not be sufficient. Sometimes using more than one approach is necessary.
   3) Identify attributes of the system being modeled
   4) Create a mathematical representation, in a computer if necessary and possible
   5) Calculate the optimum, if that sort of model is created, or use insights from the model to create improvements

22. Nominal Group Technique

a. Definition: The Nominal Group Technique (NGT) is a way to assure all the capabilities of a group are fully utilized through collaboration. Many QI efforts require input from multiple individuals and it is important to get the contributions from each individual. Sometimes a few individuals dominate an in-person discussion and contributions from others are missed. Organizations have found NGT useful in the early stages of research to develop new ideas and directions and to enhance the capability of a group. It can be used by groups of any size to identify problems as well as to develop solutions.

With the NGT individual members of a group submit their input confidentially and individually in writing. The results are tabulated and a summary of the inputs, such as which idea was mentioned most frequently, is reported back to the group. The individual response and summarization cycle can be repeated so as to reach a consensus. An open group discussion can follow as well. The intent is to allow all individuals to provide their opinion equally and have it received and distributed.

b. Literature:

- Gallagher, Morris, et al. "The nominal group technique: a research tool for general practice?" Family Practice 10.1 (1993): 76-81.
- Van de Ven, Andrew H., and Andre L. Delbecq. "The effectiveness of nominal, Delphi, and interacting group decision making processes." Academy of Management Journal 17.4 (1974): 605-621.

c. Example: A panel of experts is assembled to decide on which way to solve a particular problem. They each have a different opinion as to what approach should receive the highest priority. While all of them are familiar with the problem being addressed some are more senior and experienced. The panel leader wanted to get everyone's ideas and was concerned that a few individuals would dominate any discussion. By using the NGT the ideas were promptly gathered by e mail and summarized. The results were tabulated and a summary distributed to the full panel. A second survey was done again once the members had received a summary of the first set of responses. After that was distributed, the panel met to begin an in-person discussion of the solution.

d. Steps:

1) Identify the group membership and issue or problem to be addressed, such as the solution to a problem
2) Survey the members for their input to the issue and the priority they would give to each item
3) Summarize the responses in terms of frequency and priority but without indentifying individuals
4) Return the summary to the members
5) Repeat the survey, response and summarizing cycle as necessary and then open to panel to group discussion if appropriate for additional input

Specifics of the implementation of NGT vary.

23. Overproduction Assessment

a. Definition: One of the most common and costly types of "waste", as waste is defined in the Lean method, that occurs in healthcare is "overproduction". This refers to work done which need not be done as far as the patient is concerned. This may mean services rendered which could have been avoided, obsolete items, excessive inventory, or work being done before it is needed. It is found in all industries but may be more common in healthcare because of the feeling that extra preparation seems like more service for the patient – even when it isn't. Economists point out that much of overproduction is caused by wrong incentives; there are revenue incentives to over-order or there are incentives to store excessive inventories and to provide more services than truly necessary.

b. Literature: There are considerable literature and practice guidelines to help avoid overproduction in healthcare, although not always using that word. In terms of clinical practices it is sometimes referred to as "over-ordering" or "unnecessary ordering." The Lean literature describes the causes and types of overproduction and how to locate overproduction.

c. Examples:
- Patients being admitted are repeatedly asked the same questions by several people. Diagnostic tests, such CT scans, are ordered more often than necessary.
- Copies of forms are stored in paper form even though they are available digitally.
- Inventories larger than necessary considering the resupply frequency.
- Preparation of carts or kits batched at the start of a day which results in more inventory being processed than necessary
- Research which develops recommended new tasks that duplicate existing ones.

d. Steps: The problem of overproduction is often best addressed as part of a larger effort for quality improvement, such as in the course of a Kaizen event or through training to sensitize staff to look for such waste. Certainly asking "Why is this done?" Or asking: "What would happen if we did not do it? " can be helpful. Failure Mode analysis (see Section 11) can be used to identify cases of overproduction.

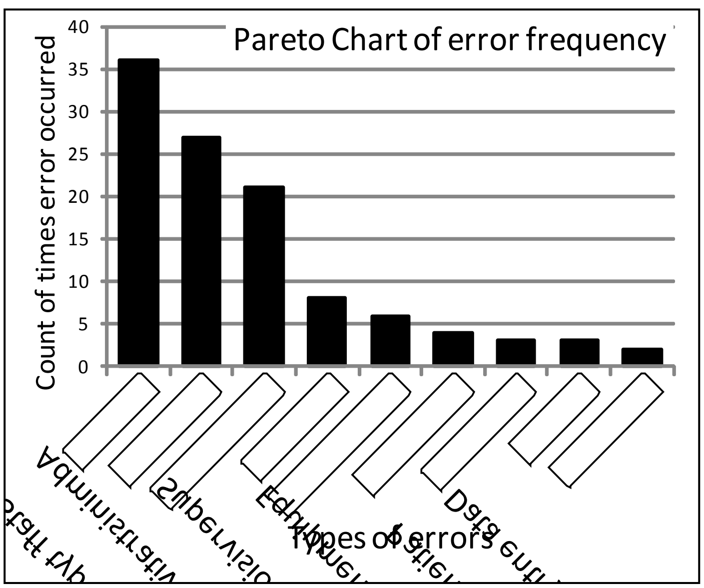
A tool to consider over production, as well other problems, is asking "Why?". The answer may prompt asking another "Why?" since the cause of a problem may itself be another problem. For example "Why did you do that?" may be answered by "Because the instructions say so." which may be followed by "Why do they say so?" and so on. The idea of "5-whys" is referred to as the idea of perhaps asking 5 times is necessary to get to the true cause of a problem.

24. Pareto Analysis

a. Definition: An analysis, typically represented by a bar chart, whereby items or problems are listed along the horizontal axis of the chart and are sorted in order of importance or frequency. This can help in prioritizing future work or identifying where attention should be focused. The chart is based on the Pareto principle or the idea that often when many factors affect a situation, usually just a few will account for most of the impact. Often 80% of the impact, such as errors or defects, is caused by just 20% of the factors – few are important, many are not. It is named after the Italian economist Vilfredo Pareto who first noticed in the early 1900s the fact that often an 80-20 proportion occurs.

b. Literature
   - Juran, J. M., & Gryna, F. M. (1970). Quality planning and analysis. New York: McGraw-Hill
   - "Pareto Analysis" http://erc.msh.org/quality/pstools/pspareto.cfm

c. Example: Data is gathered over several weeks regarding the incidences of patient falls and the unit or location of the patients when they fell. The frequencies are totaled by location and then sorted. This is shown in a bar chart below or cumulative line graph. The locations are arranged by frequency with the most frequent on the left. This highlights which few areas deserve further study and which do not.



d. Steps:
   1) Define the topic or scope of the analysis. It may be a quality improvement issue or a problem related to performance in a particular area.
   2) Identify related data. This may be existing historical data or new data which must be gathered. Generally, we are interested in the frequency of a particular item or occurrence of a problem. The data set should be of sufficient size or cover a sufficient time period to give a complete picture of the situation.
   3) Gather the data into categories. The number of categories, such as problem types, should not be too few, generally not less than about five, nor too many to be actionable.

4) Sort the data by frequency and put into a table or graph for clarity.

A spreadsheet program such as Excel is often handy to help construct a Pareto chart.

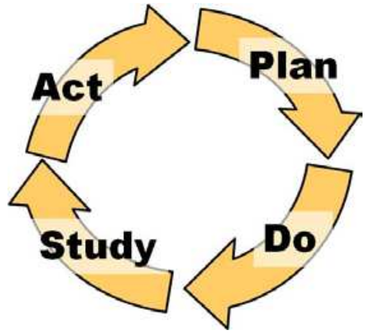
25. PDSA Cycles

a. Definition: In order to assure a successful change, an organized and feasible implementation approach must be used. Quality improvement changes, such as those that result from research findings, seem to succeed best when repeated small steps are used. PDSA cycles consist of planning the change (Plan), carrying out the change (Do), observing and analyzing the results of the change (Study) and then deciding what additional changes should be made (Act). This is a cycle, done repeatedly until the results meet the objectives. It is best to start out with a small change or test and to learn from that before full implementation.

b. Literature: Lean method literature provides descriptions and how to implement PDSA. Various publications and organizations provide guidelines, templates and examples. There is literature on examples of PDSA use, such as:
   - Van Tiel, F. H., et al. "Plan-do-study-act cycles as an instrument for improvement of compliance with infection control measures in care of patients after cardiothoracic surgery." The Journal of Hospital Infection 62.1 (2006): 64-70.
   - Guinane, C. S., J. I. Sikes, and R. K. Wilson. "Using the PDSA cycle to standardize a quality assurance program in a quality improvement-driven environment." The Joint Commission journal on Quality Improvement 20.12 (1994): 696.
   - Walley, Paul, and Ben Gowland. "Completing the circle: from PD to PDSA." International Journal of Health Care Quality Assurance 17.6 (2004): 349-358.

c. Example: A healthcare system decided to change its outpatient screening process based on results from a recent research project that determined some screening steps were unnecessary and should be dropped. The healthcare system decided on a PDSA approach. The steps followed were:
   - Plan: The object was defined explicitly: to reduce the total time for patient screening by 20% by dropping certain questions. As a temporary test, they planned to change screening at one of their clinics as of a certain date, to follow up with the clinic after a month to determine the impact on the process and to track patient outcomes to see if the change had any adverse effects.
   - Do: The change test was carried out in one clinic and related data was gathered on an ongoing basis to understand the results of the change.
   - Study: Results from the test clinic were compared to performance objectives, and conclusions were reached.
   - Act: This step consisted of determining if any further changes were needed to the new process based on the results from the clinic. This may involve further or expanded tests or deciding whether the change should become permanent. The lessons from the each PDSA cycle were used to expand the change to more of the clinics in the system.

