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PERFORMANCE IMPROVEMENT IN SURGERY

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PERFORMANCE IMPROVEMENT IN SURGERY
In Brief

Surgeons have continuously strived to improve their outcomes and stretch the ranges of interventions in the care of our patients. As procedures became more complex, technology interfaces increased, and the number of people involved in a team dramatically expanded, the risk for error and inefficiencies concomitantly rose. In 1999, public scrutiny of healthcare was brought to the forefront by the publication of *To Err is Human: Building a Safer Health System.* Multiple regulations failed to fix the problem, and in many cases added to cost, without increasing safety. In the United States, per-capita health care expenditures surpass that of every other country in the world and is nearly twice that of other high-income countries. Attempts to address the rising costs of healthcare have largely focused on payment reform; cutting costs by reducing payments and penalizing suboptimal outcomes. These have failed as the metrics incented do not necessarily reflect a path to efficiency and high reliability. A more appropriate approach, is to improve *how* care is delivered. Since greater than 20% of health care expenditures can be attributed to inefficiencies in the healthcare system, eliminating errors, defects and waste not only improves the quality and safety of the care that is provided, but also saves money. Surgeons are stepping forward once again and learning techniques for Performance Improvement initially developed in other industries and High Reliability Organizations (HROs.) They have recognized the importance of charting a process and examining each step. They are finding new opportunities in how humans interact with each other and within a system. They embrace the importance of culture in sustaining gains. This monograph will review the current nature of performance improvement techniques as applied to interventional practices. We will begin with an examination of the history of quality improvement techniques, expand upon the importance of data management and the utility of the Excel spreadsheet, and then recognize the most important part of any process – the human beings involved and Human Factors research. Several quality and performance improvement tools are then introduced: LEAN/ Six Sigma, Root Cause Analysis, and Failure Modes and Effects Analysis. Finally, we will close with an examination of how one moves from recommendation to action, and the vital role of leadership to foster engagement.

Emergence of Process Control

The basis for many of the performance improvement tools of today started 100 years ago with the work of Walter Shewhart at Western Electric's Hawthorne plant in Illinois. Previously quality was controlled by having multiple inspectors look at a finished product for defects, then return it for repair or discard. Shewart recognized that measuring and understanding the steps in the process, would signal when variation was occurring. It was Shewhart's development of the statistical process control (SPC) chart that provided a visual representation of variation. An SPC chart builds on a simple run chart by adding a measure of variation that differentiates between what we now refer to as common-cause variation (random variation) and special cause-variation (non-random variation). These concepts are coming into medicine, with the understanding that frequently used simple run charts, although easy to create, do not allow an identification of a true variation.

Process control took an additional step forward with the contributions of W. Edwards Deming and Joseph Juran. Deming popularized the PDSA (Plan Do Study Act) cycle and Juran worked in post war Japan, identifying concepts such as the Pareto Principle (80% of the problems come from 20% of causes.) The rapid expansion in capability and quality from Japan's manufacturing complex subsequently ensued. During the gas crisis of the 1980's US auto manufacturers recognized the need to compete with foreign imports and sought to learn techniques such as the Toyota Production Method, LEAN and Six Sigma. It also forced US companies to recognize the vital importance of the front-line worker in identifying areas of risk as well as providing possible solutions. This has been challenging in Medicine. The top down management style of many hospitals has made adoption of these concepts challenging. Further, surgeons were trained in hierarchical environments and taught that any error was a personal failure requiring blame. This inhibited honest discussion of the system /human interaction. Fortunately, this is beginning to change.

Measuring and Analyzing Data

Deming, Shewart and Juran all recognized that if you don't measure something, you can't fix it. They did not have the types of incredible computing power currently at our fingertips. It is quite easy to upload vast amounts of data, although with the inherent risk of "Garbage In Garbage Out." The Excel spread sheet provides an easy way to upload, organize and subsequently analyze data. There are embedded capabilities to identify outlier and fraudulent cells. Certain basic concepts will ensure that Excel can function optimally as a data storage and display tool.

Most data of clinical usefulness will be either a continuous measurement (with a decimal point perhaps) or a discrete count (frequency). In either case, if the data were measured again, the result would likely not be exactly the same. In other words, data are uncertain. This variation can be due to the property being measured or to the measurement technique itself. As the number of independent measurements increases, estimates of the amount of variability can be obtained by the standard deviation, and an estimate of the variability of the average result (central tendency) can be obtained using the standard error of the mean. Proper understanding of data sets includes an estimate of the "central tendency" (mean or median), the amount of variability (standard deviation) and the amount of bias.

At most surgical meetings and medical publications, statistical analysis uses a p value of <0.05 as a significant finding. What his really says is that there is still a 1 in 20 chance that the findings were random. The hazards of cause and effect analysis are further amplified in retrospective studies. Prospective, randomized studies control for all of the variables in life except those being studied. Therefore, the resulting outcome MUST be due to the treatment. Just because a retrospective study is comparing the same treatment and variables does NOT mean that the same conclusion of cause and effect can be made. Truly, a retrospective study can never FULLY determine cause and effect, only some ASSOCIATION. Why is this? Because a retrospective study has the variables and data already determined and probably not for the reasons currently being studied. Many of the variables in the dataset are actually the RESULT of <u>something else.</u>

When embarking on statistical analysis of an outcome, Excel can perform multiple types of t-tests. However, it is uncommon in modern medical research or process improvement to have only two groups. While this is sometimes handled by doing multiple combinations of t-tests, this introduces a large potential for error as well as violating the statistical principle of independence. The traditional method of handling multiple groups is to use Analysis of Variance (ANOVA). ANOVA is completely different from t-tests, as it is based on differences in the dispersion (variance) and not in the central tendency. Data also can be transformed for more accurate analysis and the relationships viewed visually with scatterplots and regression analysis. The deeper nuances and tips for choosing the correct test as described in more detail within that section.

Human Factors Consideration in Surgery

Historically, errors made in the surgical theatre have often been attributed to an individual practitioner's ability and skill. However, by focusing only on human error we fail to address the number of contributing factors that create the conditions for errors to occur. This view also neglects lessons for attaining safe and efficient performance seen in other high-risk industries. These include: organizational culture, teamwork and communication, physical layout, interface design and cognitive abilities. In high-risk/ high-reliability industries, these areas are often the focus of intervention.

A systems safety or human factors approach, unlike that of many human-centered perspectives, suggests that error is often the result of a combination of various work environment factors. Accidents and adverse events in complex environments occur when multiple factors break down the existing barriers and defense mechanisms within a given system. Perhaps one of the most comprehensive, and well-established models is the Systems Engineering Initiative to Patient Safety (SEIPS) model. This focuses upon the interplay of tools/ technology, organization, tasks, and environment in supporting or degrading a human's performance. Examples include the ergonomic challenges of minimally invasive surgery including the lack of depth perception, organizational attitudes toward productivity and response to adverse effects, simultaneous task overload, and noisy or distracting environments. All of these works together to create increase the risk of error. By the same token, lessons can be taken from other industries like aviation, where there is a "sterile cockpit" during times of high load – only essential communication is allowed, and extraneous tasks deferred. Checklists may reduce the chance of missing a critical event – yet they must be focused to key points, so as not to induce "checklist fatigue."

OR layout and noise are strong influencers on surgical performance. As technology has become better designed for efficient monitoring and treatment of surgical patients, the number of instruments, equipment, and connecting wires has only increased. Despite advances in technology, the size and architectural layout of the OR typically remains unchanged. In a study investigating workflow disruptions in the cardiovascular OR, researchers found that issues in the operating room layout and design contributed to about 20% of the disturbances. Of these issues, inadequate use of space, wrongful positioning of furniture and poor placement of equipment were most commonly observed. Researchers suggest that decluttering, standardizing room layout, making use of under-utilized spaces for organization of equipment/supplies, and eliminating wiring through the use of wireless technology can help to mitigate clutter in the room.

HROs also create an organizational culture that has five common themes: 1) commitment to resilience – the ability to be adaptable and bounce back from failure or upsets; 2) sensitivity to operations – paying special attention to those on the front-line who are doing a majority of the work; 3) deference to expertise – deferring to expertise (e.g., surgeons) rather than authority (e.g., administration); 4) reluctance to simplify – taking deliberate steps to create the most complete picture of a process/situation; 5) preoccupation with failure – treating any lapse or near miss as a symptom that there might be something wrong with the system. These concepts, though apparently quite straightforward, are oftentimes challenging to embed in a culture that has yet to recognize their centrality in affecting human performance.

Quality Improvement Techniques: Six Sigma and LEAN

Once a process is identified, techniques can be applied to optimize its performance either by reducing wasteful components or reducing variation in the product. Six Sigma (SS) refers to a method and set of tools with the objective of identifying errors and eliminating variation. This approach, developed by Motorola and further popularized by General Electric, aims to improve quality by identifying the root causes of defects using a data-driven, statistical framework to reach predetermined value targets. Armed with a set of tools, SS teams sponsor, manage, and complete projects in many complex environments. A vital component of

SS is the ability to meet customer-defined specifications and expectations. As such, it becomes essential to define a problem in accordance with what a customer needs. The Six Sigma concept comes from the goal of 3.4 defects per million opportunities which would be 6 standard deviations. This is the level of safety seen in aviation and the nuclear power industry. By contrast, we accept a common bile duct injury rate during cholecystectomy of less than 0.5% That is only a 2-sigma process. Six Sigma requires skilled facilitators ("Black Belts,") and can take months for a project to move to fruition.

On the other hand, LEAN involves front line driven, rapid cycle changes to reduce non-value-added activities. It is based on the Japanese word, *Kaizen*, roughly translating into a "change for better." This is a central precept in Lean and reflects the fundamental idea of a continuous iterative model for gradual improvement to satisfy the customer's needs. By producing only what is desired in the shortest time possible, it arranges and streamlines all essential processes to improve workflow. LEAN identifies seven "Deadly Wastes:" Overproduction; Excess inventory; Defects; Unnecessary transport; Unnecessary human motion; Over -processing; Waiting. Process mapping quickly identifies these opportunities, changes, often based on front line input, are instituted, and the new cycle reevaluated.

LEAN and Six Sigma are sometimes used interchangeably – they are in fact complementary – lean focuses on waste, and Six Sigma aims to reduce variability of the more efficient process.

Root Cause Analysis (RCA)

Surgeons have been involved in variants of RCAs when investigating a bad outcome (morbidity or mortality – M&Ms); in fact, some M&Ms use this format to attempt to identify the "root" of the problem. Harm events can occur not only secondary to the pathophysiology of the disease or patient related conditions but rather to system failures or process issues where errors are prone to occur in complex environments where multiple factors are at play at once (e.g. operating room). However, the answers are not always immediately apparent and a deeper dive into the data is required. RCAs should begin with the premise that we don’t know the true cause of a problem. Because medical care involved multiple disciplines, all relevant specialties should participate and “rank” is checked at the door.

The first step in an RCA is to collect the data (this can be a long and tedious process). It is also important to note that data can have flaws and careful attention should be placed in ensuring the accuracy of the data being analyzed. Next, developing a *Cause and Effect diagram*, also called Fishbone or Ishikawa diagram. This organization of thinking helps identify the “Effect” as the main outcome. The Fishbone is organized into basic categories – Materials, Methods, Measurements, Machines, Environment and Personnel. Each potential cause is placed within a category and 5 series of “why” questions will begin to identify a core or root cause. Interventions then focus on these upstream conditions.

Failure Modes and Effects Analysis (FMEA)

Whereas RCA, by nature is retrospective, FMEA allows a prediction of where a failure might occur and how likely it is to reach the patient. Originally developed by the military, and subsequently applied by NASA, FMEA maps a process and identifies where it could fail. Failure has three quantifiable components: How likely is it to occur (Frequency); How likely will the failure be missed (Undetectability); and How dangerous is the outcome (Severity). Each of the components is ranked on a 1-10 scale and multiplies together to create the Risk Priority Number or Index (RPN, RPI.) Interventions are then designed for those components with the highest RPI and the process repeated to identify new or emerging threats. FMEA is highly intensive as even a simple process, will be dissected into hundreds of steps and potential failure points. Fortunately, only a handful rise to the level of high risk. In some cases, other quality improvement tools such as RCA and human factors can be employed to create solutions.

Avoiding Drift: Leadership Behaviors that Sustain Performance

We have provided example of numerous Performance Improvement tool and techniques to diagnose and intervene systematic problems threatening the safety and quality of health care. None of these will be successful with an understanding of leadership in both achieving these goals and sustaining performance over time. There are key components to successful leadership: building a culture which values safety and efficiency; properly incentivizing personnel; developing a forward-thinking organization which is proactive rather than reactive. Each of these begins with a leader’s honest self-assessment – if you aren’t reflecting your true ideals, you will not be seen as genuine, even if the changes you support are correct. Next is an understanding of what motivates people, and it’s not always money. We all want to reach Maslow’s level of “self-actualization.” This means feeling valued, being given the opportunity to do the things that bring a sense of fulfilment and competence, and to have a clear idea what the rules are. Many organizations send mixed messages and under-communicate long term goals and institutional values. They may respond to the publicly reported metric of the day, rather than remind team members that outcomes are best when everyone sees, understands and pulls in the same direction. Leadership skills can be developed, and organizations should recognize and support emerging leaders, including equipping them with an understanding of the full range of Performance Improvement tool available to them.

Conclusion

Surgeons are in an excellent position to lead the transition to increasingly safe, high quality, affordable care. Surgeons are comfortable with ambiguity, are not hesitant to take on new challenges, and have a strong vision of what is right for the patient. By understanding how PI can be incorporated into our everyday practices, we will not only improve our patient’s experiences, but also our own job satisfaction.

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HISTORICAL PERSPECTIVES ON PERFORMANCE IMPROVEMENT

It has been nearly 20 years since the Institute of Medicine (IOM) report *To Err Is Human: Building a Safer Health System* concluded that 44,000-98,000 Americans die each year as a result of preventable medical errors.[1] This was followed in 2001 by the IOM report *Crossing the Quality Chasm*, which focused more broadly on the healthcare system and provided a practical framework for improving the delivery of care.[2] Although the IOM reports led to improved public awareness and dramatic policy recommendations, improvements in patient safety, quality and value are modest; patients continue to experience preventable harm through system and human errors and delivery of care remains costly and inefficient.[3,4,5] In the United States, per-capita health care expenditures surpass that of every other country in the world, and is nearly twice that of other high-income countries.[6] Attempts to address the rising costs of healthcare have largely focused on payment reform; cutting costs by reducing payments and penalizing suboptimal outcomes. These have failed as the metrics incented do not necessarily reflect a path to efficiency and high reliability. A more impactful approach, is to improve *how* care is delivered. Since greater than 20% of health care expenditures can be attributed to inefficiencies in the healthcare system,[7,8] eliminating errors, defects and waste not only improves the quality and safety of the care that is provided, but also saves money.

Healthcare delivery is complex, driven by advances in medical science and new technologies, multidisciplinary care, and increasingly diverse sites of service. Within the surgical realm, many adverse events are not related to operative technical errors, but from defects that occur throughout the perioperative period.[9,10] Quality improvement efforts must aim to improve systematically these processes of care. Increasingly, medicine benefits from lessons learned in other industries.

The systematic approach to quality improvement began with Walter Shewhart during the 1920s at Western Electric's Hawthorne plant in Cicero, Illinois **(Figure 1).**[11,12] Western Electric manufactured hardware for Bell Telephone, and its large Hawthorne plant, became famous for its studies in employee productivity and the origin of the "Hawthorne effect." Shewhart, regarded as the father of statistical process control, recognized that reducing process variation both improved quality and decreased costs. Initially, Western Electric had no means of monitoring or effectively managing variation. Instead, they relied on trained inspectors to ensure defective products did not reach their customers, a costly and inefficient process. It was Shewhart's development of the statistical process control (SPC) chart that provided a visual representation of variation **(Figure 2).**[13] An SPC chart builds on a simple run chart by adding a measure of variation that differentiates between what we now refer to as common-cause variation (random variation) and special cause-variation (non-random variation). This has important implications for how we interpret data and manage quality. When only common-cause variation is present in an SPC chart, the process is said to be in "control" and its performance going forward is predictable. Time and effort should not be spent trying to explain the data since it is randomly distributed and inherent to the process. In contrast, special-cause variation is unexpected. It should be investigated, and its etiology understood.

