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In Brief

Performance improvement in surgery

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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 rose concomitantly. 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 healthcare expenditures surpass that of every other country in the world and are nearly twice those 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 more than 20% of healthcare 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. 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 reviews the current nature of performance improvement techniques as applied to interventional practices. We begin with an examination of the history of quality improvement techniques, expand upon the importance of data

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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 (RCA), and failure modes and effects analysis (FMEA). Finally, we close with an examination of how one moves from recommendation to action, and the vital role of leadership to foster engagement.

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 chart that provided a visual representation of variation. An statistical process control 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 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 1980s 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. Furthermore, 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.

Deming, Shewart and Juran all recognized that if you do not measure something, you cannot 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 spreadsheet 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 in medical publications, statistical analysis uses a p value of <0.05 as a significant finding. What this 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 something else.

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 2 groups. Although 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. Analysis of variance 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.

Historically, errors made in the surgical theater 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, 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 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 work together to create or 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."

Operating room 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 approximately 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.

High reliability organizations also create an organizational culture that has 5 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 (eg, surgeons) rather than authority (eg, administration); (4) reluctance to simplify – taking deliberate steps to create the most complete picture of a process/situation; and (5) preoccupation with failure – treating any lapse or near miss as a symptom that there might be something wrong with the system. These concepts, although apparently quite straightforward, are oftentimes challenging to embed in a culture that has yet to recognize their centrality in affecting human performance.

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 of less than 0.5%. This is only a 3-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 7 "deadly wastes": overproduction; excess inventory; defects; unnecessary transport; unnecessary human motion; over-processing; and waiting. Process mapping quickly identifies these opportunities; changes, often based on front line input, are instituted, and the new cycle is reevaluated.

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

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 (eg, the OR). 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 do not know the true cause of a problem. Because medical care involves 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.

Whereas RCA, by nature is retrospective, failure modes and effects analysis 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 the National Aeronautics and Space Administration, failure modes and effects analysis (FMEA) maps a process and identifies where it could fail. Failure has 3 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 because 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.

We have provided examples of numerous performance improvement tools and techniques to diagnose and intervene systematic problems threatening the safety and quality of healthcare. None of these will be successful without 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; and developing a forward-thinking organization which is proactive rather than reactive. Each of these begins with a leader's honest self-assessment – if you are not 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 is 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 fulfillment 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 tools available to them.

In 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 performance improvement can be incorporated into our everyday practices, we will not only improve our patient's experiences, but also our own job satisfaction.