PDSA is a cycle and often shown as a graphic such as:



d. Steps: The idea of PDSA is a cycle of steps, generally implementing a small change, learning from the results and repeating the cycle until the desired change is fully complete and sustaining. A PDSA worksheet is available from a number of sources and some healthcare organizations have developed their own PDSA worksheet. These record for each step:
   - Plan - Describe the problem, the objective of the test and a description of who, what, when and where is involved. Define baseline or initial descriptive data.
   - Do - Carry out the test, document results and problems.
   - Study – Analyze the results, compare to objectives and decide on next steps or if the testing should be abandoned.
   - Act - Modify or refine the change and plan for the next cycle.

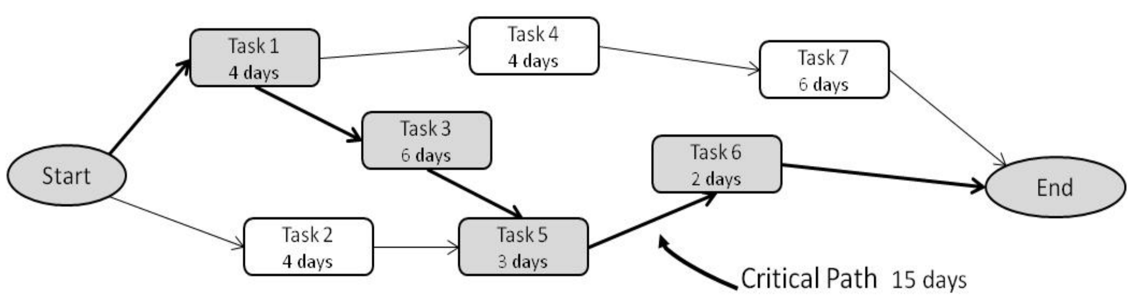
26. Program Evaluation Review Technique (PERT)

a. Definition: The Program Evaluation Review Technique (PERT) provides a way to manage a project's combination of tasks and the project's overall duration. It is used to plan a project, assess timeline risks and identify resource requirements. As a statistical tool, it is used along with the Critical Path Method (CPM) within Project Management (See Section 29).

PERT was initially used in military projects in the 1950s. It is a way to organize the expectations regarding the individual tasks in a project, particularly regarding the time required for each task. The most likely, pessimistic and optimistic time for each task is estimated. These are combined for all tasks in order to determine a project's expected completion time. The percentage likelihood that a project will be completed by a specific time can be calculated. If a research project, for example, has a required completion in a certain amount of time, PERT could be used to identify which tasks are critical to on time completion and which tasks should be accelerated in order to meet a specific deadline.

b. Literature:
- Harold Kerzner (2003). Project Management: A Systems Approach to Planning, Scheduling, and Controlling (8th Ed. ed.). Wiley. ISBN 0-471-22577-0.
- Project Management For Dummies, Stanley E. Portny
- Project Management Institute (2003). A Guide To The Project Management Body Of Knowledge (3rd ed. ed.). Project Management Institute. ISBN 1-930699-45-X. This serves as an industry standard for Project Management and the basis for being a Certified Project Manager.

c. Example: PERT is often used in research to manage the progress and balance among competing goals of performance, resources and completion time. It deals with uncertainties even when new developments are planned and little experience exists, such as is the case with research.



d. Steps:
1) Define the overall project objectives, scope and priorities
2) Identify the individual separate tasks or activities necessary for the project.
3) Estimate range of possible times for each task as well as the dependencies regarding other tasks in the project

4) Combine into a network of tasks from the start to the end.
5) Identify the critical path (longest series of tasks) and calculate metrics such as the probability of not completing the project by a specific date.
6) Review with staff directly involved with the project and revise the plans and network map if necessary due to time or resource limitations

Computer software is widely available to assist in organizing the data and calculating the results

27. Poka-Yoke Techniques

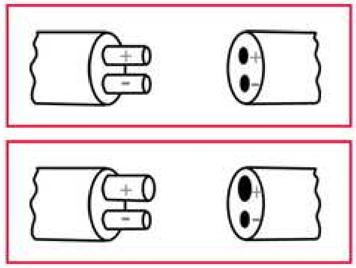
a. Definition: It is useful to organize work so that it will be done correctly, largely because there is only one way to do it or it is obvious what the proper way to do it. Poka-Yoke is a Japanese term for “error proofing” or “mistake proofing.” It is used to prevent errors by the design of tasks or workspace. Errors in healthcare are particularly serious so that methods such as this are important. Research which results in a change to an existing procedure might use it to assure work is done the new way and not the old one.

   Mistake proofing may mean that a work step can only be done one way because alternatives are physically impossible. This can be plugs that can be connected only one way or a machine that can only be started if switches are set a certain way. Information systems can be designed so that only acceptable combinations can be selected.

b. Literature:
   - Shingō, Shigeo. Zero quality control: Source inspection and the poka-yoke system. Productivity Pr, 1986.
   - Grout, J. R. "Mistake proofing: changing designs to reduce error." Quality and Safety in Health Care 15.suppl 1 (2006): i44-i49.

c. Example: Store tools in space with an outline of the tool so that it is obvious when a tool is gone or stored incorrectly.

   In the picture below the lower set of plugs is designed so as to assure the proper match of the positive and negative wires. It is impossible to connect the lower pair improperly.



Also, hospitals use colors, such as colors on patient wristbands or colored strips on the floor to direct patients to the correct area.

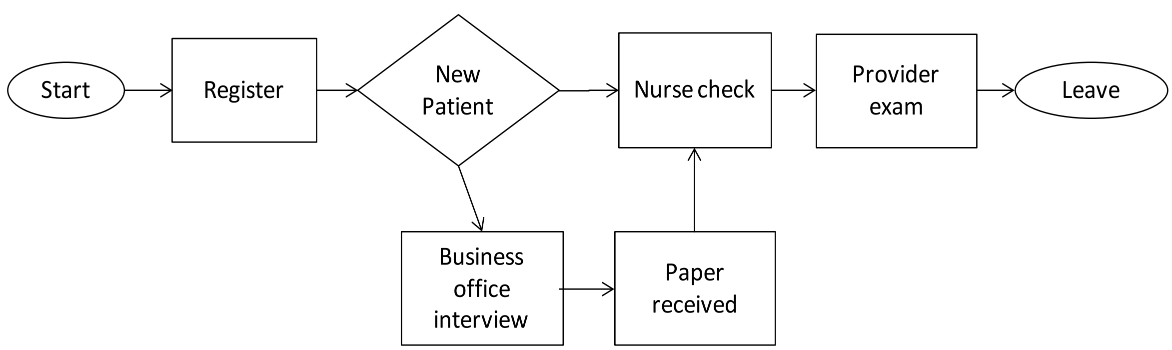
d. Steps: This concept is to identify actions that could produce an error and then design ways to prevent an error by physical design or signals that alert the user to an obvious error.
   1) Identify the need or situation where an error is possible
   2) Identify ways error could be made
   3) Implement changes so that only correct actions are possible
   4) Monitor use and revise if necessary

28. Process Mapping (also known as Flowcharting and Workflow Diagramming)

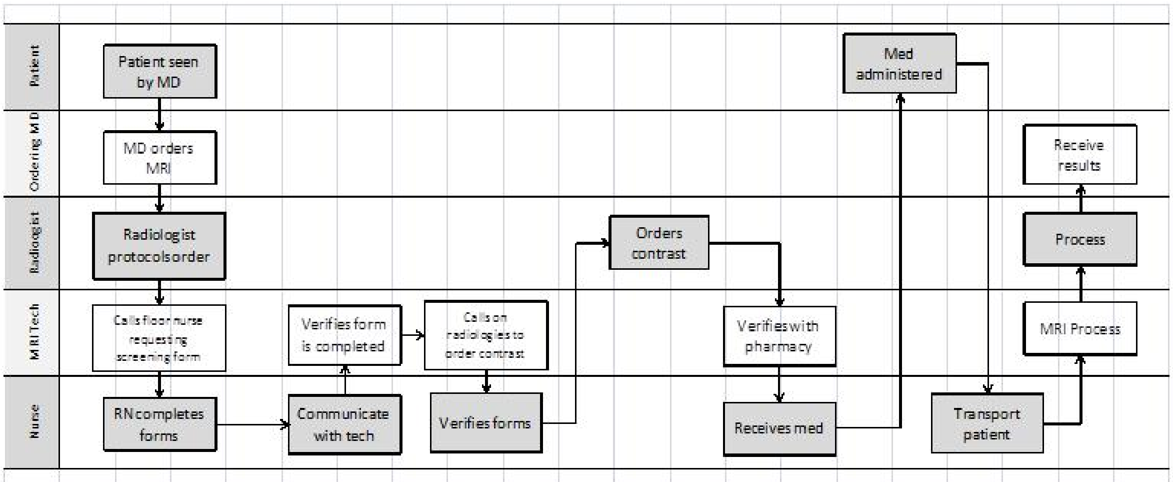
a. Definition: A drawing showing the components, relationships and sequence in which a system functions is often a good way to understand that system. There is a standard set of symbols that are commonly used. The resulting drawing can be useful for analyzing or explaining the work done by an organization. The level of detail can be relatively simple or complex. It may be called a work flow diagram, process chart or flow chart.
A complex system, such as all the steps of a hospital visit or a simpler set of steps such as a particular treatment, can be described in diagram form. This is often a good way to begin the study of an area or Kaizen Event (see Section #17) where research or an improvement is planned. The process of diagramming forces the researcher to be specific and understand how each step occurs.

b. Literature:
- Process charts have been in use since the 1920's, popularized in Gilbreth, Frank Bunker, and Lillian Moller Gilbreth "The quest of the one best way."
- Diagramming software is available with specific tools for such diagrams in MS PowerPoint, MS Visio, ABC Flowcharter.
- Hunt, V. Daniel. Process mapping: how to reengineer your business processes. John Wiley & Sons, 1996.
- Damelio, Robert. The basics of process mapping. Productivity Press, 2011.
- Pluto, Delores M., and Barbara A. Hirshorn. "Process mapping as a tool for home health network analysis." Home Health Care Services Quarterly 22.2 (2003): 1-16.
- Rath, Frank. "Tools for developing a quality management program: proactive tools (process mapping, value stream mapping, fault tree analysis, and failure mode and effects analysis)." International Journal of Radiation Oncology* Biology* Physics 71.1 (2008): S187-S190.
- Cendán, Juan C., and Mike Good. "Interdisciplinary work flow assessment and redesign decreases operating room turnover time and allows for additional caseload." Archives of Surgery 141.1 (2006): 65.

c. Example: There are many different formats for such maps.