W. Edwards Deming and Joseph Juran, like Shewhart, also began their careers at Western Electric. Deming learned statistical process control from Shewhart and promoted statistical methodologies to improve quality. He also popularized the Shewhart Cycle, later known as the Deming or Plan-Do-Study-Act (PDSA) Cycle. In 1947, Deming was assigned by the Allied Forces to post war Japan to apply his sampling techniques for the Japanese Census. While there, he taught Japanese industrial engineers and managers statistical methods and how to improve system-wide quality.[14] These techniques would later become the basis for Total Quality Management (TQM). Similarly, Juran was invited by the Union of Japanese Scientists and Engineers (JUSE) to lecture on managerial concepts for quality improvement. He emphasized the human dimension to quality and is known for applying the Pareto Principle or 80-20 rule: 80% of problems come from 20% of causes. Both men are recognized for having played a significant role in Japan's subsequent quality revolution and financial recovery.

Further growth to the quality movement in Japan during the 1950s were driven by Kaoru Ishikawa, professor of engineering at Tokyo University, and Taiichi Ohno, an industrial engineer working for Toyota. Ishikawa learned the basics of statistical quality control from the Americans, and promoted broad engagement in quality by all employees, not just management. This bottom-up approach to quality improvement was exemplified by his development of the Quality Circle.[15] He also created the Ishikawa (fishbone) diagram for problem solving, and for introducing the Seven Basic Tools of Quality: Ishikawa diagram, check sheet, SPC chart, histogram, Pareto chart, scatter diagram, and stratification or flowchart. Ohno is regarded as the pioneer of the Toyota Production System which morphed into LEAN. His model of seven wastes continue to help organizations identify non-value-added activities. These seven wastes are: transportation, inventory, motion, waiting, over-processing, over-production and defects. Ohno also introduced the problem-solving technique of asking "why" five times to understand the root cause of a problem.[16]

Prior to the 1980s, the Japanese quality revolution was relatively unnoticed in the US. With the oil embargos of the 1970s and the need for fuel efficient and dependable cars, the US automobile industry had to improve quality. They were losing market share to the higher quality and less costly automobiles coming from Japan. The 1980 NBC broadcast, "If Japan Can, Why Can't We?" highlighted the innovative products coming from Japan, ironically based on the methods of American W. Edwards Deming. US industries sent teams to Japan to study the success of companies like Toyota, and Deming's teachings were in high demand from US industries including the then Big Three automakers. This marked a new era in the US for quality management systems, now incorporating, Total Quality Improvement (TQM), LEAN, and Six Sigma.

Quality Management Systems

Quality management systems include philosophical concepts and practical tools; their implementation requires effective leadership to guide and sustain change. Although many approaches have been popularized, there are three major systems;

1. Total Quality Improvement (TQM) is a comprehensive approach to quality improvement and management tracing its origin to statistical process control. It is derived from Total Quality Control (TQC) developed by Japanese industries and the concepts of Deming, Juran, Ishikawa, and others. TQM promotes "total" organizational engagement in quality, cycles of continuous quality improvement, and the Seven Basic Tools of Quality. Popular in the 1980s and 1990s, it has since been largely replaced by other frameworks, such as Lean and Six Sigma.
2. LEAN references the Toyota Production System (TPS). As defined by the Lean Enterprise Institute, "Lean is a set of concepts, principles and tools used to create and deliver the most Value from the Customers' perspective while consuming the fewest resources and fully utilizing the skills and knowledge of those who do the work."[17]
3. Six Sigma was developed by Motorola in the 1980s and later popularized by General Electric to reduce variation, harkening back to the earlier work of Shewhart. Heavily reliant on statistical control, Six Sigma relies on a team of experts with an understanding of experimental design and applied statistics to identify and eliminate sources of variability.

Systems Engineering

Systems engineering draws on a broad range of approaches to improve quality, safety, efficiency, productivity, and service. It includes quality management strategies such as Lean and Six Sigma, statistical process control, multiple engineering techniques, queuing theory, high-reliability approaches, human-factors engineering, complexity science, modeling and simulation, and safety tools that include Root-Cause Analyses (RCAs) and Failure Modes and Effect Analyses (FMEAs). **(Figure 3).**

Applications in Healthcare

A systematic approach to quality improvement in healthcare offers an opportunity to improve quality and efficiency while decreasing costs.

In 2005, the IOM partnered with the National Academy of Engineering (NAE) to apply systems-engineering tools to healthcare.[21] In 2009 a report followed from the Agency for Healthcare Research and Quality (AHRQ) entitled Industrial and Systems Engineering and Health Care: Critical Areas of Research[22]. Subsequently a summary of recommendations was made to President Barak Obama from the Council of Advisors on Science and Technology entitled Better health Care and Lower Costs: Accelerating Improvement through Systems Engineering **(Figure 4).**[4] Despite these efforts and data suggesting that systems engineering techniques have been associated with significant improvements in healthcare quality and efficiency, these tools remain underutilized. Their adoption has been hindered by multiple barriers, including inadequate access to relevant data and analytics, health professionals not trained to think analytically about the delivery of healthcare, and industrial and systems engineers without enough knowledge of the healthcare industry.[4,23] Nonetheless increasing numbers of leading organizations are successfully employing QI/PI tools in their daily operations. These include the ThedaCare system in Wisconsin[18], Virginia Mason in Seattle[19], and Seattle Children's Hospital.[20]

Healthcare in the United States is complex, and its outcomes are heavily reliant on both the individual provider and the delivery system in which they are embedded. The same is true for the practice of surgery, where the errors in patient care occur throughout the entire perioperative period, yet systems-based improvement strategies have not been widely adopted. This is likely to change as the Centers for Medicare and Medicaid Services (CMS) and insurers incentivize the value of care provided[24,25] Physicians are a natural fit to lead these efforts; in order to do so they must understand data and its management as well as adopt systems-based improvement strategies.

MEASURING AND ANALYZING DATA

It has often been said that you can’t fix it if you don’t measure it. In modern parlance, that includes being able to analyze what is measured to understand it. Data are being collected in troves, and increasingly by surgeons themselves. The day has arrived when surgeons must identify what is important to measure, measure it, and then analyze the data to continuously improve the care being provided. While many might say that they didn’t go into surgery to crunch numbers, the modern surgeon must include analytical skills in his/her quiver, including the ability to use readily available analytical software.[27,28,29,30] Current versions of Excel spreadsheets include remarkably advanced graphing and analytical tools.[31] Many of these will be identified in this section as (**Tab Name/ Menu Name**) which represents the Tabs at the top of an Excel spreadsheet and the Menu Bar that is presented when a Tab is selected. Occasionally, a third term is included to indicate a sub-selection in Excel.

Although this section focuses on the use of Excel, there are many analytical programs. A comprehensive presentation of techniques and methods of measurement and analysis is beyond the scope of this review. For those interested in more advanced methods, an extensive presentation can be found in[32] Fortunately, these advanced methods can be connected directly to Excel using software called “R” and a “link” named R-Commander (RCmdr).[33] (“R” can be downloaded at no cost from https://cran.r-project.org.)

Understanding Data[34]

Most surgeons were not trained to understand objectively data and the methods necessary to analyze them. Most data of clinical usefulness will be either a continuous measurement (with a decimal point perhaps) or a discrete count (frequency). In either case, if the data were measured again, the result would likely not be exactly the same. In other words, data are uncertain. This variation can be due to the property being measured or to the measurement technique itself. As the number of independent measurements increases, estimates of the amount of variability can be obtained by the standard deviation, and an estimate of the variability of the average result (central tendency) can be obtained using the standard error of the mean. Further, measurement tools may not be accurately calibrated, resulting in results that are consistently a little bit off. This difference between actual and measured/estimated is known as bias. This "error" (bias) is additive to the "error" attributed to variability. Proper understanding of data sets includes an estimate of the "central tendency" (mean or median), the amount of variability (standard deviation) and the amount of bias.[35,36]

Data sets aren't perfect. In addition to measurement error, there are often errors in data entry. These may be identifiable visually by examining the data or are recognized by searching for values that are outside of the expected range. Excel has built in functions that allow searching a large spreadsheet to identify high or low values, blanks, redundancy, etc. (**Home/Conditional Formatting/Highlight Cells Rules).** Often data have been saved in "text" format, even though they appear to be numbers. This can be converted using the right click function and selecting **Format**. When a column of text data contains more than one element (such as first and last name) or only a portion of an entry is needed (e.g. last four digits of SSN), this is accomplished with (**Data/Test to File**).

All relevant data should be aggregated in a single spreadsheet. Extraneous data must be removed or moved to a separate sheet within an Excel workbook. Although it is tempting to make spreadsheets "pretty" with colors, subsections, etc., these often interfere with the ability to analyze the data and should be avoided. A simple spreadsheet with titles of data fields in the top row and uninterrupted columns of data beneath is optimal. The column names should likewise be simple without symbols. If data will be "pushed" into more advanced analytical software, such software often is "case-sensitive" and as such, unforgiving. Names for data columns in Excel should be selected with this in mind- simple, no symbols, and lower case.

Large datasets can be "sliced and diced" using (**Insert/Pivot Table**). This allows totals, standard deviation, and other data characteristics to be determined across numerous dimensions, allowing a detailed "aggregate" view of the data, including subsets.

Visualizing Data.

The human eye (and brain) has an incredible ability to recognize patterns and differences.[37] Therefore it is essential to begin the analysis of surgical data by creating graphs.[38] Excel has a wide range of advanced graphing capabilities (**Insert/Charts**). Line graphs are created by selecting the **(Scatterplot**) option, which also can create linear regression outcomes within the graph. Many analytical methods “fit” a linear equation to a set of data. The human eye and brain can recognize even small deviations from a straight line, particularly when the line is horizontal. Additionally, most statistical methods require and assume that data can be fitted to a normal distribution (bell-shaped curve), but they are often satisfactory if the data are only symmetrical. This is seldom the case in human biology. If the human eye can readily identify a “tail” extending to one side or to the other, the data may require alternative analytical methods. A frequency distribution can be created in Excel using (**DataAnalysis/Histogram**). This requires identifying a “bin” size. Look at the range of the data. If there are 100 or so data points, divide the maximum by ten to create bin size. If there are 1000 or so, divide by 20. If larger, increase the number of bins accordingly. The software will create a frequency distribution graph. Ideally, this should show a symmetrical, single peak. Look for a tail to one side (skewed) or two peaks (bimodal).

Once visualized, data can be examined more closely using an “add-in” found in Excel named “**Data Analysis**” and found in “Analysis Tool Pack” **(File/Options/Add-Ins/AnalysisToolPack).** Within Data Analysis, “**Descriptive Statistics**” performs the “common” statistical tests on each variable in the dataset. A few simple “rules of thumb” simplify understanding. First, look to see if the mean and the median are the same. If they are, the variable is probably “normal”. Next, look at the “skewness”. If the skewness is more than +/- 0.5 the data are probably not normal. If greater than +/-1.0, they are definitely not normal. Look at the minimum and maximum and ask if these are reasonable values. If not, an outlier may be present. Then examine the range. If it is more than 50% greater than four times the standard deviation, there are outliers or non-normality.

Hazards of Cause and Effect Analysis

Some cause and effect (outcome) studies are prospective, but most are still retrospective (because they’re easier and don’t take many years for results).[39,40] Prospective, randomized studies control for all of the variables in life except those being studied. Therefore, the resulting outcome MUST be due to the treatment. Just because a retrospective study is comparing the same treatment and variables does NOT mean that the same conclusion of cause and effect can be made. Truly, a retrospective study can never

FULLY determine cause and effect, only some ASSOCIATION. Why is this? Because a retrospective study has the variables and data already determined and probably not for the reasons currently being studied. Many of the variables in the dataset are actually the RESULT of something else. In other words, the purported CAUSE variables and RESULT variables are not measured and so not in the dataset. A classic textbook example is the association of arm length with reading skill. As arm length increases, so does reading skill. Cause and effect? No, both are the result of age. Fifty years ago, Austin Bradford Hill wrote a set of criteria for determining the likelihood of a cause and effect relationship (Bradford Hill criteria). While these have been tweaked and modified over the years, the fundamental principles are the same. To be able to say there is a cause and effect relationship, one must convincingly demonstrate that a cause and effect relationship is both reasonable and likely. Unfortunately, no analytics software can ascertain reasonableness and logic. If the relationship isn't immediately reasonable, then it probably isn't cause and effect. Many retrospective wound infection studies, for example, identify factors that "cause" wound infections that on close look are very unlikely to be causative.

Correlation/Collinearity.

The origin of data in retrospective datasets leads to yet another problem. Because many of the variables are actually the result of something else, unmeasured, they are often very highly correlated and collinear. If highly correlated variables are all left in the analysis, in effect, the unmeasured causative variable is being included in the analysis MORE THAN ONCE, leading to an excessive weighting. Collinearity can be identified by performing a correlation matrix. Correlation and covariance are very closely related concepts, but correlation is simpler and more understandable**.** Correlation between two variables can range from -1 (perfectly correlated but in the opposite direction) and +1 (perfectly correlated). Zero means there is no correlation between those two variables.

The **(Data/Data Analysis/Correlation)** module will create a correlation matrix (a 2x2 table of all possible comparisons in the selected data). If all of the input variables as well as the outcome variable are selected, two different analyses are performed simultaneously: identifying possible adverse **collinearity** in the input variables and identifying possible meaningful **association** between input and outcome variables.[41]

What ins an "Independent" Variable?[42]

Surgical outcome studies often contain the word "independent". Independently predicts, independent variables, etc. But independent has two very different meanings, depending on the context. Input variables are called "independent", while the outcome variable is named "dependent". But the independent variables may not, in fact, be mathematically independent of each other. And they certainly aren't necessarily "independent predictors". Mathematical independence requires an analysis that demonstrates it (see Correlation/Collinearity). Prediction requires that the Bradford Hill criteria (or similar) are fulfilled.[43]

Measures of Central Tendency and Dispersion.

Central tendency is estimated by three metrics; mean (the mathematical average of the data), median (the middlemost value in a set of data), and mode (the most frequent item in the data set).[44] In the case of a truly normal set of data, the three should be identical. As a dataset becomes more "non-normal", the mean becomes less representative of the central tendency, while the median continues to be meaningful. While useful in a few specific situations, the mode is not particularly helpful except in unimodal, normal datasets, in which the mean and median are still preferred. The mean, median and mode are all determined in **(Data/Data Analysis/Descriptive Statistics).** Even measuring the same object will not give the same result on a repeated basis, so all data contains "dispersion" around the central tendency. Traditionally, it was assumed that all data were "normal" (which is why the word normal is used). The crudest measure of dispersion is the range (minimum value to maximum value). It includes 100% of the data but provides little additional information. The variance is the basic measure of dispersion, but it is not in the same units of measurement as the original data, so its square root, the standard deviation, is used. The standard deviation applies to the dispersion of an entire dataset, essentially estimating the range expected for 95% of the data, with 2.5% expected to be larger or smaller. This holds well if the dataset is normally distributed. A similar term, standard error of the mean, applies to the expected dispersion of the measure of central tendency, the mean. It indicates how much the mean is expected to vary if the data are measured again. While it can still be calculated, its true meaning tends to diminish as a dataset deviates from normality. The range, variance, and standard deviation are all determined in **(Data/Data Analysis/Descriptive Statistics).** Standard error of the mean (or simply standard error) must be calculated using a “cell-function” in Excel by dividing the standard deviation by the square root of “n”, the sample size.

t-Test and Analysis of Variance

Modern statistics originated about 100 years ago as an extension of probability theory. The t-test was one of the first published statistical methods.[45] It is limited in being able to compare two groups. Although it is modestly resilient to non-normality of the data (robust), it is less flexible with very unequal sample sizes or marked differences in variances between the two groups of data. In principle, the t-test calculates a “pooled” standard error, representative of ALL of the data, on the null assumption that there is no difference. If the difference in the means of the two groups is greater than two times the pooled standard error, there is less than 5% chance that the two means are from the same set of objects ($p<0.05$). Several forms of t-test can be performed in Excel: paired samples, equal variance and unequal variance **(Data/Data Analysis).** Paired samples can only be used when both measurements were obtained in the identical subjects. Use of equal variance requires that the variances are known or shown to be equal and yields the same result as “unequal variance” in most instances. Therefore, it is usually safer to NOT assume equality. An alternative approach is to use “distribution-free” methods such as the Wilcoxon (unpaired) or Mann-Whitney (paired).

It is uncommon in modern medical research to have only two groups. While this is sometimes handled by doing a bunch of t-tests, this introduces a large potential for error as well as violating the statistical principle of independence. The traditional method of handling multiple groups is to use Analysis of Variance (ANOVA). ANOVA is completely different from t-tests, as it is based on differences in the dispersion (variance) and not in the central tendency. It assumes that all of the variances are normal and that the variances of individual subsets can be added together to get the variance of the entire set. If this assumption is correct, then ANOVA is an extremely powerful tool, allowing a wide range of subset analyses and comparisons as well as comparison of more complex methods, such as regression. Several ANOVA methods are available in Excel. **(Data/DataAnalysis/ANOVA**). "Single Factor" is like performing a t-test for more than two groups (but using variance). The two "Two Factor" methods allow analysis in two dimensions (such as diabetics/non-diabetics in one dimension and different prophylactic antibiotics in the other). With and without replication is an important distinction. "Replication" in statistics means measurements in different samples/subjects, not repeated measurement of the same sample. **ANOVA Two Factor with replication** would be used if a single measurement (or the average of multiple measurements) was made in each patient. **ANOVA Two Factor without replication** uses single measurements or the average of multiple repeated measures. Note the distinction between "replication" and "repeated measures". As previously indicated, ANOVA is very sensitive to deviations from normality. Many measurements in medicine involve time, waiting time, survival, length of stay, for example, and length of time is almost always exponential. Many other clinical variables are similarly non-normal. Often a suitable mathematical manipulation (such as the logarithm) will "transform" the data satisfactorily, allowing ANOVA. If no suitable transform can be found, the Kruskal-Wallis test can be used.

Regression, Classification and related methods

Most surgical outcome studies utilize some variation of regression or classification methods.

In brief, regression is a technique which determines a relationship between a set of input variables and an outcome that is an actual measurement (continuous variable). It has numerous requirements and assumptions. The result of a regression analysis is an equation that relates the inputs to the outcome. Statistical analysis of the regression utilizes a form of ANOVA. Regression is a very old (and still relevant) technique, but modern high-speed computers have allowed the development of alternative methods that primarily address the failure to meet the assumptions of regression.[46] These modern techniques are increasingly seen in the surgical literature and should be in the armamentarium of the surgeon interested in outcome analysis. A remarkably strong module for regression is found in Excel **(Data/Data Analysis/Regression)**

Classification is similar to regression in concept but utilizes a binary (yes/no, lived/died, etc) type of outcome and very different mathematics. Surgical outcome studies that address the factors related to post-op infection or pulmonary embolus, for example, use classification techniques. Logistic regression has been the workhorse approach to classification studies, but once again modern computers have allowed the development of approaches that address the failure to meet the assumptions of logistic regression.

Advanced Analytics

This section has addressed some basic concepts of statistics and some methods that are available in Excel. In addition, it has introduced a few modern concepts of statistics as relevant to surgical outcome with references that provide more detailed explanations and methodologies for the interested reader. The software "R", previously mentioned, is arguably the most powerful statistical software currently available, and it's free! It links directly with Excel, allowing data in an Excel spreadsheet to be analyzed using an extensive roster of modern analytical methodologies. A comprehensive introduction to "R" and its application to Health Systems Analytics and surgical outcomes can be found in.[47] This reference contains a glossary of terms and a large number of primary references to important statistical and analytics concepts relevant to surgical outcome analysis.

HUMAN FACTORS CONSIDERATIONS IN SURGERY

While much progress has been made in reducing adverse events in healthcare, the overall rate of errors remains high, even if not associated with death or significant injury.[48] Moreover, among all areas in the healthcare setting, most adverse events are associated with surgical care.[49] A 2013 review of 14 studies involving surgical adverse events found that unintended injury or complication occurred in about 14.4% of patients in which 5.2% of these events were potentially preventable.[50]

Surgical teams are required to integrate with progressively complex technology, communicate and coordinate among several multidisciplinary team members with differing levels of expertise, problem solve on the spot as unforeseen patient challenges arise, and manage cost and time limitations mandated by the organizational priorities.

Historically, errors made in the surgical theatre have often been attributed to an individual practitioner's ability and skill.[51] However, by focusing only on human error we fail to address the number of contributing factors that create the conditions for errors to occur. This view also neglects several factors that are vital for attaining safe and efficient performance in other high-risk industries. These include: organizational culture, teamwork and communication, physical layout, interface design and cognitive abilities. In high-risk/ high-reliability industries, these factors are often the focus of intervention.

A systems safety or human factors approach, unlike that of many human-centered perspectives, suggests that error is often the result of a combination of various work environment factors. Accidents and adverse events in complex environments occur when multiple factors break down the existing barriers and defense mechanisms within a given system.[52] Human factors approaches apply information about human behavior, cognition, limitations, and abilities to the design of systems and their components for safe and efficient use.

In applying a systems safety approach in healthcare, several frameworks and conceptual models are available. Perhaps one of the most comprehensive, and well-established models is the Systems Engineering Initiative to Patient Safety (SEIPS) model, supported by the Agency for Healthcare Research and Quality (AHRQ).[53]

The SEIPS model maintains that a person (e.g., surgeon, nurse, technician) performs a range of tasks that require the interaction of other team members, the use of various tools and technologies, and that these tasks are performed within a given physical environment under specific organizational conditions. It investigates factors impacting surgical performance within these six components (**Figure 5**). None of these components stand alone, they are all part of an interacting system. Their interactions can produce different performance outcomes including safety, health, and quality of working life. Each of these factors impact surgical performance.

The Person

A human factors approach does not focus on the errors made by a particular person; rather, human factors use knowledge about human behavior, attitudes, and cognitions to understand and redesign systems and processes so that errors are less likely to be made in the future. The *person* perspective focuses on the proactive identification of what fosters high quality surgical performance, rather than highlighting surgical mistakes and developing reactive methods to address these missteps. Perhaps most central to mitigating threats to patient safety in surgery is an individual's ability to detect and recover from failures in the system before they reach the patient .This skill can be described as error management, which Leval argues is a marker of surgical excellence.[54] Wiegmann found in cardiac surgeons, 3.5 errors per case were made on average; however, most of these were detected and remedied before any harm to the patient occurred.[51] Yang and colleagues documented an average of 11 errors occurred in each case, whereby 77% were intercepted by a circulating nurse and the remaining 23% were mitigated before an adverse event occurred.[55]

Leadership is also important when girding a surgeon to act as a barrier to threats in the system. Historically, great surgeons were recognized based on their technical abilities, knowledge of the subject matter, and diagnostic expertise. However, nontechnical abilities such as effective communication and individual leadership style ultimately translate into improved patient safety and better outcomes.[56] Central to leadership is our ability to manage ourselves and our relationships with others. These skills have been described by Daniel Goleman as *Emotional Intelligence.*[57] Emotional intelligence (EQ) consists of four domains: 1) self-awareness – the ability to read one's own emotions and recognize their impact; 2) self-management – the ability to control one's emotions and impulses and adapt to changing circumstances; 3) social awareness – the ability to sense, understand, and react to other people's emotions; and 4) social skills – the ability to inspire others with a compelling vision and to help others develop by offering feedback and guidance. Emotional intelligence correlates with many of the competencies that contemporary medical curricula strive to deliver.[58] Components can be quantified using platforms such as the Bar-on EQ-I,[59] the Schutte Self-report Emotional Intelligence Test,[60] and the Wong and Law Emotional Intelligence Scale (WLEIS).[61] No one person is strong in all components, and coaching programs can be designed based on the pattern.[62]

Teamwork/Communication

Practitioners do not work alone, there is a high degree of interaction within surgical practice. A "team" is often conceptualized as two or more individuals with task interdependencies who have a shared goal – in this case a successful surgery or ideal patient outcome. However, the complexity of healthcare necessitates that teams are dynamic, inconsistent, and have nebulous boundaries, at best. Teams often interact with one another, or have smaller sub-teams, and larger, overarching and overlapping teams. Teamwork has been extensively studied in the context of surgery, often focusing on a specific discipline and how to improve teamwork and performance in that unique discipline. Teamwork can cause or prevent adverse events, and much research has gone into improving teamwork .[63]

The core competencies of teamwork are often disputed. Salas argues for the "big five" core competencies of teams which influence effectiveness: team leadership, mutual performance monitoring, backup behaviors, adaptability, and team orientation.[64] Their model supports these five competencies with three coordinating mechanisms: shared mental models, closed loop communication, and mutual trust. Communication mechanisms are key. In the surgical domain, communication is inherently multi-modal, with individuals communicating not only face-to-face, but also via virtual and written means. Communication failures happen often in the operating room.[65] In the cardiovascular operating room, Cohen found that 17.4% of all flow disruptions were purely communication-based.[66] Some research has indicated that communication failures are largely verbal failures and often involve a surgical attending.[67] Nonverbal communication by facial expressions is inhibited by surgical masks and the need to concentrate on the surgical field. Common interventions that can alleviate communication failures include team training,[68] checklist implementation and team briefings,[65,69] and implementing stricter protocol-driven communication.[70] Implementing a protocol-driven communication (similar to a sterile cockpit in aviation) decreased frequency of communication issues from 11.5 per case to 7.3 per case, on average.

Interventions for communication failures (e.g., team training and checklists) are also common for other teamwork competencies. One prominent approach is TeamSTEPPS^{TM}, developed by the Agency for Healthcare Research and Quality (AHRQ) and Department of Defense (DoD).[71] The TeamSTEPPS^{TM} curriculum is heavily influenced by the "big five" core competencies of teamwork, and includes assessment of the organization's readiness for change, training, implementation, and sustainment. The tools and strategies include briefings and debriefings, cross-monitoring, a two-challenge rule, and handoff guidelines. Handoffs include patient information transfer and are prime instances for communication failures – handoffs are often varied in function, content, and practice.[72] Handoff mnemonics can support provider memory. More than 20 mnemonics are being used and tested in various settings[73] the most frequently employed SBAR, standing for Situation, Background, Assessment, and Recommendation.[74] This is frequently used in nursing, there is often little standardization across departments or hospitals. and there are cultural challenges to ingraining these approaches that need to be addressed concomitantly. The TeamSTEPPS^{TM} curriculum includes the importance of organizational cultural change, to the other interventions supporting team functioning.

Tasks

Several studies have investigated the role of surgical task factors (e.g., job demands such as workload, time pressure, cognitive load, and attention) on performance and safety.[53] Physical workload can be excessive with prolonged muscular load, awkward and constrained postures, and/or repetitive movements[75] It is further impacted by task duration and strength requirements. As operative procedures become more complex, surgeons are at a greater risk of work-related injury. In laparoscopic surgery, muscular fatigue from prolonged and awkward surgical postures has been implicated in physical symptoms such as neck and back pain, as well as repetition injuries in the hand and elbow.[76] Cognitive load is the proportion of attentional resources demanded by the tasks. Tasks that are more difficult are associated with higher workload, leaving little or no spare attention to respond appropriately to new or unexpected events, increasing the likelihood of errors.[77,78]

There are several tools to measure mental workload; one of the most widely used (subjective) instruments is the National Aeronautics and Space Administration-Task Load Index (NASA-TLX).[79] Recently, healthcare researchers developed a new version of the NASA-TLX designed for surgery called the surgical task load index (SURG-TLX).[80] Studies investigating workload using both the NASA-TLX and the SURG-TLX suggest there is a positive relationship between workload and errors in performance. For example, increased extraneous mental and physical demands were associated with decreased suturing performance.[78]

In addition to detriments in surgical performance, workload issues have been shown to relate to physician burnout.[81] While there are multiple factors that contribute to physician burnout including inherent resilience, high workload due to the menial clerical tasks and documentation in the EHR are a major pain point. A time-motion study involving direct observation of over 50 physicians found that the average physician spent 49% of their time completing bookkeeping tasks. Moreover, physicians spent twice as long on EHR-related tasks than they did on clinical work.[82]

Several solutions have been suggested to decrease harmful task related factors in the surgical environment. Recent literature has demonstrated the positive impact of intraoperative targeted stretching micro breaks (TSMBs) on surgeons' experienced pain and fatigue, physical functions, and mental focus.[83,84] Perhaps more common, however, is the introduction of a checklist to mitigate errors during stressful situations. When well-designed and implemented under the correct circumstances, checklists can be incredibly useful.[84] However, when designed or implemented inappropriately, checklists can cause additional issues such as "checklist fatigue".[85]

Other interventions focus on physician workload and burnout. Podnos found that introducing another healthcare team member to assist with non-clinical duties and tasks could help reduce the hours and workloads of surgeons in training. For example, when health technicians worked a 40-hour week conducting clerical work and selected patient care activities, surgical intern work hours decreased by 17 hours, allowing for more time in the operating room.[86] Major organizations, such as the American College of Surgeons has taken a leadership role in addressing the multiple factors associated with burnout and surgical practice.

Tools/Technologies

Participation in any surgical environment requires interacting with complex tools and advanced (or sometimes antiquated) technologies. While tools and technology can improve surgical performance and patient care, they are sometimes poorly designed and can increase errors by creating inefficient work processes. For example, medical devices that are similar in design and purpose may not always function with the same user inputs (e.g., turning one control element to the left for manufacturer "A" and turning an identical looking control element to the right for manufacturer "B").[87] In fact, nearly half of all recalls of medical devices are due to design flaws, with certain devices being associated with dangerously high use-error rates.[51]

Medical device usability testing is one approach to help mitigate these design flaws. Recent guidance from the Food and Drug Administration (FDA) addresses many of these issues; however, it is oftentimes unfeasible to fully investigate the usability of every device prior to its implementation.[88] Additionally, even when devices are well-designed, they can have unforeseen impacts on other work processes in the system. The introduction of new technology can introduce a range of unanticipated inefficiencies and risks.[89]

Prior to the implementation of new tools/technology, it is imperative that surgeons and other team members are prepared and trained on the potential hazards and new procedures associated with the tools. There is a need for training to be included anytime that a new tool or piece of technology is implemented in the surgical system. Some have argued that stringent regulations including audits of initial performance and comparison of standard approaches should be required if new tools/technologies. The use of FMEA, discussed later in this manuscript can provide preemptive identification of risk points. In appropriate situations, to training these skills involves the use of medical simulation. Simulators can be used to investigate the effectiveness of new instruments with no impact to actual patients.[90]

Physical Environment

Within the OR, the “environment” refers to the physical space, equipment, and all the individuals within that space. While most OR team members have adapted to the ever-increasing complexity of the surgical theatre, several factors have the potential to impact surgical performance and patient safety. These include lighting, temperature, noise, traffic and physical layout of the room.