Diagrams can be arranged in various formats. Typically time flows from left to right or top down. One popular version, called a "swim lane" map, involves segmenting the map by organizational unit. The swim line map demonstrates when work on a process moves from one organizational unit to another. Many such movements back and forth between units may be an indication of waste.



d. <u>Steps</u>:

1) Define a process or system to be analyzed by the diagram.
2) Determine the type and level of detail necessary. Often, such diagrams are first sketched simply and the details and rearrangements are done as the understanding of the system emerges. It is possible to do an overall diagram and then to do separate more complete diagrams of the details of each area.
3) Draw the diagram from the start of the process, indicated by the “start” symbol, through the endpoint, with an “end” symbol.
4) Once a first draft is done, review the diagram with the people who directly do the processes diagrammed to see if they concur, and revise accordingly. This may mean reviewing the diagram with nurses, doctors or technicians but the graphic nature of the diagrams makes them relatively easy to explain.
5) Review the resulting diagram for bottlenecks, unnecessary steps and other opportunities for simplification or improvement in the system drawn.

29. Project Management

a. <u>Definition</u>: Project management is a discipline to assure that a successful project occurs. The challenge is to balance the three conflicting objectives of performance (results), time and cost. Improvement regarding one objective often has an undesirable effect on the others. Improving performance may increase the time necessary, for example. Certification in project management and a published body of knowledge are available from the Project Management Institute.

A project consists of a set of tasks, each of which requires time to complete. Other than the initial task, tasks are generally dependent on prior tasks and the entire set of tasks can be viewed as a network. The longest path through the network determines the duration of the entire project. This longest path, or critical path, can be calculated by an algorithm or Critical Path Method (CPM).

b. <u>Literature:</u>
- A guide to the project management body of knowledge. Project Management Institute, 5th edition (2013). This book (PMBOK) provides a comprehensive set of project management methods and is widely recognized the basis for a certification as a project manager.
- Project Management: A Systems Approach to Planning, Scheduling, and Controlling by Harold R. Kerzner, 11th edition (2013). This book aligns with PMI's Project Management Body of Knowledge (PMBOK).
- Shirley, David. Project Management for Healthcare. CRC Press, 2011.
- Belson, David, Chapter 21, Project Management, in Patient Flow: Reducing Delay in Healthcare Delivery, Springer, International Series in Operations Research & Management Science, Hall, Randolph (Ed.), 2nd ed. 2013.

c. <u>Example</u>: A research proposal may envision a large or small endeavor but in either case success will generally depend on having the necessary plan in place at the start and throughout. This means setting a well-defined objective, a scope limiting the range of things the project plans to address, tasks, responsibilities and a timeline. The project should have a way to control changes to the scope, which often result in cost overruns or late completion. Project management’s methods provide ways to track progress in comparison to the plan. Software is available to develop the project plan, to monitor progress and communicate responsibilities.

30. Responsibilities Matrix

a. Definition: A two dimensional matrix showing assignments and personnel which helps to identify duplications and gaps in the allocation of responsibilities among personnel. The effectiveness of an intervention in clinical and other processes may be hindered due to duplicate (or missing) responsibilities. Finding duplicate duties makes is possible to reduce overproduction or unnecessary work. A Responsibilities Matrix can be used to organize the hierarchy of responsibilities and specify who is accountable for each task.

b. Literature: Literature on business process reengineering, organizational design and project management discusses this method.

c. Example: The chart below was done to identify responsibilities in pre-op surgery and help find duplications in the surgery prep interactions with patients.

	Physicians Order	Surgeons Order	Work-Ups	Surgery Consent	Blood Consent	Schedule Surgery	Receive Medical Record	Medical Record Audit	Check Paperwork	Check in Admitting	Get Patient from waiting room
Clinic Clerk	x	x	x	x	x	x	x				
Scheduler						x					
Pre-Op Nurse			x	x	x			x	x		x
Registration Clerk									x	x	
Pre-Op Clerk							x	x	x		x

d. Steps:

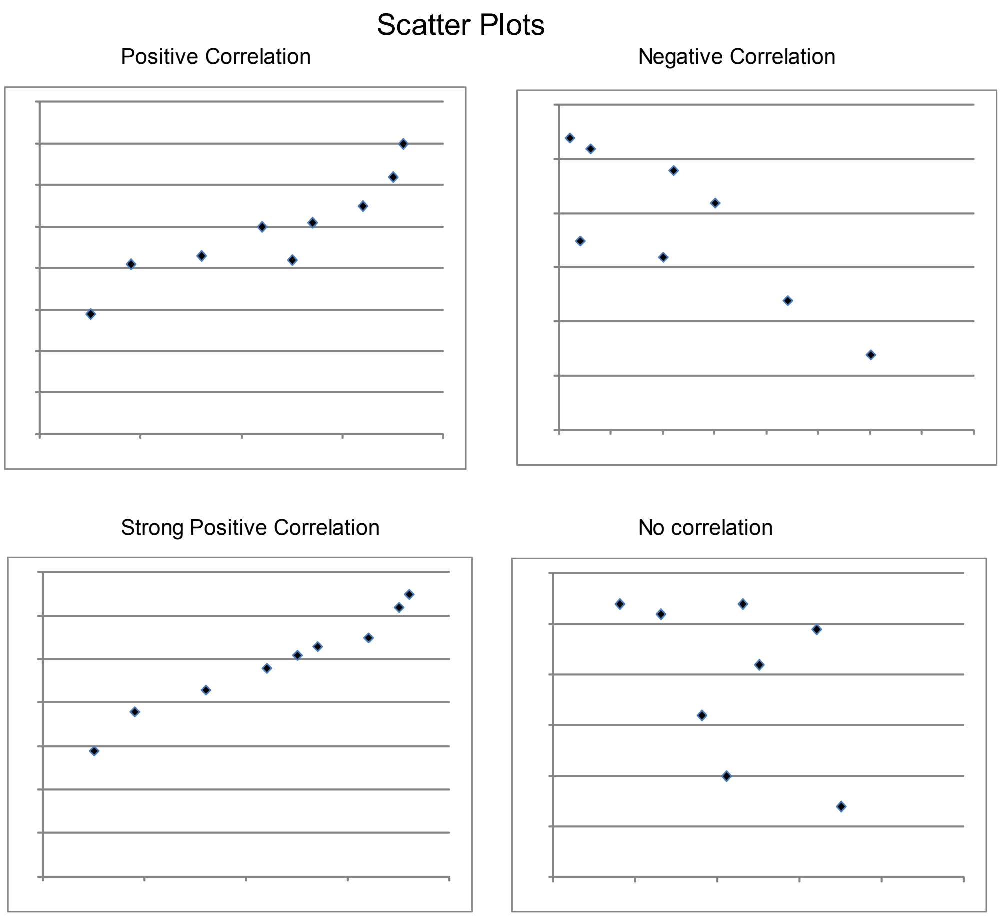
1) Identify the responsibilities or tasks to be represented.
2) Determine what each individual does with respect to these responsibilities. It is often necessary to interview each individual separately to accurately gather this data.
3) Prepare the matrix. Responsibilities may not be binary (yes or no) but include other aspects such as who is the leader and who has a role to follow others.
4) Evaluate the results; look for redundancies or gaps.

31. Scatter Diagram

a. Definition: A two-axis graph is used to display values with the intent to visually determine if a relationship exists. Pairs of measures, such as price and quality or age and weight, can be plotted against one another to identify the direction and strength of the relationship. Statistical tools exist to quantify such correlations but often the relationships are evident from just looking at the diagram. The Scatter Diagram is useful during a group discussions or brainstorming, along with other methods such as the fishbone diagram, to determine causes of problems and opportunities for improvement.

b. Literature: Many books and articles discuss scatter diagrams along with other quantitative tools for quality improvement. This particular method is often cited in literature about Total Quality Management (TQM), such as:
   - Quality Management for Organizational Excellence: Introduction to Total Quality (6th Edition) by David L. Goetsch and Stanley Davis (2009)
   - Bamford, David R., and Richard W. Greatbanks. "The use of quality management tools and techniques: a study of application in everyday situations." International Journal of Quality & Reliability Management 22.4 (2005): 376-392.
   - Reynard, Sue, ed. Scatter Plots: Plain & Simple. Oriel Incorporated, 1995.

c. Example:



d. Steps:

1) Determine two measures in which you are interested. For example, incidents of a quality problem and another type of incident, such as use of a certain procedure. For this method, the data should be a range of values such as a count of the number of events or positive integer quantities. It is not as useful for continuous or binary data.
2) Gather data on occasions where the two measures are recorded.
3) Plot as an X-Y graph of data points as shown above. MS Excel will do scatter plots.
4) Merely observe the relationship, if any, and consider what such a relationship might imply.
5) Optionally, calculate the statistical correlation to quantify the direction and certainty of the relationship.