OR layout and noise are strong influencers on surgical performance.[91] As technology has become better designed for efficient monitoring and treatment of surgical patients, the number of instruments, equipment, and connecting wires has only increased. Despite advances in technology, the size and architectural layout of the OR typically remains unchanged. This has led to cluttered equipment, and entangled lines and wiring (known as the spaghetti syndrome).[92] When coupled with the challenge of working with several multidisciplinary team members (oftentimes including medical students and other visiting observers) the cluttered layout of the OR restricts team member movement, hinders the access and maintenance of lines and wires, and increases the risk of accidental line disconnection. Traffic in and out of the OR during surgery has been found to distract the operating surgeon.[93]

In a study investigating workflow disruptions in the cardiovascular OR, researchers found that issues in the operating room layout and design contributed to about 20% of the disturbances. Of these issues, inadequate use of space, wrongful positioning of furniture and poor placement of equipment were most commonly observed.[66] Researchers suggest that decluttering, standardizing room layout, making use of under-utilized spaces for organization of equipment/supplies, and eliminating wiring through the use of wireless technology can help to mitigate clutter in the room.[92]

Over-cluttered environments containing multiple team members and numerous pieces of equipment, each with their own alarm/alerting systems can lead to increased noise and impact outcomes in the OR. One study found that patients whose operative environments had higher sound levels were more likely to develop a surgical-site infection.[94] In another study, OR noise above 80 decibels was associated with a significant increase in medical errors.[70] Bear in mind however, that completely eliminating noise in the OR is not only impractical but is unlikely to be accepted by the surgical team members.

Healthcare has more recently applied the “sterile cockpit rule” used in aviation to reduce nonessential activities and discussion during periods of high workload. For example, Wadhera and colleagues introduced a structured sterile cockpit-driven protocol in cardiac surgery and saw significant reductions in communication breakdowns.[70]

Organizational Conditions

Most organizations have accepted the idea that whenever a human is involved with a process, error is inevitable. However, there are high reliability (HROs)organizations that operate in high-risk environments that continue to function at incredibly safe levels. Wieck and Sutcliffe found that HROs design work systems to anticipate risks and recover from errors when they occur. They do this through their commitment to five values/actions: 1) commitment to resilience – the ability to be adaptable and bounce back from failure or upsets; 2) sensitivity to operations – paying special attention to those on the front-line who are doing a majority of the work; 3) deference to expertise – deferring to expertise (e.g., surgeons) rather than authority (e.g., administration); 4) reluctance to simplify – taking deliberate steps to create the most complete picture of a process/situation; 5) preoccupation with failure – treating any lapse or near miss as a symptom that there might be something wrong with the system.[95]

The values and actions align well with the concept of safety culture in numerous organizations. Wiegmann and colleagues (2010) describe safety culture in healthcare as the “extent to which individuals and groups will commit to personal responsibility for patient safety, act to preserve, enhance, and communicate patient safety concerns, strive to actively learn, adapt and modify behavior based on lessons learned from mistakes, and be rewarded in a manner consistent with these values”.[51]

Safety culture has been found to play a substantial role in patient safety and even surgical outcomes. In a cross-sectional study of 91 hospitals, those with better safety climate overall, had a lower incidence of publicly reported Patient Safety Indicators (PSI), such as deep vein thrombosis and surgical site infection.

Safety climate was measured using the Patient Safety Climate in Healthcare Organizations (PSCHO) survey focusing on senior managers' engagement, organizational resources, overall emphasis to patient safety, unit safety norms, unit support and recognition for safety efforts and fear of blame / fear of shame. A 1 SD improvement in safety climate was associated with a 10% lower risk of a hospital experiencing an adverse PSI.[96] With respect to surgical outcomes specifically, a recent study found that of seven hospitals included, those with higher surgical unit safety culture scores (measured using the Hospital Survey on Patient Safety Culture (HSOPS)) were associated with lower colon surgical site infection (SSI) rates.[97] Programs that support the synergy of hospital administrators, leaders and front-line providers improve safety culture in healthcare organizations. Interventions such as TeamSTEPPS,[71] Comprehensive Unit-based Safety Program (CUSP; a model for safety improvement focused on educating staff in the science of safety, identifying defects, engaging leaders, learning from defects and implementing teamwork tools)[98] and executive walk rounds (frequent visits to patient care areas by individuals in leadership positions)[99] positively influence safety culture.

Human Factors Methods

Much has been discussed regarding the different work system factors to be considered when applying a human factor approach to surgery. However, some may still be concerned with understanding how to identify threats to the system in general. Due to the diversity of the field, numerous methods have been applied in human factors approaches to improving safety and efficiency in healthcare. Data-collection methods used to investigate each of the systems factors described above include observations, interviews and questionnaires.

Observational research identifies intra-operative flow disruptions   communication failures, poor layout and operating room design, and team performance during a process. Semi-structured interviews and focus groups are employed to understand organizational and individual factors that influence teamwork in surgery. Specific questionnaires investigate factors and attitudes that may influence surgical performance. Incident and event reporting systems are a rich source of data for diagnosing safety issues when analyzed with a human factors lens, but must be coupled with a nonpunitive approach to self-disclosure.[100] The methods listed here are not exhaustive. For a comprehensive review of human factors methods applied across several industries, see Stanton et al., 2017.[101]

Conclusions

A human factors or work system approach can be applied to surgery in many ways. The important takeaway message, is that measures of success cannot be determined by surgical skill alone. The work systems approach argues that the process of delivering care involves several moving parts, functioning in all levels. Integrating human factors and a work systems approach into performance improvement is key. Individuals must be considered in conjunction with their team, their environment, their tasks, their tools, and their organization. By understanding how all the parts fit together as a whole, a human factors and work systems approach allows for a more comprehensive understanding of surgery, and healthcare.

QUALITY IMPROVEMENT METHODOLOGIES: LEAN AND SIX SIGMA

Six Sigma

Surgeons have been slow to incorporate industrial process control methods and other reliability techniques, but such methods have been applied successfully to many areas of importance in surgery including operating room processes impacting throughput, waiting times, and postoperative lengths of stay.[102] Quality management tools can easily and effectively identify process control problems that occur on most surgical services.

Six Sigma (SS) refers to a method and set of tools that utilize statistical analysis to measure and improve an organization’s performance, practices, and systems with the objective of identifying errors and eliminating variation.[103] This approach, developed by Motorola and further popularized by General Electric, aims to improve quality by identifying the root causes of defects using a data-driven, statistical framework to reach predetermined value targets. Armed with a set of tools, SS teams sponsor, manage, and complete projects in many complex environments such as healthcare. A vital component of SS is the ability to meet customer-defined specifications and expectations. As such, it becomes essential to define a problem in accordance with what a customer needs.

A sigma (σ) is a measure of the standard deviation on each side of the mean in a normally distributed curve (Figure 1).[104] Moving a statistical process to higher levels of Sigma results in a considerable reduction in errors and waste. Reducing the rate of errors or defects in processes to the level of six standard deviations from the mean (Six Sigma) or 3.4 defects per million opportunities (DPMO), is the goal of this method. This translates to a defect-free rate of 99.99966%. By contrast, the incidence of bile duct injury during laparoscopic cholecystectomy is in the range of 1 per 1,500, representing a "defect" rate of 95 DPMO.[105] At this level of quality, one would expect 20 commercial airline accidents daily. Six Sigma places a large emphasis on quantitative data analysis focusing on non-human factors to identify areas of variability and it's causes.

In general, there are foundational principles that guide the SS approach. For example, a core belief that all processes can be measured and improved.[106] Success results from continuous efforts to achieve stable and predictable processes. Ongoing monitoring of statistical process control is crucial and, when processes are deemed out of control, a thorough causal assessment its essential. Furthermore, achieving sustained results requires full commitment from the entire organization particularly senior administration and leadership. For the most part, eliminating variation and standardizing processes saves money and improves quality in the long run. At the core of SS are the five problem-solving steps of Defining, Measuring, Analyzing, Improving, and Controlling (DMAIC) **(Table 1)** to incrementally improve an existing process. The DMAIC sequence is used as an iterative method to create a more efficient, stable, and sustainable system.

Lean

Lean is an integrated system of principles, practices, and tools, developed by Toyota Motor Corporation, with a focus on eliminating waste and decreasing production time (cycle time).[107] It aims to ensure the greatest value for the patient through the systematic identification and elimination of non-value-added activity. In contradistinction to Six Sigma, Lean focuses on improving the flow between processes rather than the processes themselves. The application of Lean principles engages all team members in developing solutions to problems, bottlenecks, and other barriers with a focus on the customer. A core concept of Lean is that most waste occurs in waiting rather than during the time spent producing the product or service.

Lean has been successfully used in healthcare and, specifically, in the surgical environment.[108,109] For example, by minimizing waiting time and other non-value-added activities across the entire episode of perioperative care resulting in reducing the patient's duration of stay, infection rate, and overall costs.[110,111,112,113,114]

The Japanese word, *Kaizen*, roughly translating into a "change for better", is a central precept in Lean and reflects the fundamental idea of a continuous iterative model for gradual improvement to satisfy the customer's needs. By producing only what is desired in the shortest time possible, it arranges and streamlines all essential processes to improve workflow. One of the guiding frameworks in Lean involves the 6S events after incorporating Safety more recently (Table 3). While Lean concepts are powerful, their application requires many of the tools used in Six Sigma for implementation. For example, a Pareto analysis tool is helpful in prioritizing where efforts should be focused (Figure 2)

Anything other than the minimum amount of materials, equipment, parts, space, and labor time, which are essential to add value to the product is considered waste (*Muda*).[115] The types of waste in Lean are listed in **(Table 2)**. In addition, it is common to view non-utilized talent where individuals are not working to the "top of their license or training as a type of waste.

The Integration of Lean and Six Sigma

Each of these frameworks have distinctive elements which complement each other (Figure 2). Used in combination, Lean Six Sigma (LSS) is a powerful quality management technique for improving the effectiveness of processes and the reduction of waste.[116] As used in healthcare and other service industries, Lean Six Sigma can improve many production and transactional processes. The benefits of combining these methods uses a structured approach resulting in the engagement of frontline staff, a strong customer focus, the commitment of management, the use of process improvement tools, the creation of high-performing interdisciplinary teams, reductions in error and waste resulting in increased productivity and cost savings.[117] Ideally, Lean methodology is usually introduced initially to improve efficiency and eliminate waste followed by Six Sigma methods for reducing variations and maintaining control of processes.

Synergy exists between the drive for better quality of health outcomes and increased productivity. Poor outcomes negatively impact productivity. By translating the voice of the patient into operational requirements using LSS, healthcare organizations can exceed patient needs, expectations, and perceptions resulting in greater patient and provider satisfaction and workforce retention. This iterative process can be harnessed by learning healthcare organizations and leads to continuous improvements in quality and process.

Successful Implementation of Lean Six Sigma:

Implementation of LSS requires several complementary skills ranging from project management and data analysis to change and operations management. As such, a team of knowledgeable, well-trained individuals are essential. The analytic activities necessary involve both strong statistical analysis capabilities as well as the use of visual, graphical elements.

Access to raw quality data in real-time in the form of process measurements is also important (103, 104). Data that can be reliably followed over time to create statistical control charts with pre-defined upper and lower control limits is advantageous. Such control limits are determined by the capacity of the process and identifies when processes are out of control.

Lean Six Sigma projects can be difficult to implement, and many efforts fail from a lack of preparation, an insufficient time frame, or a lack of real commitment from senior leadership. Simply teaching the methods and tools of LSS to others, while important, is insufficient to achieve full implementation. Getting people to adopt new ways of working and not revert to the old system is often the most challenging aspect of implementation. Ongoing coaching of front-line staff is essential to ensure sustainability of effort.

Sponsorship is essential for adoption. Without the full support of management, no change will stick. It is often the case that management wants improvement but is unwilling to fully commit resources and personnel buckling to pressures from other stakeholders who are not fully invested in the work or are threatened by change. Change management practices and techniques are key tools for implementing LSS and will go a long way toward ensuring success.

Finally, complete and relentless communication throughout the implementation process is essential. Additionally, a full stakeholder value assessment will help identify potential sources of barriers and opposition to change. Communications must address the questions: Why are we doing this? Why now? What happens if we don't change? Fundamentally, the application of LSS to improve processes of care is a deliberate organizational act which should not be done lightly and which requires the help of systems engineers and quality experts as well as full commitment from all levels.

ROOT CAUSE ANALYSIS

An important part of analyzing data is for it to help you identify problems or issues. These “issues” can be related to the data itself, the outcome or measure being looked at or simply a part of a major problem.

Whatever the problem is, it is important to learn to identify the main cause of the problem. A helpful tool in the assessment of problems is “Root Cause Analysis” or RCA.

Surgeons have been involved in variants of RCAs when investigating a bad outcome (morbidity or mortality – M&Ms); in fact, some M&Ms use this format to attempt to identify the “root” of the problem.[117] Harm events can occur not only secondary to the pathophysiology of the disease or patient related conditions but rather to system failures or process issues where errors are prone to occur in complex environments where multiple factors are at play at once (e.g. operating room).

Understanding types of errors (or effects), frequency and origin of these issues can help an organization achieve systematic changes which can enhance patient safety initiatives and avoid worse outcomes. This concept was initially introduced by the father of healthcare quality (Avedis Donabedian in 1966). Certainly, healthcare organizations and patients have learned the importance of quality care and reporting outcomes.[118]

The Joint Commission (TJC) expects meaningful improvements in patient safety at each organization by maintaining a culture of safety. Certainly, application of the RCA process can help achieve such status, with many VA systems actually submitting RCAs to state Patient Safety Centers.[119,120] The TJC also provides a helpful guide like the “Root cause analysis in health care: tools and techniques from Joint Commission resources”.[121]

RCAs can be used in a variety of settings, including understanding the root problem of a process (not necessarily a bad outcome), for example one might want to understand the root cause of why patient satisfaction surveys show low ratings for a particular office, or why an otherwise uncomplicated procedure has an unnecessary prolonged length of stay or cost, etc.[122] Although relatively a new tool used in healthcare, RCAs have been used widely in other high reliability industries to uncover issues, problems or potential problems.[123]

Designing an RCA

Whatever the variant used, there are some important concepts in RCAs. The purpose in general is to get to the root of the problem or issue. This process should be:

-Impartial,
-Multi-disciplinary, and
-Bias-free.

Ideally staff most familiar with the process being investigated should participate (e.g. a scrub tech if looking at reasons why an OR tray is too crowded).**[121,122]**

The first step in an RCA is to collect the data (this can be a long and tedious process). It is also important to note that data can have flaws and careful attention should be placed in ensuring the accuracy of the data being analyzed. Next, developing a *Cause and Effect diagram*, also called Fishbone or Ishikawa diagram. **Figure 6.)** This organization of thinking helps identify the "Effect" as the main outcome.

A Fishbone exercise is best carried out with an experienced facilitator.

a) Write 4-6 main categories on a whiteboard, flip chart or electronic file
b) Write the effect of the problem as the head of the fishbone
c) List all possible causes of the problem (effect) within the main categories (listed in a).
d) Brainstorm ideas on why these issues occurred
e) Prioritize (based on expertise – and multidisciplinary recommendations) the most important causes
f) Identify the top 3 causes and determine if additional steps are needed (e.g. more data collection, expert review, etc)
g) Apply the 5 Why methodology on each item[122]

Fishbones lead to the 5 Whys

Several "Causes" can contribute to such effect and it is rare to find just one cause but rather a combination of issues leading to the "effect" (or problem). It is important to isolate the major categories or contributors as the causal factors. Once all major factors are identified, sub-analysis if these factors can lead to identification of one or many root causes.[122,123,124]

An example of such approach is detailed in Figure. Note that in this example, the effect or problem is a prolonged length of stay for uncomplicated appendectomies at a random facility. This effect is labeled in the head of the fish as "Delays". The main categories and subcategories were brainstormed with other disciplines. The lean six sigma process improvement team helped identify unique categories and targets for intervention leading to excessive delays in length of stay for these cases. Each facility or practice might have different priorities, therefore the importance of involving key stakeholders in these reviews.

An important component of an RCA is to help identify "Why". The 5 Why methodology is commonly applied, and its intent is to methodically brainstorm the causes of a problem. Most often than not, teams observe a symptom of the problem rather the problem itself. Asking why, helps to arrive to the answer with data. Most problems can be solved by further advancing the question 5 times, however one could get an answer even at the second why.[122,124] Figure x is a 5 Whys template. In examining our long LOS in appendectomy, the fishbone and 5 why's were complementary in identifying key issues. **(Figures 7, 8, 9)**

An implementation team addressed each issue with key stakeholders in the emergency department, operating room, and nursing. We were able to increase the outpatient appendectomy rate (length of stay less than 24 hours) from 23% in FY2015 to 53% by FY2017, including an overall reduction in total amount of hours spent in the hospital from presentation to the ED to discharge in excess of 11 hours in average: from 40 hours in FY2015 to less than 29 hours by FY2017 (data not published).

Optimizing the outcome from an RCA

Going through the RCA process in isolation is not enough. The main driver for an accurate RCA is data. Many of the tools mentioned in the Data Management of this manuscript are utilized to identify outliers and ensure reliability and reproducibility.[125] Large databases (such as the American College of Surgeons National Surgical Quality Improvement Project – ACS-NSQIP) have checks and balances to support accuracy. NSQIP requires surgical registrars to receive ongoing training and periodic audits to ensure data accuracy and avoid inter-operator variability. All data should be reviewed by a second independent set of eyes to pick up inconsistencies.

Because of preexisting bias, it is vital that an RCA be multidisciplinary. Even with a multidisciplinary approach, there may remain lack of institutional commitment to institute recommended changes.[126]

FAILURE MODES AND EFFECTS ANALYSIS (FMEA)

"Failure is not an option." Attributed to Gene Kranz during Apollo 13 mission

Although Kranz never uttered those words, the analysis and prevention of failure was brought to age during the Apollo program.[127] FMEA was first developed by engineers and the military in the early 1950's to analyze how a process could go wrong after failure of a component of that process.[128] Its use became more widespread during the technological expansion of aerospace and manufacturing in the 60's and led to improved quality, less production downtime, and the ability to anticipate where failure might occur. The prevention of individual process failure is a component of the "Swiss Cheese" model of harm – multiple failures must line up for the event to occur.[129]

Medicine has been late to the game; however, the increasing technological complexity of patient care and the multiple opportunities for failure and harm makes its value even greater. FMEA is now being employed in high risk situations such as emergency intubation, vascular access and ECMO in the ICU and radiation therapy. [130] [131,132,133] Site marking, and the Universal Protocol were outgrowths of FMEA in dealing with wrong site/ wrong side surgery. Although it would seem logical to focus this modality in areas where adverse outcomes are significant, there is also improvement opportunities in routine, high volume activities such as patient flow through a clinic or assuring that inpatients consults are handled in an efficient and accurate manner. [134,135]

FMEA is proactive and predictive

Clinicians are most familiar with post hoc analysis. The weekly M&M examines an undesirable outcome, and working backward, tries to identify what caused it and how it could be prevented. Over the years, themes emerge centering around communication, individual judgment, and transitions of care.

Significant adverse events undergo root cause analysis, a more structured, focused, retrospective review.

FMEA looks at a process prospectively, and attempts to identify what could go wrong, how likely it is that the defect will be detected, and the significance of the impact to the final result. It allows prioritization of the failures and can direct resources to where they will do the most good.

It is important to understand that failures can occur in many forms and that safeguards must be designed to address the upstream and downstream results. **(Figure 10)**

In the first examples, individual failure modes each have their own downstream effect. The processes may be occurring simultaneously but are not directly linked or dependent on each other. These must be analyzed and ameliorated separately. The second example, is one of redundancy, where a single failure will not induce the undesired effect. This can be seen in the design of safety devices on high pressure presses that require the operator to press 2 buttons simultaneously, one with each hand, to prevent crush injury. The final situation is the most dangerous, analogous to a chain reaction. A single failure sets off a cascade of effects. Each downstream effect must be detected and blocked separately.

Organizing an FMEA

As in any engineering process, specific steps are undertaken

1. Assemble the team – members should be from multiple disciplines and includes experts in the subject matter.
2. Graphically describe the process – for analyzing wrong side surgery, there are hundreds of touch points. multiple inputs and potential failure points, **(Figure 11)** is an example developed in examining the vulnerabilities that lead to a wrong site surgery.
3. Conduct the analysis – this is an open brainstorming session that describes every conceivable failure, and its downstream effect. Working with experts, each failure is graded on the likelihood of occurrence (O), how detectable the failure is (D), and the severity of the result

(S). Specific tables assess each of these on a 1-10 scale. Detectability is inherently inverse – low detectability creates risk. Multiplying these together creates a risk priority number or index (RPI) ranging from 1-1000. **(Figure 12)** Emphasis is initially placed on those failure points with the highest RPI. A separate analysis of *criticality* is the sub-product of occurrence times severity which can be used to further differentiate among the outcomes.

4. Identify interventions and how to measure effectiveness – because the goal is to prevent the failure, the intervention should have some measurable effect on the detectability or occurrence of the defect. **(Figure 13.**) Severity can be mitigated, but it is best is the event is prevented.
5. Assess success – implementation of process improvement will identify new vulnerabilities. A single fix may have multiple branching positive downstream effects. The list should be reprioritized as new information becomes available.

The process can seem overwhelming as each step is subdivided and multiple failure points identified. In Niv's FMEA of consultations in an Academic Medical Center, they initially identified 11 steps. Each of those steps were further analyzed and 80 specific failure points identified.[135] Of these 80, 3 rose to the top by RPI, and allowed focused intervention. Howard's review of Rapid Sequence Intubation similarly identified 104 potential failure points in in 44 subprocesses. Although 35% were considered major, their occurrence was low and eventually 5 effective interventions were instituted. In our own analysis of a wrong side surgery, we found a bitemporal risk profile – initial mis-bookings that were propagated forward, and failure to adhere to marking and site visualization immediately before the incision. Focused revisions to protocols and the electronic booking system have reduced these risks.

FMEA is a powerful tool in the hands of a surgeon tasked with improving patient care. A knowledge of its scope and limitations will allow effective integration with other members of the performance improvement team.

AVOIDING DRIFT: LEADERSHIP BEHAVIORS THAT SUSTAIN PERFORMANCE

Previous chapters in this monograph have provided a framework to diagnose and intervene on those systematic problems that threaten the safety and quality of health care. In this chapter, we will address some of the leadership tools needed to both achieve these goals and sustain performance over time.

In doing so, we acknowledge that every institution has its own intrinsic culture ("if you have seen one academic medical center, you have seen one academic medical center"). Still, we would argue that all our institutions are more alike than they are different. Moreover, similar leadership principles apply even if the tactics may need modification depending on the situation.

In specific we will consider what leaders can do to successfully address the following key objectives:

1) building a culture which values safety and efficiency
2) properly incentivizing personnel
3) developing a forward-thinking organization which is proactive rather than reactive

Building a culture which values safety and efficiency

In his book "Organizational Culture and Leadership", Edgar Schein discusses the challenge associated with defining the term "culture".[136] Culture, in and of itself is an abstract concept; however, it drives nearly all of the forces present in social and organizational situations. Culture is not only shaped by leadership behavior, but it can also influence and constrict how we behave within our hospitals. Culture is created when individual beliefs lead to shared experiences that solve a current problem. However, it is the leader who initiates this process by demonstrating his or her beliefs, values and assumptions in both words and deeds.

Aligning an organization not only necessitates a definitive vision and set of goals, but also requires sustained enthusiasm for the change process. Oftentimes, employees are motivated to change their behaviors only when the issues are so bad that they pose an existential threat. This too often produces only temporary motivation that dies down as soon as the issues are less pressing.[137]

There is a critical balance between the magnitude of the goals and the time projected for completion. Goals must be grand enough to inspire. The great architect and city planner of Chicago, Daniel Burnham (1846-1912) famously said, “Make no little plans, they have no magic to stir men’s blood.” If goals are exclusively short-term and modest, employees often lose focus and ambition. Engaged personnel may become discouraged, thinking that their leaders do not have faith in their ability to make real change. Conversely, if goals are truly unrealistic or too long term, people wonder if they have a long enough tenure to enjoy the outcome. In fact, most individuals won’t commit to long-term transformation unless they see expected results within 12-24 months. [138] By dividing large tasks into a series of important interim goals that are attainable, but not easily so, a greater motivation and sense of urgency is created. Moreover, this method allows for the systematic development of short-term wins to both meet and celebrate which has been found to increase this sense of urgency. [138]

There are many styles of leadership and most of them can be successful depending on the situation. However, it is imperative that the style is matched to the personality of the leader and the demands of the situation. One thing is clear: To be consistent and credible, your behavior must be based on an individual’s “true self.” If you are introverted, it is not necessary or recommended that you morph into the most outgoing person at every social occasion. Fundamentally, one must spend some effort to identify and augment the ways in which they feel comfortable interfacing positively with others. Simply put, individuals will not be as successful if they can’t find a personal style that allows regular and appropriate acknowledgment of the value of their peers. It is possible that an appreciative note or email is more aligned with one’s personality than a spontaneous hallway chat. An invitation to meet for coffee may work better for certain individuals than a scheduled office appointment. As long as someone’s methods are recognized as being genuine and consistent with past behavior, colleagues will be attuned to affirming actions.

While charismatic leadership is easily identified and often praised, in truth, the most durable and successful leadership styles empower others rather than concentrating the creative energy in one individual. The best strategies revolve around making colleagues feel better about themselves and their contributions. For example, transformational leadership, characterized by motivation, consideration of individual needs/abilities, and idealized influence has been found to positively influence team behavior in the operating room.[139] If a leader can create that sense of personal pride within her followers, a true sense of ownership is engendered, and expectations are lifted.

Another key attribute of successful leaders is consistency. This extends to both personal conduct and core values. People perform better if they can reliably predict their leader's highest priorities and have a clear understanding of how they should conduct themselves. Creating such stable and shared expectations is the process by which we hardwire behaviors of excellence into employees and ingrain a culture of personal responsibility into the organization.

Studies of diverse work environments have demonstrated that employees who understand the connection between their individual efforts and the overall goals of the organization are more engaged, focused, and productive.[140,141,142] At every level, effective communication is the key to maintaining this type of focus. For example, if a nurse does not understand that increased duration of urinary catheterization is strongly associated with risk of urinary tract infections (UTI), does not know the hospital's data regarding UTI rates and related patient outcomes, and is unaware of the Medicare policy that penalizes hospitals for catheter-associated UTI, he/she may find a hospital's directive to remind physicians to remove urinary catheters to be arbitrary or pointless; predictably, compliance with such a directive will be poor.

While there is a tendency to direct the most attention to carefully fashioned communications that are disseminated across the institution, small, personal interactions which reinforce a shared purpose are often more effective in boosting employee morale. To our disadvantage, the healthcare industry is saddled with a culture in which negative feedback dominates. When was the last time you heard of a surgeon calling the radiology department schedulers to thank them for fitting in that urgent CT scan? But consider how such a brief "pat on the back" might impact the individual who received it, and for no cost at all.

When these types of positive and unexpected courtesies become more frequent, surprising benefits can accrue. It begins at the top with supervisors who are inclined to complement rather than criticize. While it is not desirable to over celebrate modest achievements, as credibility can be lost and expectations "dumbed down," the best leaders can find at least one thing each day that is, in fact, accomplished above and beyond expectations and be sure their team hears about it.

Successful organizations have learned to provide frequent reminders of excellent outcomes while weaving individual efforts into the positive result.[142] As just one example, reuniting a grateful patient, successfully treated for a life-threatening disease, with the nursing and medical staff who provided the hospital care is always a compelling narrative. The pride created in the responsible unit is invariably shared across the entire staff and provides real motivation to live up to the highest institutional standards.

In healthcare, more than nearly any other industry, we are fortunate that the majority of workers are "other directed" and have already demonstrated great dedication and persistence to reach their positions. Put most simply, the single most important job for a leader is to activate this intrinsic motivation within her followers.[143,144] To this point, Brown and Gunderman explain that physician satisfaction and performance are closely tied to maximizing the time physicians perform the professional activities that they enjoy doing.[145] Shanafelt and coworkers studied a large number of internal medicine trainees at the Mayo Clinic and confirmed that high satisfaction, better patient care and low burn-out rates were best correlated with more time being spent on the services they most value personally.[146] There is every reason to be believe this is true for all health care workers.

It logically follows that the key to successful organizations is creating those structures and processes which administratively support this goal; that is, allowing professionals to do what they have been trained to do. Leaders need to visualize themselves as agents to break down the barriers that too often stand between highly motivated caregivers and their patients. Every administrative modification needs to be evaluated in the context of its impact on workflow or it will be resisted irrespective of benefit.

Most experienced leaders have learned this lesson, sometimes painfully. Not long ago, we implemented a novel and accurate method to precisely quantitate blood loss on sponges during surgery. A strong case was made for the utility of this information and strong physician champions stepped forward. Implementation required a change in the established workflow for handling discarded sponges, which leadership did not consider to be a substantial modification. In reality, however, this change was a real impediment to acceptance. Despite strong technical support, the process was viewed negatively from the start; nurses complained stridently that the process change distracted them from more critical tasks. In short order, implementation failed until the equipment was modified to make it considerably more user friendly. Life moved forward but retrospective assessment made it clear that if we had looked at the application through the lens of our nursing colleagues first (i.e. asking the simple question - were we making it easier or harder for them to do their most important tasks?), much aggravation could have been avoided.

Leaders can gain valuable insights by focusing not only on what *isn't* working well in an organization but also by identifying what *is* working well. Understandably, we often find ourselves responding to shortcomings rather than identifying high-performing people, units, or departments and investigating what it is that makes them successful. The most obvious solution involves redesigning the workflows in less successful units so that they function more similarly to those in the higher performing units. Such internal benchmarking avoids the push back often seen when "outside" solutions, sourced from other institutions or consultants, are introduced. At the least, using methods already in place somewhere within the hospital defeats the argument that the local problems are so unique that no outside remedy will suffice.

Tracking the efficacy of process improvements in health care surely requires accurate data, but more than anything it requires a willingness to objectively evaluate the day-to-day functions in person. Many leaders have adopted routine tours of hospital units, physician's clinics, research laboratories, and even the cafeteria, a concept now commonly known as "managing by walking around."[147] Keeping your eyes and ears engaged can yield remarkable insights about what is going on at the ground level. Rounding in this manner also allows leaders the opportunity to visibly recognize and reward movement towards the organization's goals. Yogi Berra, a philosopher of the highest order, had it right: "You can see a lot by watching."

Properly incentivizing personnel

It is generally accepted that "you get what you incent." Like most aphorisms, there is much truth in the statement. That being said, it is not always possible to predict what the precise impact of a given incentive is on personal and group behaviors or what secondary consequences may ensue. This is particularly true in professional occupations like medicine in which there is considerable latitude for personal discretion.

Despite the obvious attractiveness of higher incomes, there are important limitations of using financial incentives to drive behavior. For one, the major satisfier of high performing professionals is not compensation *per se*. While it may seem counterintuitive at first consideration, this turns out to be true irrespective of the industry.

In his book "What Got You Here Won't Get You There," Marshall Goldsmith interviewed 200 "stars" from a wide variety of for-profit and non-profit organizations.[148] He was interested in understanding what factors predisposed the retention of such high performers, considering that their success undoubtedly made them attractive to lucrative offers elsewhere. In these anonymous and detailed interviews with valued employees, he asked, "Why will you be here in five years?" He noted that the top three responses rarely included salary or bonuses. Rather, respondents frequently cited work satisfaction and interpersonal factors – "I like the people I work with. I enjoy the work. The organization is giving me the chance to do what I want to do."

While straightforward on the surface, these simple answers reflect a highly nuanced blending of personal satisfaction and team goals. They suggest that for high performers, pride in individual achievement and participation in positive group behaviors are the key motivators of outstanding work. The risk of discounting these drivers is not trivial.