32. Simulation Modeling

a. Definition: Discrete event simulation is the use of a computer model to replicate operations to gain understanding of a system being modeled. This is done without requiring changes to the real system itself. Computer software is available to facilitate creation of such models which incorporate the random variations and logic of the actual events being modeled. Simulation modeling includes constructing the computer model, confirming its validity in reflecting the real system modeled and experimenting with the computer model so as to forecast likely outcomes in terms of operations or quality. Thus discrete event simulation provides a safe and cost effective way to experiment with proposed improvements. Simulation models are used to investigate functions in all areas of healthcare including patient movement, information flow and disease processes. Specialized software is available for healthcare modeling but generic simulation software is frequently used in health care as well.

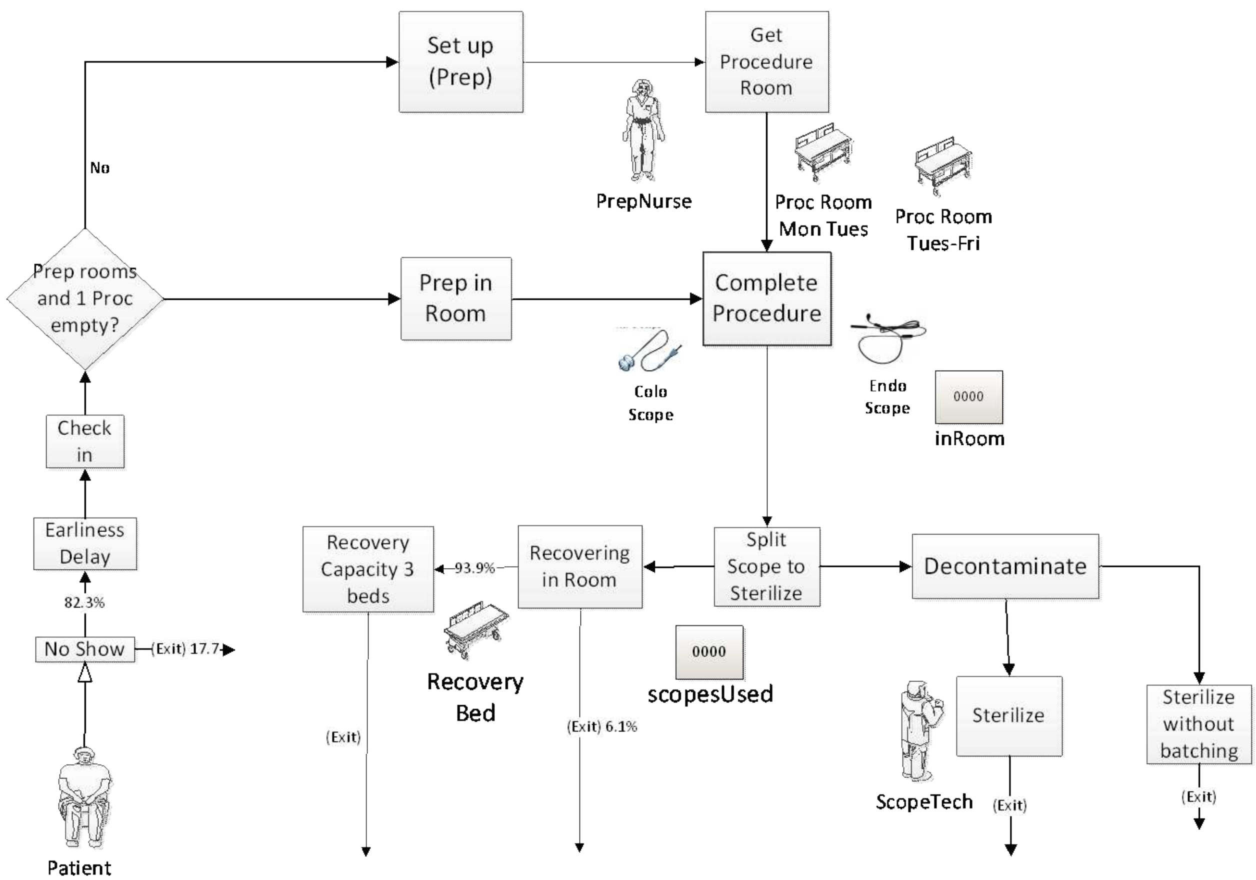
b. Literature:
- Rutberg, Matthew Harris, et al. "Incorporating Discrete Event Simulation Into Quality Improvement Efforts in Health Care Systems." American Journal of Medical Quality (2013): 1062860613512863.
- Jacobson, Sheldon H., Shane N. Hall, and James R. Swisher. "Discrete-event simulation of health care systems." In Patient flow: reducing delay in healthcare delivery. Springer US, 2006. 211-252. (Provides many references)
- Jun, J. B., S. H. Jacobson, and J. R. Swisher. "Application of discrete-event simulation in health care clinics: a survey." Journal of the operational research society 50.2 (1999): 109-123.
- Günal, M. M., and Mike Pidd. "Discrete event simulation for performance modelling in health care: a review of the literature." Journal of Simulation 4.1 (2010): 42-51.

Several simulation software packages are available some of which were created specifically for healthcare. These include:
- From ProModel Corp.: MedModel, Clinical Trials Simulator, and Process Simulator
- From Rockwell Automation: Arena simulation software.
- From FlexSim Software Products: FlexSim Healthcare Simulation
- From Lanner Group Ltd. WITNESS simulation software which has a version for pharmaceutical, consumer health and medical products manufacturing.

c. Example: Many functional areas in healthcare have benefited from the use of digital simulation models. The discrete events simulated can be such things as a clinical procedure, an administrative decision or patient attributes. Particularly popular are models of a hospital ED, surgery, outpatient clinics and various ancillary departments to model patient flow and to develop and test improvement alternatives in these areas. The simulation models can be built using available hospital data on the timing of patient movement and processes. Often the programming and resulting model are displayed graphically and animated. The model’s intent can be to improve productivity, quality, resource utilization or other attributes.

An example might be to determine the impact of implementing a new type of equipment where there is a choice in the number of devices to purchase. Various combinations scheduling and staffing the use of the devices could be tried and the simulation used to forecast the effect on patient visit time, costs and patient outcomes.

A department or clinic's patient flow can be modeled. The model can be displayed as a flow diagram on a computer screen with icons of patients and staff moving about a diagram. Shown below is a diagram for a simulation model of patient flow in a colonoscopy clinic that was used to improve patient and staff schedules.



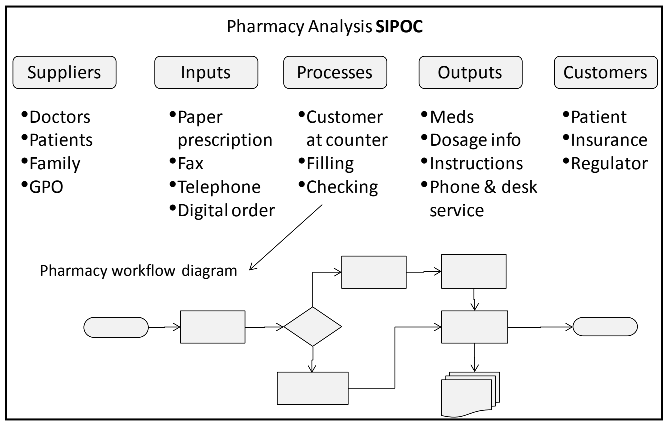
Simulation model of a GI clinic

d. Steps:
1) Define the problem and objectives to be addressed
2) Gather data needed for the model's attributes such as volumes, times and patterns of flow
3) Design and program the simulation model incorporating the descriptive data
4) Test (validate) the model to be sure it reflects the situation being modeled, including its ability to correctly react to changes to the system.

5) Run potential improvement within the simulation model and evaluate the forecasted simulation outcomes. If the improvements appear worthwhile in the simulation, test the changes in the real life system to assure that these improvements can be achieved.

33. SIPOC (Suppliers, Inputs, Processes, Outputs, and Customers) Model

a. Definition: A structured way to address a quality improvement by considering all the relevant elements before starting on the improvement effort. Included are Suppliers, Inputs, Processes, Outputs and Customers (SIPOC). This is often presented in the form of a diagram or table. An improvement team can use this combination of information to plan the necessary changes. A table summarizing these facts related to a complex project is helpful. Often a standard format is used to present the SIPOC elements.



b. Literature:

- Rasmusson, David. The SIPOC picture book: a visual guide to the SIPOC/DMAIC relationship. Oriel Incorporated, 2006.
- Simon, Kerri. "SIPOC diagram." Retrieved January 15 (2007): 2008.
- Pocha, Christine. "Lean Six Sigma in health care and the challenge of implementation of Six Sigma methodologies at a Veterans Affairs Medical Center." Quality Management in Healthcare 19.4 (2010): 312-318.

c. Example: Before beginning an effort to improve the quality of a pharmacy department where there had been issues such as missing medications, the team decided to begin with a SIPOC table to identify all the inputs, outputs, and customers related to the current pharmacy operation. This helped the team identify the range of people and data they needed to gather as well as who they needed to contact regarding problems, operational information and priorities.
The SIPOC exercise can be a useful step for any team beginning a change to current operations, such as the implementation of a research intervention, in order to assure that all aspects of the process are considered and that no elements are ignored.

d. Steps:

1) Set up a space or paper for preparation of the SIPOC table. This could be a wall area if it is to be done with a team of people.
2) Prepare a high level process map.
3) Identify the SIPOC elements.

4) Review with personnel directly involved: staff, customers, stakeholders and others.
5) Revise and prepare the final version.