Over the last decade, most academic medical centers have strongly focused their compensation decisions and incentives for clinical faculty on measures of clinical productivity. Commonly used metrics include the numbers of procedures or clinic visits and work relative value units (wRVU). To correct for payor mix and ensure financial balance, others look exclusively at cash collected. To mute excessive competition between faculty, who are, after all, essentially partners in medical practice, many organizations including ours have modified productivity measures to include sectional or organizational targets in addition to individual targets. The weight assigned to group goals generally increases as physicians become more senior with greater management responsibilities.

These types of incentives and performance expectations are both useful and necessary. It is unquestioned that the financial benefit is always appreciated and is influential in sustaining motivation and retaining high performing practitioners. That said, there is considerable evidence that, irrespective of the industry, cash incentives alone are limited in their ability to reshape culture and organizational behavior. The critical misstep is overreliance on their power coupled with an illusion that fine-tuning incentives will be uniformly effective in modifying the behaviors of professionals.

For the last 10 years, we have included certain quality metrics and cultural expectations in our incentive plans. We are not convinced it has substantially impacted behaviors. This may reflect the fact that these measures are necessarily somewhat subjective and personal attribution of process improvement or deterioration may be difficult. As well, the total cash allocated for meeting citizenship and safety goals ranges from 15% to 25% of the potential bonus pool and is substantially less than the rewards for high research or clinical productivity.

As other professions now know, we are learning that cash bonuses must be combined with non-financial "intrinsic rewards" in order to be effective.[149] Organizations have approached this balance in a variety of ways: 1) adjusting the work schedules of high performing physicians such that a more ideal distribution of research, clinical, and personal time can be achieved, or 2) providing additional resources (assistants, research support, etc.) that make their day-to-day lives more productive and enjoyable.[150,151]

Two additional lessons appear clear. After the initiation of any incentive program, it is important to objectively assess the true "downstream" effects and adjust appropriately. While too frequent modifications to an incentive plan can be unsettling to all, maintaining an ineffective program more seriously undermines managerial credibility. Second, and most importantly, a great incentive program cannot act as a substitute for hiring and promoting the right people whose values parallel that of the organization as a whole. This nurturing of human capital is unquestionably a key leadership responsibility.

Developing a forward-thinking organization which is proactive rather than reactive

We close with perhaps the greatest challenge. How can we insure that the complex organizations we work within maintain a vigilance for potential safety hazards and proactively pursue "fixes" even before problems occur? Such an attitude runs counter to one of the great maxims and one very applicable to surgical practice: "if it ain't broke, don't fix it."

Proactive safety activities are best supported in organizations that exhibit a strong safety culture. Organizations with a positive safety culture are characterized by shared beliefs of the importance of safety, mutual trust, and confidence in the effectiveness of preventative measures. An organization with a positive safety culture is better prepared to identify and diagnosis safety hazards proactively, before an incident or accident occurs.[152]

To anticipate problems, we need early warning systems. The slightly misnamed "near miss" describes that disaster that nearly happened except for good fortune. In our institution we have worked to strongly encourage and reward our citizens for recognizing and reporting these events. Incident reporting, when conducted appropriately, can provide an organization with valuable information about potential systemic vulnerabilities that can be corrected before a major unsafe act occurs.[153] This practice requires an exceptional level of professionalism as these incidents rarely involve just one person and no one likes to be thought of as an informer on their fellow practitioners especially when "nothing bad happened." We counter this tendency by emphasizing the systemic nature of most medical errors or potential errors. This evolution has been further advanced by incorporating sophisticated human factor analysis into our reviews of the most serious reports.[154]

Another important source of information on potential risks is currently underutilized. We believe that more transparency between institutions would allow each of us to learn from others' experiences, before that same error surfaces on our floors or operating rooms. An excellent example of such information sharing in another high-risk industry is the Natural Transportation Safety Board's practice to regularly release substantial details of any serious safety event or crash in private or commercial aviation Shipping or commercial carriage.[155] While there are undoubtedly substantial reputational and medical-legal impediments to public disclosures of adverse medical events, sharing of de-identified accounts within a peer review protected consortium would be an attractive solution.

Finally, there has been much discussion of the value of a “blame free” culture which would further encourage reporting and full exposition of any safety related event. Indeed, the majority of medical errors and safety violations are both unintentional and not ascribed to the behavior of one individual divorced from the hospital ecosystem. Still, it is not uncommon for a single practitioner’s actions to be a primary trigger for system failure.

In his pathbreaking 1979 book *Forgive and Remember*, Charles Bosk classified medical error as either technical and judgmental (“non-normative”) or moral and behavioral (“normative”).[156] In a healthy medical culture, these non-normative errors need to be discussed and addressed, but are forgivable if the incidence is low, paralleling the expected complication rate of a treatment or procedure. In contrast, normative errors reflect the *character* of the physicians much more than their *competence*. Violation of these norms is evidence of fundamental dishonesty or culpable lack of discipline. Such behavior merits censure or even exclusion. While we understand the advantages of avoiding the reflexive assignment of blame, we have viewed knowingly violating hospital policy, especially as regards safety issues, as a classic normative error and hence unacceptable.

Conclusion

Given the extraordinary complexity of medical care, maintaining high levels of performance in quality and safety is perhaps the single greatest leadership challenge in modern hospitals. This is especially true for large tertiary centers with critically ill patients and a strong reliance on technology. Sustaining excellence in these critical areas requires extraordinary attention to the entire work environment along with the strongest interpersonal skills among leaders at every level.

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Figures

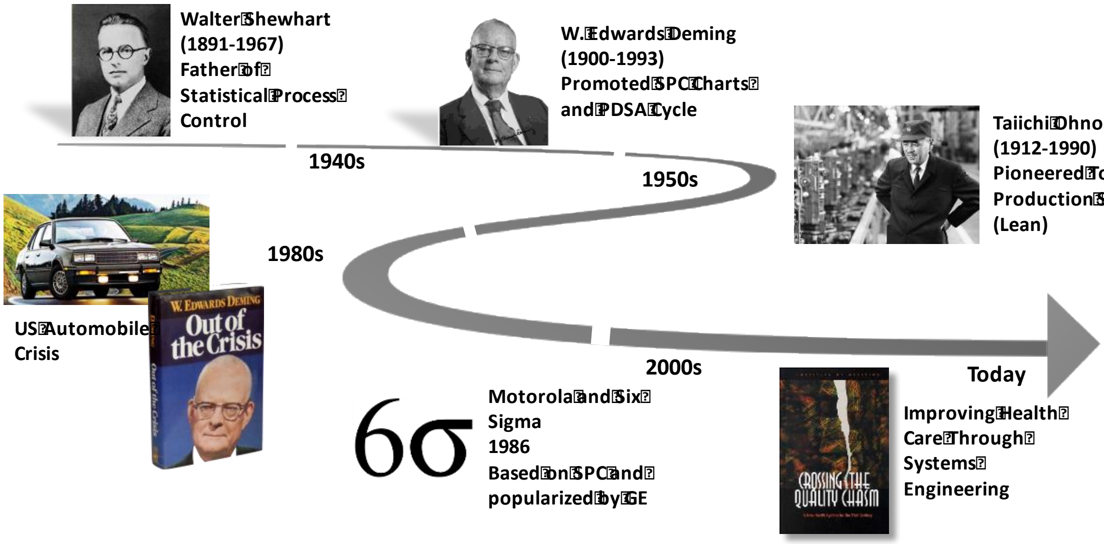
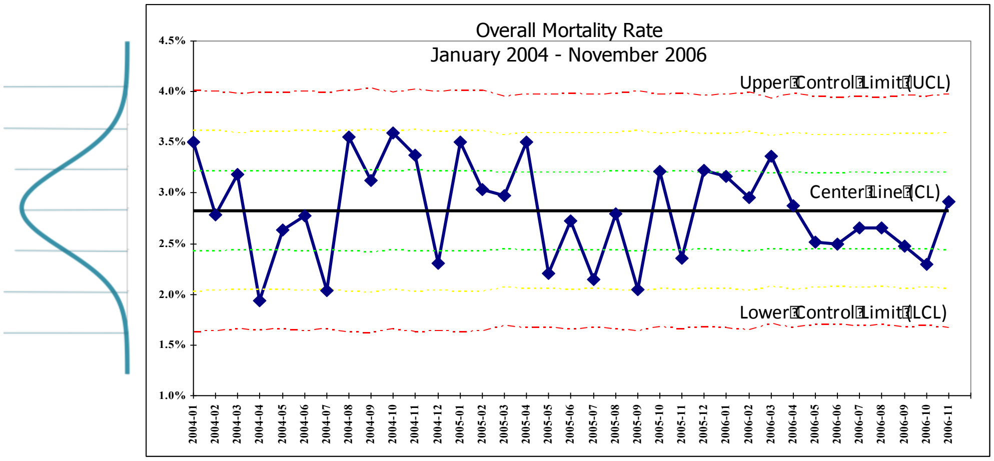


Figure 1. History of Systematic Quality Improvement



*UCL and LCL are drawn 3σ from CL

Figure 2. SPC Chart of Mortality. Only common-cause (random) variation is observed. It would be incorrect to attribute any single data point to "good" or "bad" performance

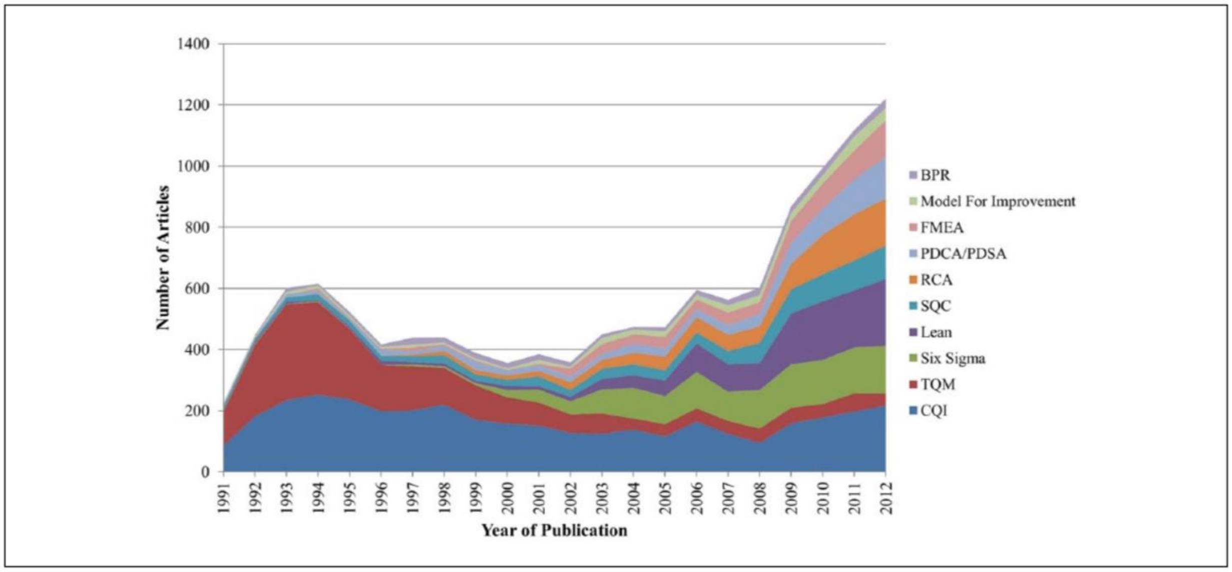
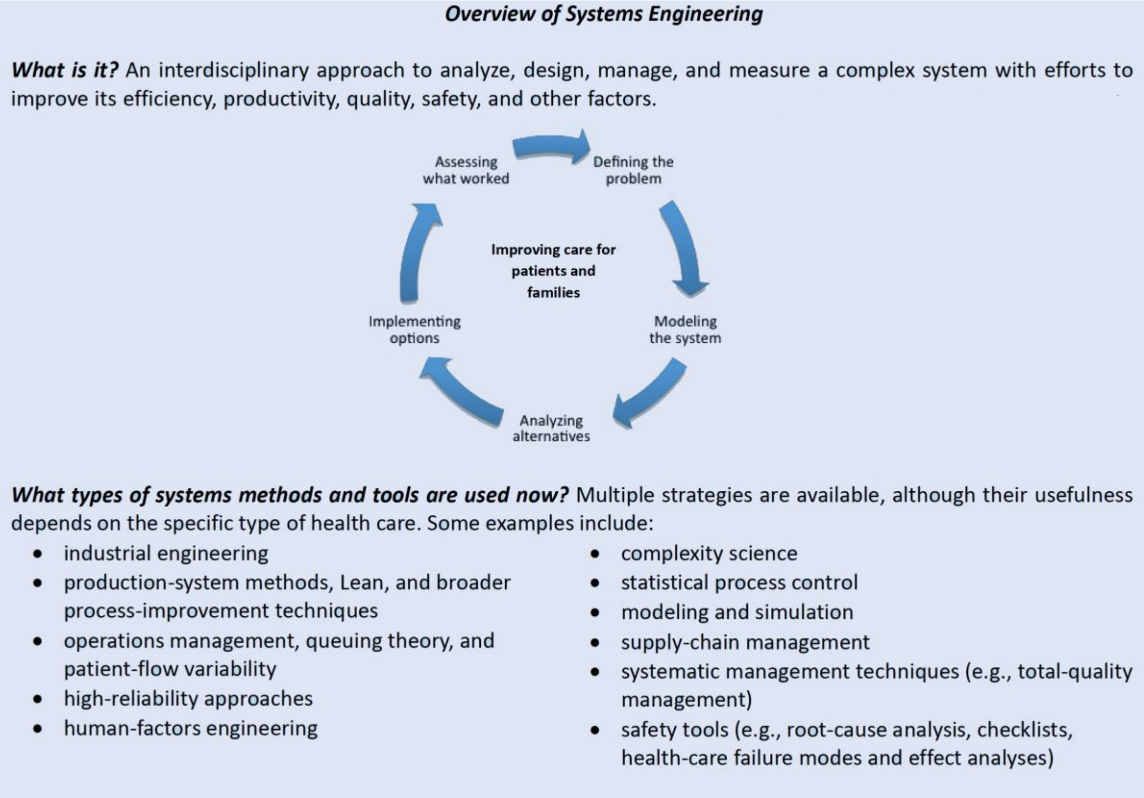


Figure 3. Annual publication volume for health care quality improvement methodologies, 1991-2012. Adapted from Health Care Quality Improvement Publication Trends[26]



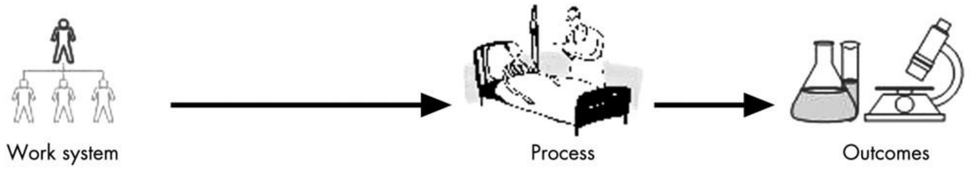
Overview of Systems Engineering

What is it? An interdisciplinary approach to analyze, design, manage, and measure a complex system with efforts to improve its efficiency, productivity, quality, safety, and other factors.