34. Six Sigma Approach

a. Definition: Six Sigma is an improvement approach incorporating many methods with a particular focus on quality as well as statistical control over processes. Based on data, improvement particularly comes from reducing unwanted variability. It shares many attributes with the Lean Approach (see Section 19). Six Sigma is a registered service mark and trademark of Motorola Inc. Other early adopters of Six Sigma who achieved well-publicized success include General Electric. By the late 1990s, about two-thirds of Fortune 500 organizations had begun Six Sigma initiatives with the aim of reducing costs and improving quality.[3] Training and certification in Six Sigma is available from many organizations. The term “six sigma” comes from a reference to variability. A standard deviation is used to compute variability and is often labeled with the Greek letter sigma (σ). A good design results in only 3.4 defects out of a million, which is 6 standard deviations or Six Sigma, although this is not always achieved.

Six Sigma focuses on understanding and controlling a process with the use of quantitative tools. It makes a nice fit with research projects because both focus on understanding processes and often use extensive data analysis. Six Sigma’s ideas offer the researcher opportunities for quality improvement in both conducting research and producing improved results. For example, Six Sigma is used to speed up the completion of the development of a medical device and it is used to track changes in quality and to reduce laboratory errors.

Many of the methods covered in this handbook are commonly referenced as part of Six Sigma as well as Lean or the Toyota Production Process. As a result of the overlap of Six Sigma and Lean, some refer to the “Lean Six Sigma” (LSS) method. The following are tools which are particularly part of Six Sigma but less often part of Lean.

- Control chart (see section 6)
- Statistical analysis such as design of experiments (see section 8) and analysis of variance (ANOVA)
- Modeling and optimization (see section 21)
- DMAIC (see section 9)

b. Literature: There is an extensive literature on Six Sigma but much of it is not focused on healthcare or research.

- Schweikhart, Sharon A., and Allard E. Dembe. "The applicability of Lean and Six Sigma techniques to clinical and translational research." Journal of investigative medicine: the official publication of the American Federation for Clinical Research 57.7 (2009): 748.
- Gras, Jeremie M., and Marianne Philippe. "Application of the Six Sigma concept in clinical laboratories: a review." Clinical Chemical Laboratory Medicine 45.6 (2007): 789-796.
- Pyzdek, Thomas, and Paul A. Keller. The six sigma handbook. Vol. 486. New York, NY: McGraw-Hill, 2003. Gygi, Craig, and Bruce Williams. Six sigma for dummies. John Wiley & Sons, 2012.

[3] http://en.wikipedia.org/wiki/Six_Sigma

- Lean Six Sigma for Hospitals: Simple Steps to Fast, Affordable, and Flawless Healthcare by Jay Arthur (2011)
- Improving Healthcare Quality and Cost with Six Sigma, by Brett E. Trusko, Carolyn Pexton, Jim Harrington and Praveen K. Gupta (2007)
- Koning, Henk, et al. "Lean six sigma in healthcare." Journal for Healthcare Quality 28.2 (2006): 4-11. Adams, Rella, et al. "Decreasing turnaround time between general surgery cases: a six sigma initiative." Journal of nursing administration 34.3 (2004): 140-148.

c. Example: Six Sigma improvement projects generally follow a cycle called DMAIC (Define, Measure, Analyze, Improve, and Control) (see Section 9). For example, a research group wanted to improve the outcomes from a particular surgical procedure. First they defined in detail the sequences of processes involved. This is the Define step in DMAIC whereby a team representing all disciplines mapped the workflow, gathered statistical data and determined the issues that should be addressed. The team developed a clear written definition of the clinical decision making, the equipment involved and the patient mix. The next step was to Measure and Analyze the data available. Data was needed on a sufficient number of surgeries and the various aspects of each case. Also relevant literature was an input to the team. Of particular interest was variability and trends defined in statistical terms so that inferences could be gained about the system they were studying. This provided an insight into the factors causing problems and what was related to patient outcomes. By gaining such an understanding, particularly quantifying the relative importance of each factor, the team could know where improvements were necessary and which were priorities. Then, improvements were developed. The measurement and analysis also provides data for determining the cost-effectiveness of the changes. The source of improvements can come from several of the methods as discussed in the handbook such as a Kaizen, brainstorming or simulation modeling. The analyses above provided what should be expected in quantitative terms. The final step in the Six Sigma DMAIC cycle is to standardize the improvements and make sure the changes remain. Thus control, the C in DMAIC, is needed to sustain the changes.

d. Steps: Six Sigma improvement projects generally follow the DMAIC cycle and assume that there is always room for additional improvement. Thus the DMAIC cycle should be repeated (Define, Measure, Analyze, Design, Verify – or DMADV). These steps are similar to the Lean approach's PDSA (Plan, Do, Study, Act) where the emphasis is more on the change step whereby Six Sigma places relatively more emphasis on the analyze aspect. However both these sequences of steps are useful and can be used together. When the objective is to develop something new a DMADV sequence is followed, which is sometimes referred to as Design Six Sigma.

35. SMART (Specific, Measureable, Attainable, Relevant, and Time-Sensitive) Goals

a. Definition: To better assure a QI effort's effectiveness, it is important that the direction of a research project, or other efforts, should be directed to goals. The attributes of so-called SMART Goals are that they are Specific, Measurable, Attainable, Relevant and Time-sensitive. The acronym makes clear the aspects that goals should have. Specific goals should be simple and clearly defined. Measurable goals should provide tangible evidence from available data. Attainable goals should be achievable but demanding. Relevant goals should measure the outcomes relevant to the desired results. Time-sensitive goals identify when they are to be achieved and often result in a tension between the urgency of getting results and the limitations in place. SMART goals incorporate all these aspects and must be written down and circulated to those affected by them.

b. Literature:
- Meyer, Paul J. "What would you do if you knew you couldn't fail? Creating SMART Goals." Attitude Is Everything: If You Want to Succeed Above and Beyond. Meyer Resource Group, Incorporated (2003).
- Doran, George T. "There's a SMART way to write management's goals and objectives." Management Review 70.11 (1981): 35-36.
- Bovend'Eerdt, Thamar JH, Rachel E. Botell, and Derick T. Wade. "Writing SMART rehabilitation goals and achieving goal attainment scaling: a practical guide." Clinical rehabilitation 23.4 (2009): 352-361.

c. Example: A clinic decides to implement a new screening procedure. The organization wants to be sure the change is effective and decides to begin with SMART goals, which are; Specific – the new procedure is to be applied to all new and existing patients, Measurable - the goal will be to record use of the procedure in the clinic's electronic information system which will produce data on the number and percentage of patients screened, Attainable – they plan to have the procedure used for more than 95% of patients who visit each month, which is feasible, Relevant – the goals respond to expectations of the nursing department's leadership, Time-sensitive - the improvement must be fully implemented by the end of the year.

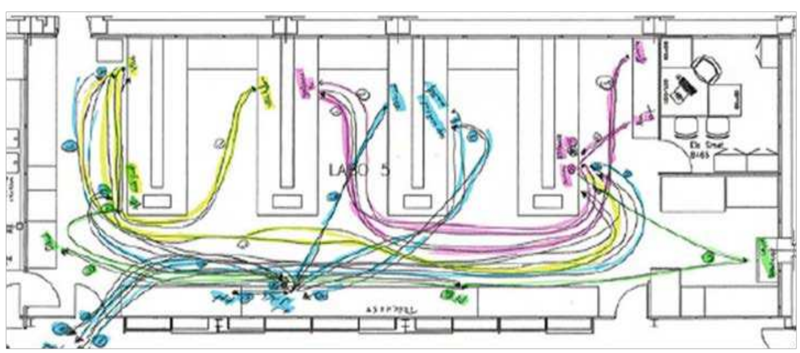
d. Steps:
1) Set goals while following the SMART attributes, write them down and circulate them to those affected.
2) Track the results against the goals with specific tasks to achieve them.
3) Report the results on a regular basis.
4) As changes take place, continue to focus on the goals and revise plans as necessary to assure achieving them.

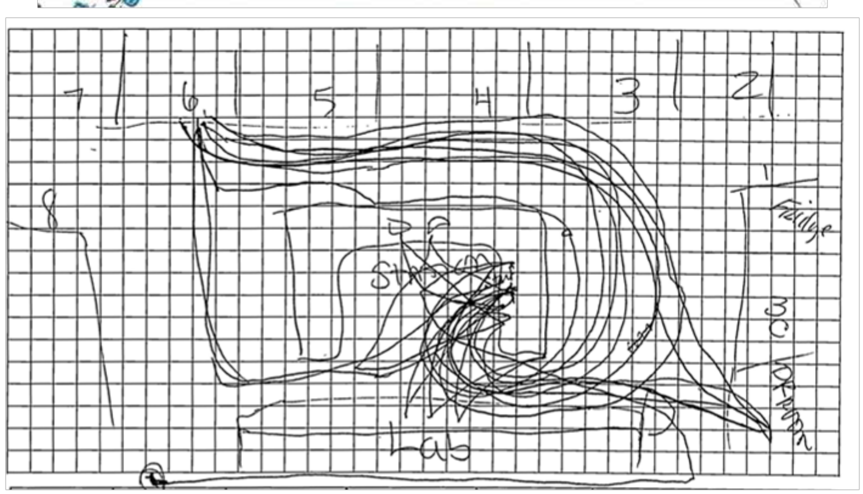
36. Spaghetti Diagram

a. <u>Definition</u>: A graphic which presents the actual movement as a particular process is executed or as work is done in an area. It can help identify wasteful or unnecessary movement and opportunities for improvement. This may mean changes to equipment location, reassigning work responsibilities or changing the facility layout (see also Section 16). Sometimes the effectiveness of a process is constrained by a poor arrangement of the space and such a diagram is a simple way to understand it. The Spaghetti Diagram is done by drawing on an area's floor plan with a continuous line showing the movement of a particular person or group. By drawing the line with a pencil or pen and not lifting it up from the page while observing a worker, a pattern of movement often is visible from the drawing. The observation and drawing should be done over a long enough time period to get sufficient movement, which could vary from a few minutes to longer periods, such as several hours.

b. <u>Literature</u>: Spaghetti diagrams are explained and examples given in books on the Lean Method or Toyota Production System. The diagram creation and use are relatively self evident.

c. <u>Example:</u> By observing a worker, such as a nurse or physician, and tracing her movement continuously on a floor plan of the area where she is working, a continuous line will show what movement is occurring over a limited time. Perhaps an hour or two will be sufficient to diagram the movement pattern. The result can help identify movement that could be reduced by rearranging the workplace.





Sometimes the drawing can be done over an architectural layout, although generally a rough sketch of the floor plan, along with key equipment, is sufficient.

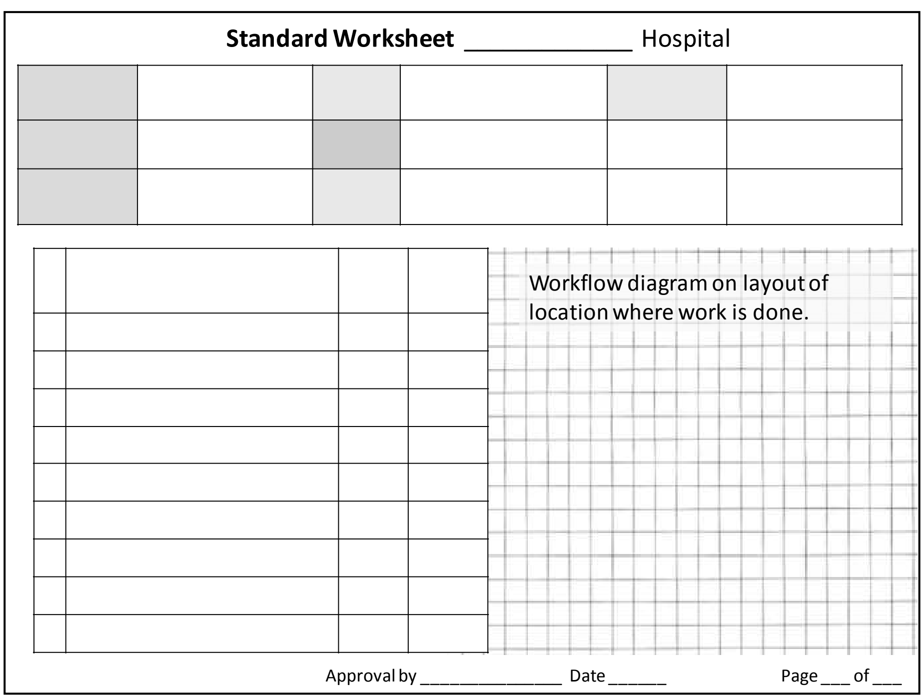
d. Steps:
   1) Determine the location in need of study and arrange to observe work being done there on a normal basis. This is an example of Gemba (see Section 14) by observing work in place, as it is normally done.
   2) Obtain a drawing or floor plan which provides a simple layout of the workplace. Or make a simple sketch of the workplace layout, including workplace equipment which might be relevant to the movements involved.
   3) While observing a worker, trace his movement on the drawing without lifting the pen or pencil. Do this for a sufficient time period such that patterns, if they exist, emerge.
   4) Review the resulting drawing for opportunities for improvement. The drawing can also provide information for future workspace designs.

37. Standard Work

a. Definition: Good quality (and good productivity) requires that work be done in a consistent way. Interventions to develop a better way will only have an impact if the new practice results in a change that is consistently and reliably implemented. Lean improvement practitioners have found that documenting a new way is absolutely critical for sustaining the change. Standard Work includes a written description which is communicated and followed by the staff involved. It describes in a clear manner what activities should occur, their sequence, and the approximate amount of time required. Standard Work is useful for audits, assures consistency, supports safety, is useful for training and is a starting point for future improvements. The lack of Standard Work often results in lower quality and productivity. However, the Standard Work documents are not intended to constrain efforts or limit future improvements.

b. Literature: Standard Work is explained in most books on the Toyota or Lean Method (see Section #20). Standard work is included in many articles about implementing Lean in healthcare, such as:
   - Laing, Karen, and Katherine Baumgartner. "Implementing 'Lean' Principles to Improve the Efficiency of the Endoscopy Department of a Community Hospital: A Case Study." Gastroenterology Nursing 28.3 (2005): 210-215.
   - Ng, David, et al. "Applying the Lean principles of the Toyota Production System to reduce wait times in the emergency department." CJEM 12.1 (2010): 50-57.

c. Example: Standard work is always documented as a narrative often with graphic and in a standardized format for the institution where it will be used. Such as:



Graphics in the standard work documents are often helpful such as pictures of computer screens or the layout of workspace with the flow of work shown on it. When research develops a new or changed procedure it should be documented as a Standard Work. This becomes the basis for the new procedure's training and verification that it is being followed.

d. Steps: The improvement intervention first determines the proper way for a particular type of work to be done. Or, if there is no intervention or change involved, the best way to do certain work is determined and selected as the standard. The work is then documented and approved. The standard work document generally includes:
   - Description
   - Responsibilities
   - Documents (if any)
   - Time, such as Takt time (see section 38), and volume expectations (if any)
   - Approvals

   The document may include process maps, templates, worksheets and checklists. Detailed versions are sometimes referred to as a Standard Operating Procedure (SOP). The completed document is made available to all who are affected by it, are given necessary training and informed how to access it when needed.

38. Takt Time

a. Definition: The concept of Takt time (based on a German phrase Taktzeit for meter or pace) is to balance workloads so that flow is continuous. This will help maximize throughput and minimize wasteful inventories between steps as well as idle time. Takt time is determined by calculating the ratio of time available to work during a given period, such as a day, divided by demand (units) for that time period. For example, the overall Takt time for a hospital laboratory would be the available hours in a day divided by the number of procedures to be done in a day resulting in an hourly rate necessary to meet the demand. The pace is then equalized among each step that is involved.

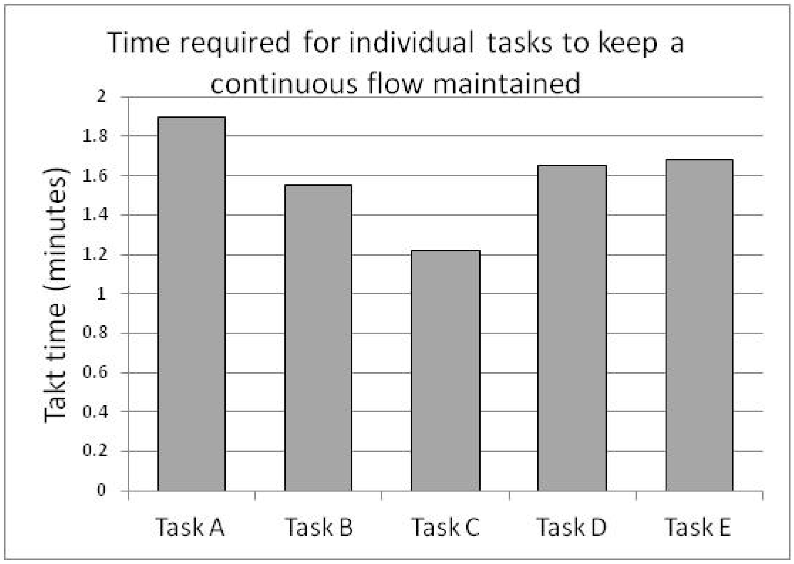
b. Literature:
- Jackson, Thomas Lindsay. Standard Work for Lean Healthcare. CRC Press, 2011. (This book does not focus on Takt time but it describes its use and related methods)
- Raisinghani, Mahesh S., et al. "Six Sigma: concepts, tools, and applications." Industrial Management & Data Systems 105.4 (2005): 491-505.
- Crane, Jody, and Chuck Noon. The definitive guide to emergency department operational improvement: employing lean principles with current ED best practices to create the “no wait” department. CRC Press, 2011. (Discusses Takt time and other methods from this handbook as applied to a hospital emergency department.)

c. Example: Patients are to be screened in a clinic following a new set of procedures, as in the research example proposal in Section III. The clinic needs to serve 25 patients who arrive during a 4 hour clinic’s day. Since the screening takes 17 minutes there will need to be 1.8 (or two) clinic staff available (25 patients x 17 minutes/patient) / (4 hours x 60 minutes/hour). This will assure that the capacity meets the demand. The patients will need to be served every 9.6 minutes ((4 hours x 60 minutes/hour) / (25 patients)), the Takt time for the clinic.

Another example: The patient flow in surgery was subject to delays, idle time and patient dissatisfaction due to excessive wait time. A hospital improved the flow so it was more continuous and smooth by reviewing the requirements in each step: registration, pre-op, staging, surgery, recovery and discharge. By balancing the workload and required pace in each area there was a net increase in daily throughput with very little change in total labor requirement. This was accomplished by moving certain tasks from one step to another. Of course, some tasks could not be moved, but enough tasks were moveable and changes in staffing could be done to achieve continuous flow.

d. Steps:
1) Determine the demand, i.e., what volume is required each day or hour or other time period for a particular type of work being studied.
2) Determine the available productive time (excluding breaks, meeting times, etc.) to service the demand.
3) Calculate the Takt time for the day (or other time period).

4) Compare the Takt time for a particular step to the Takt times for other steps in the sequence of steps so as to level the time requirements in each. For example, in the graph below, work could be moved into steps B and C from the other steps to create a smoother workflow.