What types of systems methods and tools are used now? Multiple strategies are available, although their usefulness depends on the specific type of health care. Some examples include:

- industrial engineering
- production-system methods, Lean, and broader process-improvement techniques
- operations management, queuing theory, and patient-flow variability
- high-reliability approaches
- human-factors engineering
- complexity science
- statistical process control
- modeling and simulation
- supply-chain management
- systematic management techniques (e.g., total-quality management)
- safety tools (e.g., root-cause analysis, checklists, health-care failure modes and effect analyses)

Figure 4. Overview of Systems Engineering. Adapted from Better Health Care and Lower Costs: Accelerating Improvement Through Systems Engineering[26]



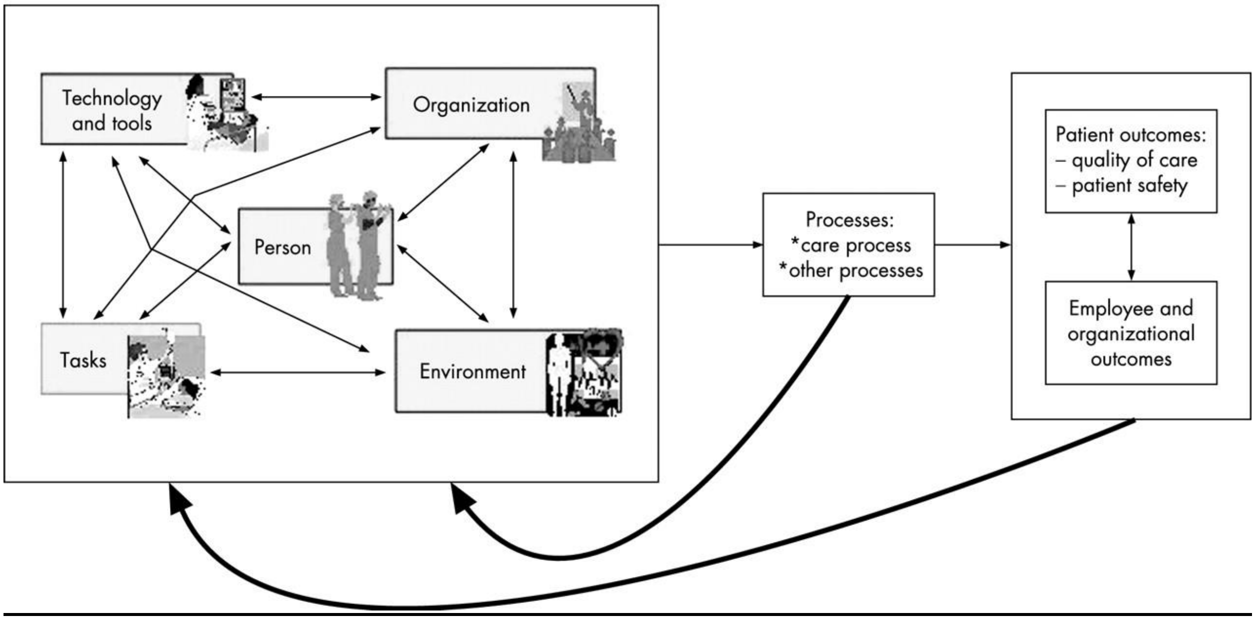


Figure 5 The SEIPS model of Human Factors. from Carayon [53]

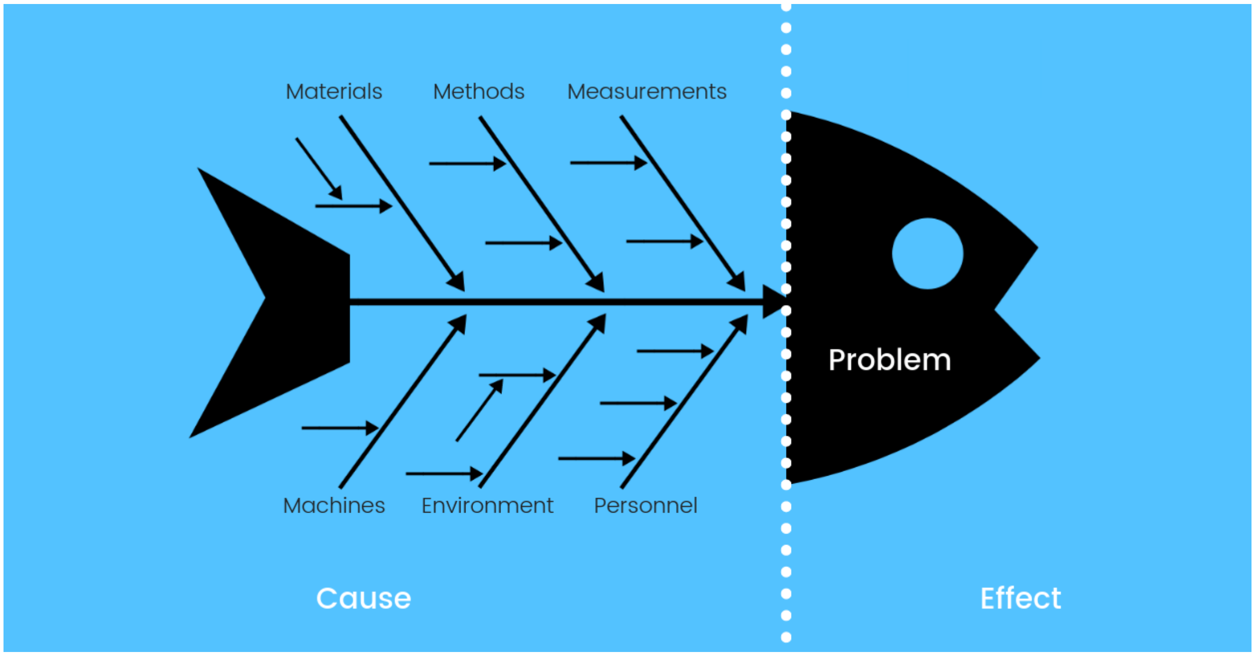


Figure 6. The basic Fishbone (Ishikawa) diagram

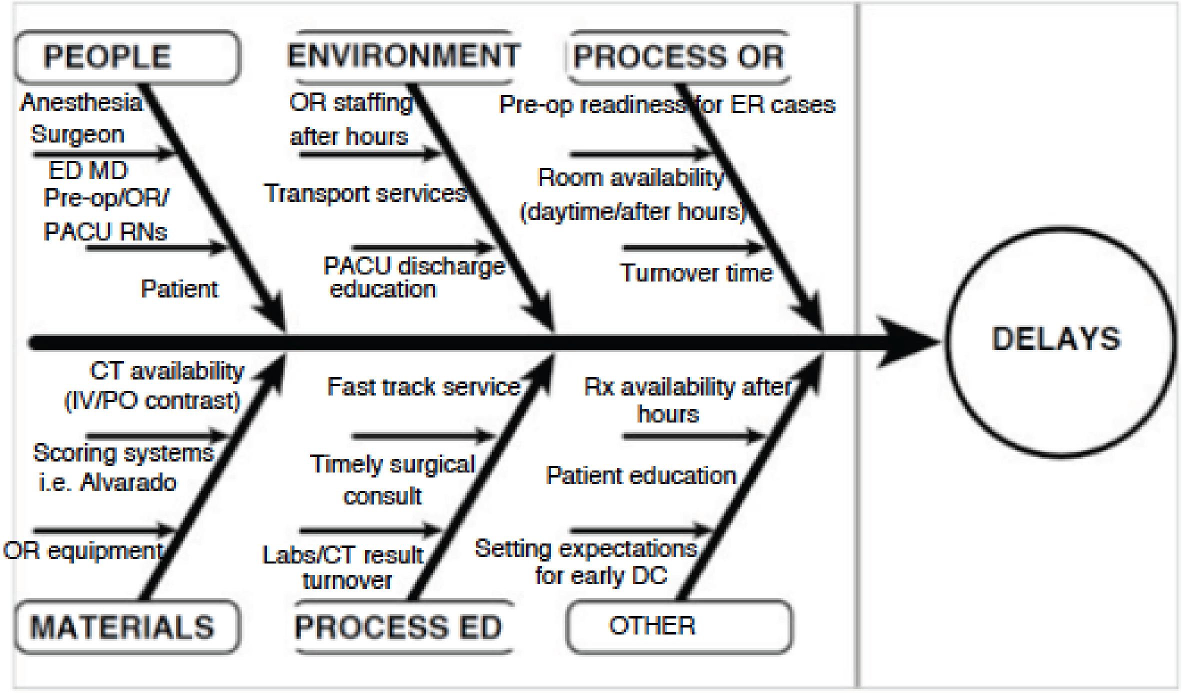


Figure 7. Fishbone diagram developed at Cedars-Sinai Medical Center in response to long LOS for uncomplicated appendectomy.

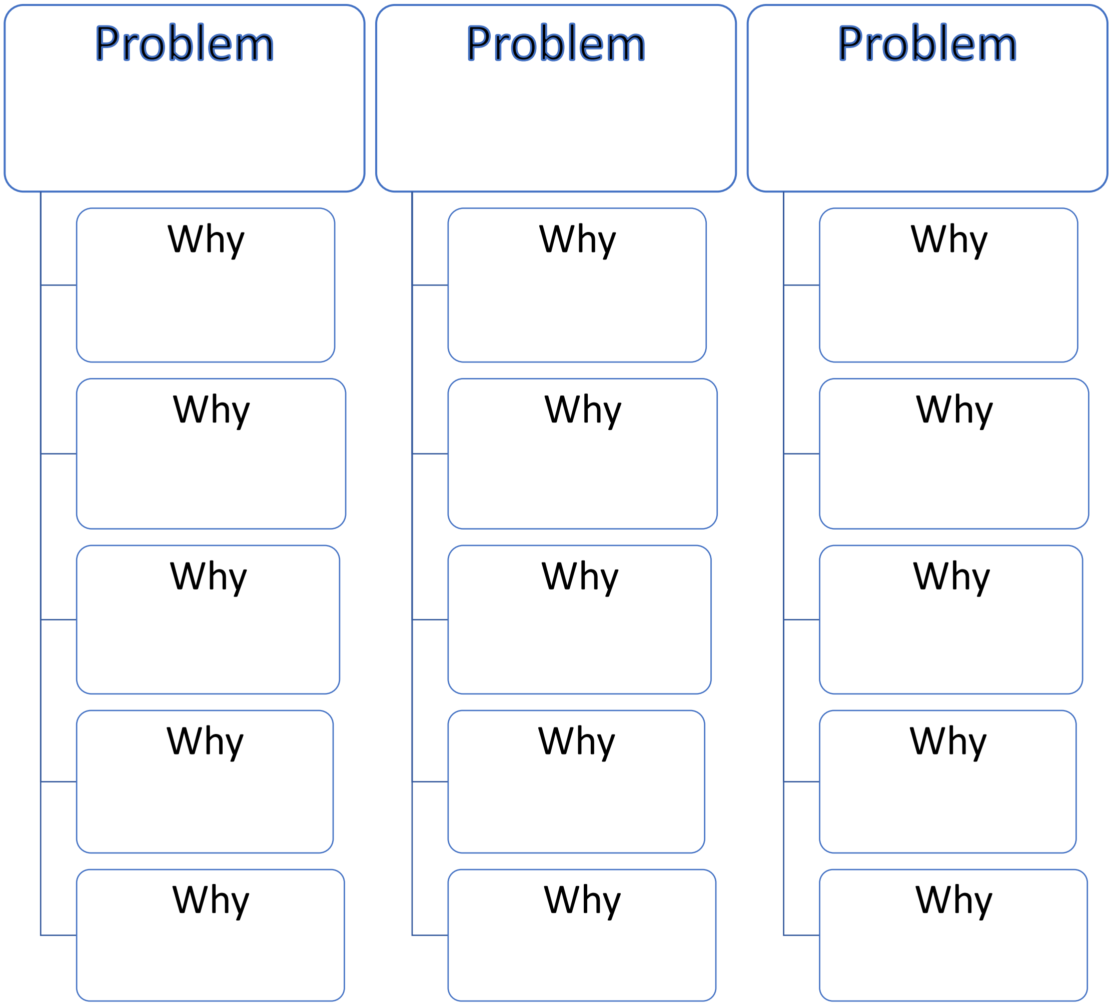


Figure 8 The basic 5 Why'

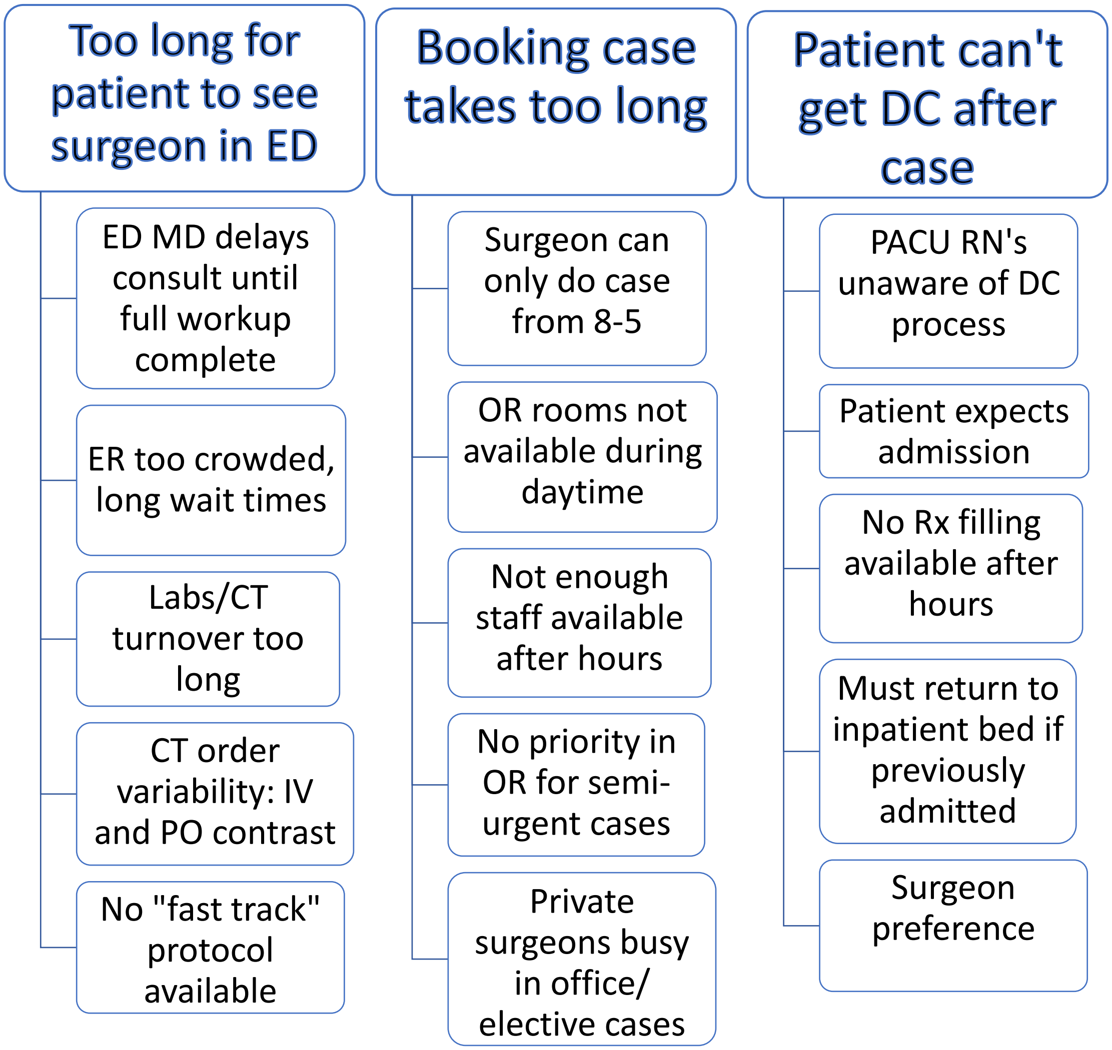
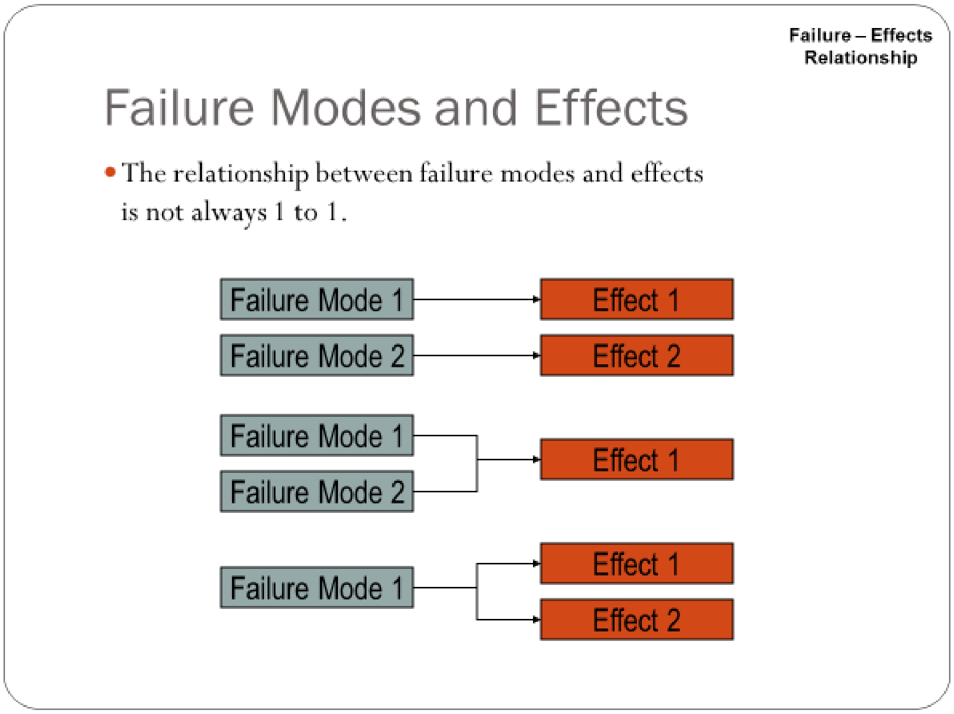