39. Theory of Constraints

a. Definition: The theory of constraints (TOC) looks at operational problems as being the result of multiple limitations in a sequence of tasks. In a health care setting, work is usually constrained by the capacity within a series of steps or processes. One of those constraints will be the most limiting one (i.e., the “bottleneck”) and relaxing that constraint is necessary for any improvement to occur. TOC provides a practical approach to improvement by eliminating limits to performance.

b. Literature:

- Goldratt, Eliyahu M.; Jeff Cox. The Goal: A Process of Ongoing Improvement. Great Barrington, MA.: North River Press. ISBN 0-88427-061-0.
- Theory of Constraints: Applications in Quality and Manufacturing, Stein, Robert E., ISBN 10: 0824700643 / ISBN 13: 9780824700645
- We All Fall Down: Goldratt's Theory of Constraints for Healthcare Systems, Julie Wright and Russ King. 353 pp. Great Barrington, Mass., North River Press, 2006. ISBN: 0-88427-181-1. And see review N Engl J Med 2006; 355:218-219, July 13, 2006 by Stephen G. Pauker, M.D.

c. Example: In patient flow, TOC can be applied to increase the daily capacity of a clinic, a hospital department or an entire hospital. The steps below are followed so as to determine which element, such as the number of beds, staffing or equipment, limit the daily capacity. TOC can also be applied to administrative or clinical procedures when the throughput needs to be increased or quality improved.

d. Steps:

1) Map the system, gather operational data and develop an understanding of current limitations and inefficiencies.
2) Identify the constraints to quantity or quality and identify the most limiting constraint.
3) Get the most out of the constraint by redesign or by or shifting part or all of the work elsewhere.
4) Support the ongoing improvement of the constraints and increase capacity which is now feasible.
5) Go back to the first step such as repeating in a PDSA cycle (see Section 25).

40. Time Study & Work Measurement

a. Definition: In order to understand or improve a process it is often useful to know the time required to do the work involved. This can be done by direct observation of people doing the work (time study) or by developing the time necessary by combining known times for elements of the work (predetermined time standards) or by work sampling. Adjustments may be necessary for the physical demands and the pace at which work is executed. When properly done, these methods provide valid, accurate and useful measurements of the time and effort involved in work. Such information is useful when considering an intervention in current work practices that may change the amount of work time required.

   Time and motion study or time-study refers to the overall analysis of the time required to do work. It was initially developed in the early 20th century and is used to standardize work and evaluate workers' efficiency.

   A researcher proposing a new procedure may wish to know how much time a particular new task will take. This can be developed through predetermined time standards or by observing similar work. Time requirements may be necessary for cost effectiveness analysis (see section #7) that is needed for approving a new procedure.

b. Literature:
   - Barnes, Ralph Mosser, and Ralph Mosser Barnes. Motion and time study. Vol. 84. New York: Wiley, 1958.
   - Pizziferri, Lisa, et al. "Primary care physician time utilization before and after implementation of an electronic health record: a time-motion study." Journal of biomedical informatics 38.3 (2005): 176-188.
   - Burke, Thomas A., et al. "A comparison of time-and-motion and self-reporting methods of work measurement." Journal of Nursing Administration 30.3 (2000): 118-125.
   - Predetermined time standards are available for healthcare. Time elements can be combined to determine the total time required for a particular situation. For example, MTM-HC is a standard database devoted specifically to healthcare activities available from The MTM Association for Standards and Research (see http://www.mtm.org/systems.htm).

c. Example: Research indicated the need to add an additional procedure to existing ones in the treatment of a particular diagnosis. The steps involved were well known but there was concern over the cost of the proposed change, particularly how much it would add to existing departmental staffing. In order to decide whether to proceed with the new procedure it was decided to determine the expected work time required. By observing work elements of similar procedures it was possible to calculate an accurate estimate of the time required for the new procedure. By work sampling the time currently spent by staff on existing work was determined as well as the availability of time for the new procedure. Once implemented additional time studies could be done to determine if the actual required time was the same as the expected time.

d. Steps: If the objective is to determine the time required for a particular item of work then the steps are:
   1) Plan the study by considering the overall objectives and selecting the most appropriate time study method. Sometimes organizations have their staff themselves record the time taken for tasks that they themselves do, but this method often proves to be inaccurate.
   2) Train observers regarding how best to gather data and so that all observers consistently follow the same procedure and that observations are made of work being done in a normal manner and not significantly affected by the observation process.
   3) Conduct the observations and record times. In many healthcare situations this is challenging because staff may be doing multiple tasks simultaneously or the particular task being done is not obvious (such as work on a computer terminal or use of a telephone).
   4) Review the data. Some observations may be biased or invalid and cannot be used. Individual time measurements will vary and sufficient observations will be necessary for a desired statistical level of confidence. Additional data gathering may be necessary.
   5) Combine data as necessary and calculate desired metrics such as averages. Adjustments may have to be made concerning the pace of work – staff may be working faster or slower than normal, for example.

   If the objective is to determine the percentage of time used for a particular item of work then work sampling methods may be used. This is a helpful technique that is less distracting for the staff than direct time study observations. Steps for work sampling are:
   1) Make preliminary observations to determine the variability of the data and the probability of observing items to be measured. This is necessary to determine necessary sample size.
   2) Determine sample size for desired level of accuracy and confidence level.
   3) Train observers as to how to make observations and what they are to record.
   4) Select a method to initiate random observations in terms of their frequency and occurrence. The idea is to observe randomly so that all relevant times have an equally likely chance of being selected.
   5) Make observations on random basis and record the data.
   6) Using the results calculate the desired metrics and determine if the information meets the objectives of the study.

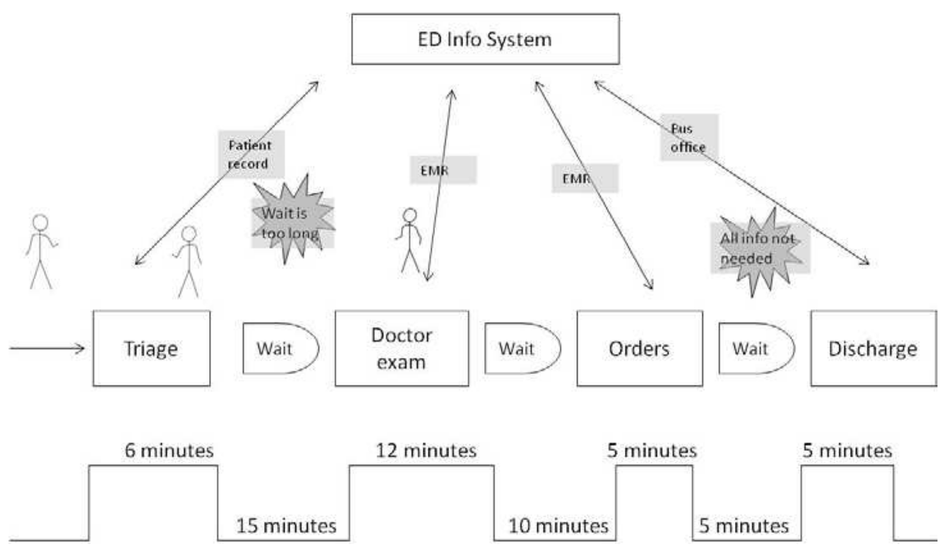
There are a number of ways to measure the time and effort involved in work. The particular approach will depend on what information is needed and the environment in which work is being done.

41. Value Stream Map

a. Definition: A map or diagram which displays not only the sequence or flow of processes but also includes "value" as it is defined within the Lean method. Value is work done that is desired by the customer (patient) versus non-value added work or waste that is not desired by the patient, such as waiting or redundant processing. Based on a process map (see Section 28), the time taken for each step, such as registration at a doctor's office visit, is described as a set of value-added time and non-value-added time. Totals of these times across the entire map provide the overall proportion of these two types of times. The intent is to create a picture of where opportunities exist for improvement. If a QUERI research project envisioned a new set of tasks, the value stream map (VSM) might be a good way to look at how close the plan is to an optimal one.

b. Literature:
   - Rother, Mike; Shook, John (2003). Learning to See: value-stream mapping to create value and eliminate muda. Brookline, MA: Lean Enterprise Institute. ISBN 0-9667843-0-8.
   - Jimmerson, Cindy, and Amy Jimmerson. Value stream mapping for healthcare made easy. Productivity Press, 2009.
   - Lummus, Rhonda R., Robert J. Vokurka, and Brad Rodeghiero. "Improving quality through value stream mapping: a case study of a physician's clinic." Total Quality Management 17.8 (2006): 1063-1075.

c. Example: The VSM is often drawn with a separate timeline showing the value and non-value time. Such as:



Similarly, a value stream map can be used to assure all the time taken to do interviewing or other data gathering during research can be assessed to identify non value added elements which should be reduced or eliminated. Researchers have found this method is perhaps best used before much data gathering has been done, and can shorten the data gathering phase and improve the quality of results. Other benefits from such analysis can be improvements to the data gathering design such as better metrics or opportunities for redesign. See Ullman, Fredrik, and Roman Boutellier. "A case study of lean drug discovery: from project driven research to innovation studios and process factories." Drug discovery today 13.11 (2008): 543-550.

d. Steps:

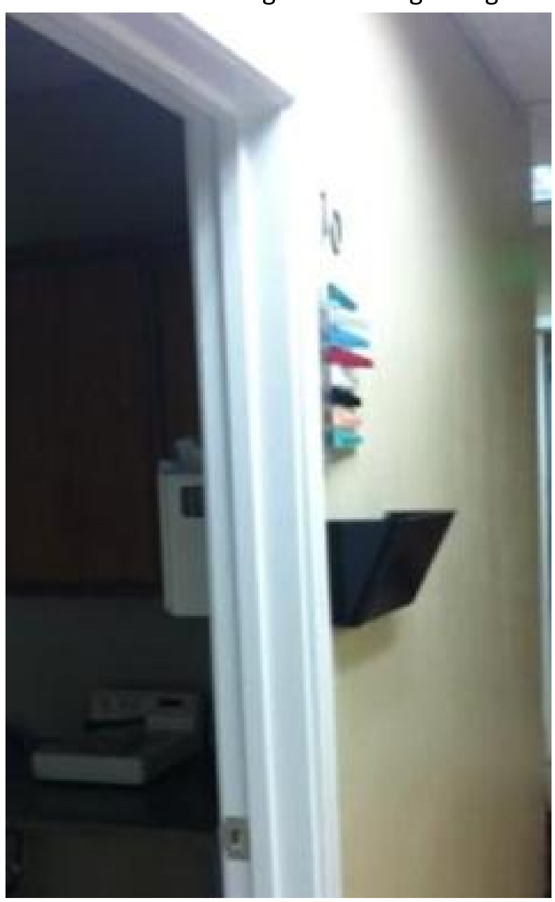
1) Identify all processes in the sequence of interest and develop a process map (see Section 28)
2) Determine the value added (VA) and non-value added (NVA) time for each process
3) Draw the VSM and identify problem areas
4) Analyze the results regarding the proportion of NVA time which is the extent of the opportunity for improvement
5) Determine changes to reduce the NVA time and, of course, implement them.

42. Visual Controls

a. Definition: Often communications can be simply and clearly communicated with a visual message, like a traffic light. Toyota found these to be very effective and efficient ways to assure efficient operations and they are applicable in healthcare as well. Visual displays are a way to keep both staff and patients informed and to provide direction for necessary actions. The recommendations resulting from research may require a change to current practices and visual controls can alert staff to the changes as well as reinforcing the recommended practice.

b. Literature: Most books on the Lean Method also describe visual control ideas.
   - Galsworth, Gwendolyn. "Visual Workplace -Visual Thinking." Visual-Lean Enterprise Press, Portland (2005).
   - Furman, Cathie, and Robert Caplan. "Applying the Toyota Production System: using a patient safety alert system to reduce error." Joint Commission Journal on Quality and Patient Safety 33.7 (2007): 376-386.

c. Example: Wall flags outside a clinic exam room to give clues regarding the status of the patient within.



Exam room doorway in a clinic with colored flags to indicate status of patient inside.

Another term covering a similar idea is the “Andon”. It comes from the Toyota method and refers to a clear prompt message regarding the status of production. Often it is used to highlight problems or delays and is used to provide the worker with the opportunity of stopping production for quality issues or when assistance is needed. In healthcare this would be the idea that clear signs are generated when work is not proceeding correctly. All staff should be in position to alert others to a problem and stop a procedure when necessary. In a research setting an Andon could be used to alert staff to the existence of a new procedure or a way to flag the occasion where an intervention is not happening as planned.

43. Waste Assessment

a. Definition: Waste (referred to as "Muda" in Japanese Lean terms) is work that is unnecessary or of no value from the customer's (or patient's) point of view. Eliminating waste is one of the primary objectives of the Lean method. In healthcare waste includes over-ordering and unnecessary procedures as well as inefficient steps in clinical processes. The Lean literature identifies seven types of waste, which are:

1. Overproduction. Doing too much such as more tests than necessary or over-referral to specialists. (see #23)
2. Waiting. This is probably the most common complaint by patients. Waiting waste can include work waiting to get done, supplies waiting to get used or information needed but waiting for processing.
3. Unnecessary processing. Using overly complex equipment for a simple task, such as using an expensive tool when a simple low cost one is available.
4. Staff movement. Having staff walk more than the minimum necessary or equipment or materials moved further and more often than necessary. Also, motion required for a task is something to be minimized or avoided.
5. Defects. Zero defects are the ideal. Errors, clearly, have no value. Setting up systems to prevent errors is far better than a system to catch errors, although both may be needed.
6. Transportation. Patient and material movement should be as near to zero as possible. The quality and effectiveness of patient care should avoid movement from one location to another. Movement of services to the patient is preferred over moving the patient but if the patient has to be moved, such as for radiology, the path should be short.
7. Inventory. Holding materials, even holding patients, in anticipation of future steps is to be avoided. Accumulation of inventory hides problems and holding represents a cost.

Just going looking for waste is challenging but by watching for these types of waste and being trained with examples of each, the observer is better at finding cases of waste.

b. Literature:

- Berwick, Donald M., ; Andrew D. Hackbarth, Eliminating Waste in US Health Care, JAMA. 2012;307(14):1513-1516. doi:10.1001/jama.2012.362.
- Womack, James P. and Daniel T. Jones Lean Thinking: Banish Waste and Create Wealth in Your Corporation, Productivity Press; 2nd edition (2003) Texts on the Lean method always include a discussion of waste.

c. Example: An egregious example of waste is orders for unnecessary tests such as CT scans for minor injuries, which is reported to have a high frequency of over-ordering. However, waste includes unnecessary walking by nurses due to a poor work layout, inventory of supplies more than is necessary to avoid being out of stock, and duplication of questions asked of patients.

d. Steps:

1) Train staff in identifying the various types of waste. By seeing examples of each type of waste, the observer is more likely to indentify waste in the workspace.
2) Observe actual processes in place and identify waste. It is helpful to categorize each waste occurrence as one of the seven types of waste so as to be sure the full extent if a problem is identified. Some of the tools discussed in this handbook are helpful in identifying waste such as a Spaghetti Diagram (see Section 36) to identify the waste of unnecessary movement.
3) Eliminate each waste found. This may require new procedures, instructions or changes to a workspace.
4) Combine activities to reduce waste.
5) Implement ongoing systems to prevent waste from reoccurring, such as with visual systems (see Section 42)

V. Concluding Notes

The methods listed here are not all of the possible quality improvement methods available. This is a list of the most useful and common ones and the methods that are particularly applicable to healthcare and research. Also, many methods here are referred to by multiple names. Some practitioners use one label while others use a different one for the same thing. Some methods have Japanese and well as English names as a result of the Toyota Company's work in this area. Some English speaking organizations utilize the Japanese names and while others use the English equivalents.

Lean and Six Sigma serve as umbrella terms for many of the methods in this handbook and they overlap each other in practice. Some also refer to "Lean-Six Sigma" (LSS) as a combined reference when using parts of both.

We have not described some broad approaches to Quality Improvement which may also be helpful, such as:

- The Malcom Baldrige National Quality Award: An award program from the US National Institute of Standards and Technology (NIST) recognizing success in safety, outcomes, and reducing cost. The awards are applicable to all industries and a health care set of awards are part of the program. Some providers have found that preparing their application for the award is useful in itself. See http://www.nist.gov/baldrige/enter/health_care.cfm
- ISO-9000: a set of standards from the International Standards Organization to assure that technical standards are followed on a worldwide basis.
- Total Quality Management (TQM): focuses on the use of multiple quality initiatives. TQM recognizes that an organization's culture must support quality and can be achieved through a focus on such aspects as leadership, communications, training and integrity.
- Industrial Engineering: a branch of engineering since the 19th century with a focus on improving systems involving such elements as people, equipment, information and materials. Industrial Engineering is a common in university engineering program. Students with undergraduate or graduate degrees have learned methods, such as those in this handbook, to improve productivity in any industry.

VI. Additional References

1. The applicability of Lean and Six Sigma techniques to clinical and translational research, Sharon A Schweikhart, Allard E Dembe, Journal of Investigative Medicine (Impact Factor: 1.96). 10/2009; 57(7):748-55.
2. Brown, Mark Graham. Baldrige Award Winning Quality--: How to Interpret the Baldrige Criteria for Performance Excellence. CRC Press, 2013.
3. Van den Heuvel, Jaap, et al. "An ISO 9001 quality management system in a hospital: bureaucracy or just benefits?." International Journal of Health Care Quality Assurance 18.5 (2005): 361-369.
4. Sahney, Vinod K. "Evolution of hospital industrial engineering: from scientific management to total quality management." Journal of the Society for Health Systems 4.1 (1992): 3-17. Industrial Engineering has a long history in healthcare, starting in the early 1900's and continues to this day.
5. Chassin, Mark R., and Jerod M. Loeb. "High-Reliability Health Care: Getting There from Here." Milbank Quarterly 91.3 (2013): 459-490. Explains the Joint Commission's reliance on Lean and Six Sigma in improving health care.

VII. Glossary

- **Effectiveness** The degree to which an objective is achieved. Treating patients more correctly regarding their condition would be an improvement in effectiveness.
- **Efficiency** The degree to which a minimum amount of resources is used to produce a particular output. Seeing more patients in a day with the same staff would be an improvement in efficiency.
- **Lean** Performance improvement based on ideas developed by Toyota and earlier industrial improvement innovators. Particular emphasis is placed on reducing waste and a focus on customer (patient) value. It shares many concepts with the Six Sigma method. Sometimes Lean is called the Toyota method or Toyota Production System.
- **Method** A systematic series of steps to accomplish something. In this handbook synonymous with a "tool."
- **Productivity** Economists define productivity as a ratio: output divided by resources used to produce the output. In the case of healthcare productivity is often measured by patients seen or bed-days divided by labor hours. Productivity in research is more difficult to define since the output is less easily quantified.
- **Six Sigma** Performance improvement based on ideas developed at Motorola and earlier industrial improvement methods. Particular emphasis is placed on reducing errors and variation. Statistical tools are employed. It shares many tools with the Lean method. Due to this overlap the term Lean Six Sigma (LSS) is sometimes used.
- **System** Interconnected components in a group with an overall purpose.