Figure 9 Portion of 5 Why's Analysis for long appendectomy LOS at Cedars-Sinai Medical center

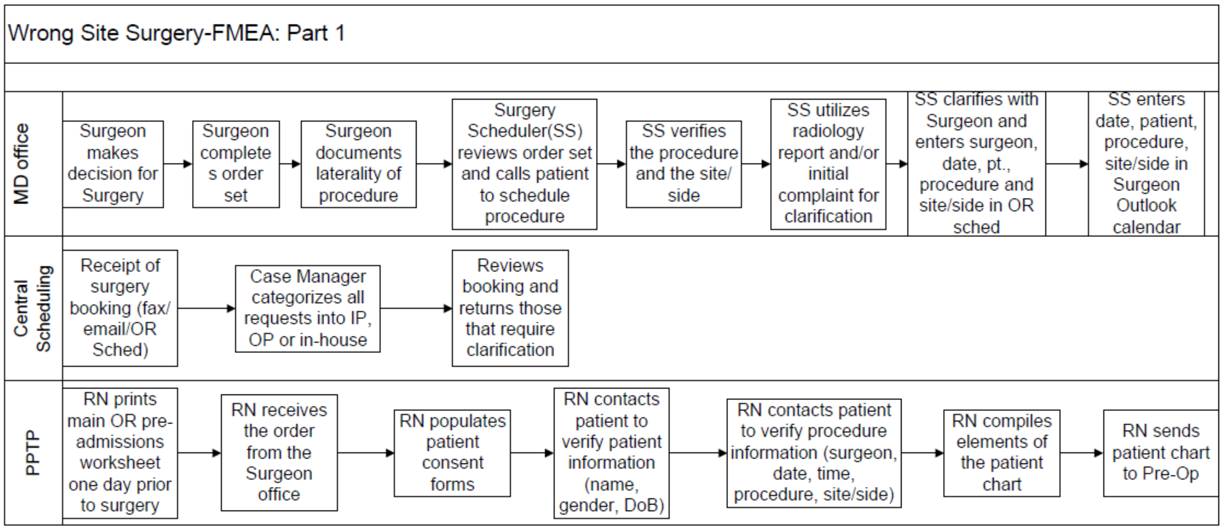


Failure – Effects Relationship

Failure Modes and Effects

- The relationship between failure modes and effects is not always 1 to 1.

Figure 10 Various relationships of Failure Modes and downstream effects



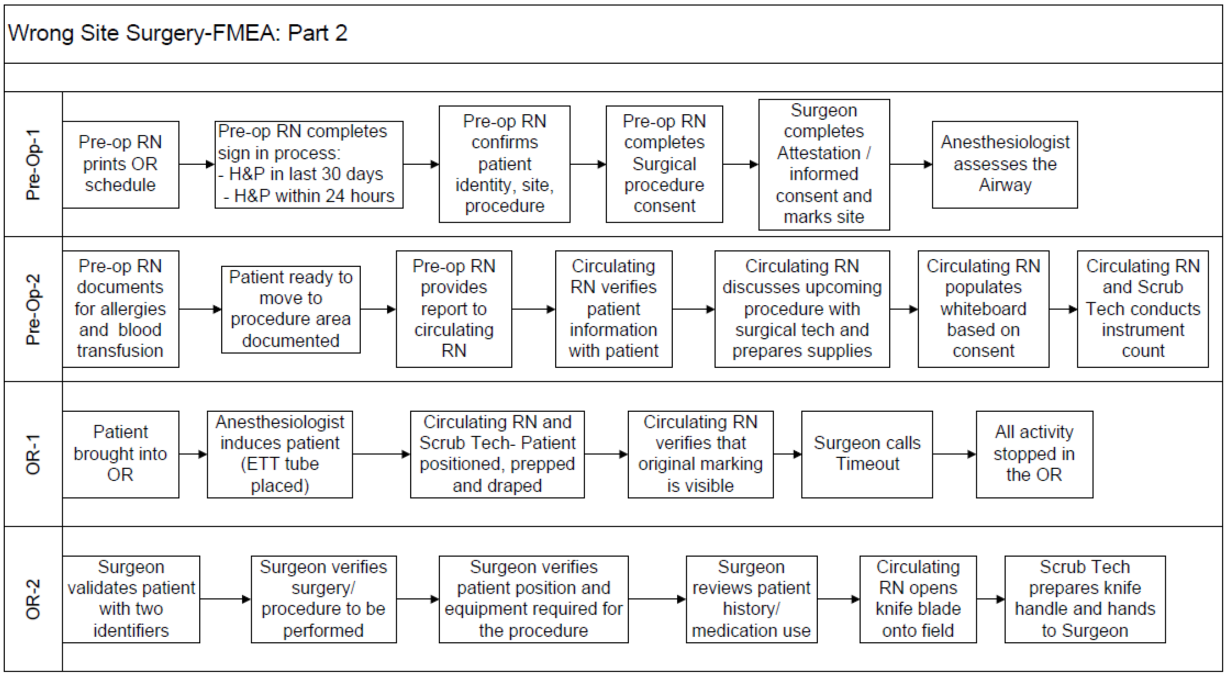
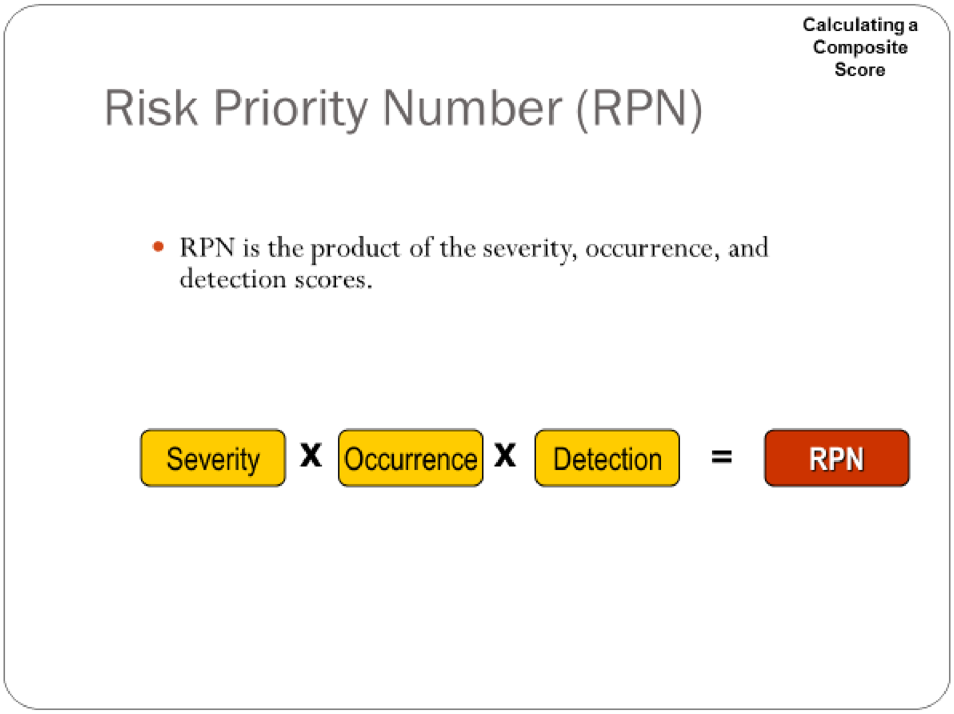


Figure 11 Portion of Process Mapping and Failure Modes in examining wrong side surgery at Cedars-Sinai Medical Center



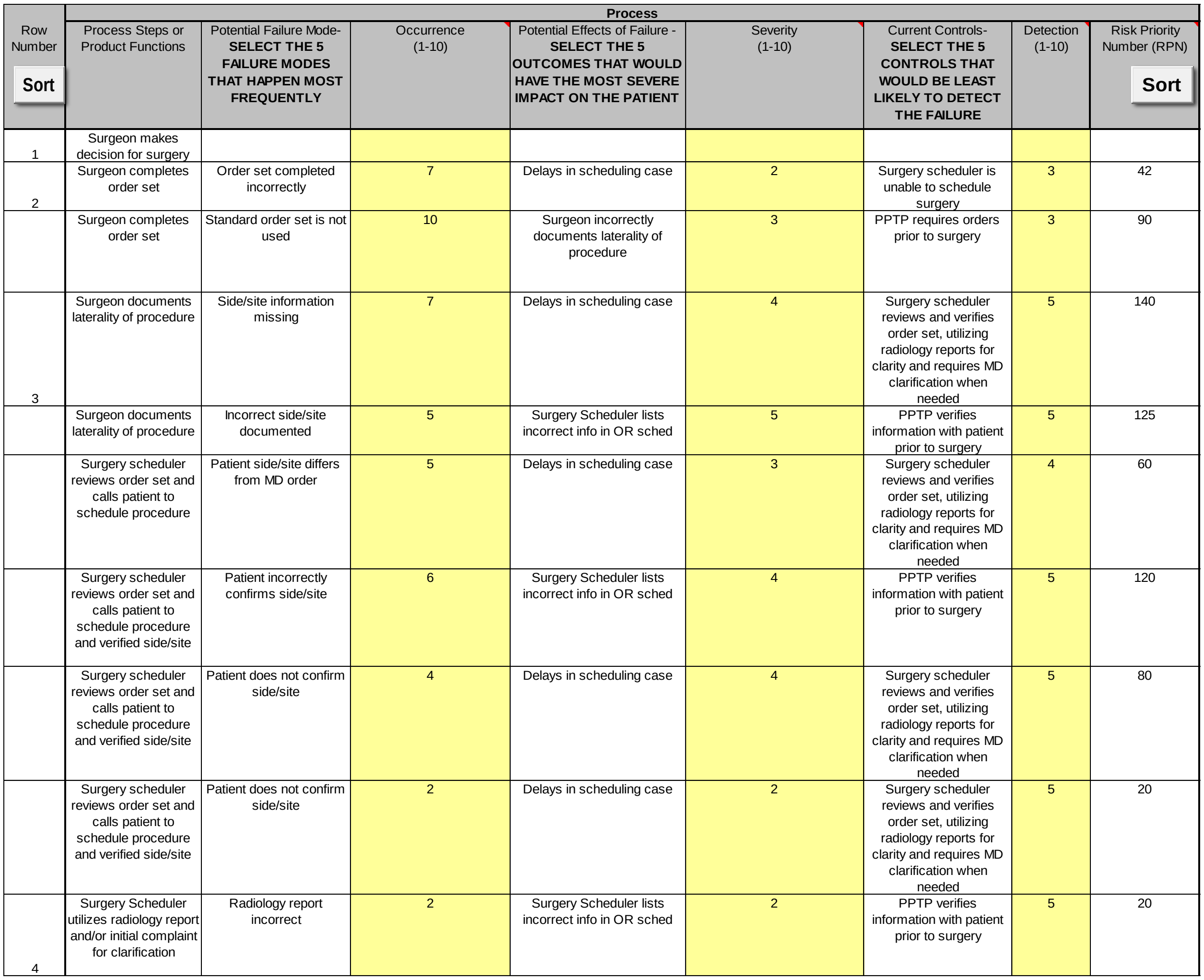
Calculating a Composite Score

Risk Priority Number (RPN)

- RPN is the product of the severity, occurrence, and detection scores.

Severity X Occurrence X Detection = RPN

Figure 12 Determining the Risk Priority Number



Row Number Sort	Process							
	Process Steps or Product Functions	Potential Failure Mode- **SELECT THE 5 FAILURE MODES THAT HAPPEN MOST FREQUENTLY**	Occurrence (1-10)	Potential Effects of Failure - **SELECT THE 5 OUTCOMES THAT WOULD HAVE THE MOST SEVERE IMPACT ON THE PATIENT**	Severity (1-10)	Current Controls- **SELECT THE 5 CONTROLS THAT WOULD BE LEAST LIKELY TO DETECT THE FAILURE**	Detection (1-10)	Risk Priority Number (RPN) Sort
1	Surgeon makes decision for surgery							
2	Surgeon completes order set	Order set completed incorrectly	7	Delays in scheduling case	2	Surgery scheduler is unable to schedule surgery	3	42
	Surgeon completes order set	Standard order set is not used	10	Surgeon incorrectly documents laterality of procedure	3	PPTP requires orders prior to surgery	3	90
3	Surgeon documents laterality of procedure	Side/site information missing	7	Delays in scheduling case	4	Surgery scheduler reviews and verifies order set, utilizing radiology reports for clarity and requires MD clarification when needed	5	140
	Surgeon documents laterality of procedure	Incorrect side/site documented	5	Surgery Scheduler lists incorrect info in OR sched	5	PPTP verifies information with patient prior to surgery	5	125
	Surgery scheduler reviews order set and calls patient to schedule procedure	Patient side/site differs from MD order	5	Delays in scheduling case	3	Surgery scheduler reviews and verifies order set, utilizing radiology reports for clarity and requires MD clarification when needed	4	60
	Surgery scheduler reviews order set and calls patient to schedule procedure and verified side/site	Patient incorrectly confirms side/site	6	Surgery Scheduler lists incorrect info in OR sched	4	PPTP verifies information with patient prior to surgery	5	120
	Surgery scheduler reviews order set and calls patient to schedule procedure and verified side/site	Patient does not confirm side/site	4	Delays in scheduling case	4	Surgery scheduler reviews and verifies order set, utilizing radiology reports for clarity and requires MD clarification when needed	5	80
	Surgery scheduler reviews order set and calls patient to schedule procedure and verified side/site	Patient does not confirm side/site	2	Delays in scheduling case	2	Surgery scheduler reviews and verifies order set, utilizing radiology reports for clarity and requires MD clarification when needed	5	20
4	Surgery Scheduler utilizes radiology report and/or initial complaint for clarification	Radiology report incorrect	2	Surgery Scheduler lists incorrect info in OR sched	2	PPTP verifies information with patient prior to surgery	5	20

Figure 13 The RPI table for wrong side surgery.

TABLE 1. DMAIC

D: Define the problem, the customer’s requirements, and the project’s goals.

M: Measure and collect data on the current process to understand the problem

A: Analyze data and decide which problems to tackle first based on a Pareto analysis which identifies the elements most responsible for the problem.

I: Improve the process verifying that the improvements work.

C: Control the processes to ensure that errors don’t creep in again.

TABLE 2. Lean’s classic seven “Deadly Wastes.”

1. Overproduction (producing items ahead of demand)

2. Inventory (excess material and information)

3. Defects (production of items not conforming to customer’s specification)

4. Transport (unnecessary transport of materials or equipment)

5. Motion (unnecessary human movements or strain)

6. Over-processing (process steps that are not required)

7. Waiting (idle time and delays)