Chapter 17

A Systems Engineering Approach to Improve Healthcare Quality

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ABSTRACT

The healthcare crisis in the United States has prompted the Institute of Medicine [IOM] and National Academy of Engineering [NAE] to collaborate to address how systems engineering could be used to redesign processes and delivery systems in healthcare. A collaborative effort funded by Robert Wood Johnson Foundation, the National Science Foundation, NIH, and NAE, brought together engineers and healthcare professionals to examine engineering applications and systems engineering tools as they apply to the healthcare system. The full report, Building a Better Delivery System: A New Engineering/Health Care Partnership, outlines several recommendations to close the growing gap. In response the Clemson University-GHS partnership demonstrates how systems engineering principles can be used. In this research, the authors present several concurrent research efforts being pursued as a partnership between Greenville Hospital System and Clemson University, and variety of tools that can be used to study and solve complex issues faced in healthcare. In particular, the authors suggest where both human factors and quantitative systems modeling can be used to provide insight and recommendations for changing existing processes.
DESIGNING A HEALTHCARE IMPROVEMENT FRAMEWORK AT GHS

Greenville Hospital System (GHS) is a leader in providing healthcare for the Upstate of South Carolina. As with any healthcare organization, GHS is striving for continuous improvement, and there seems to always be room for improvement in this field. Whether the performance measures are based on patient satisfaction, overall healthcare delivery, adverse outcomes, errors, etc., significant improvements can be realized.

In partnering with Clemson University, GHS can combine the ability to deliver state-of-the-art modeling and data analysis while grounding the results and outcomes in research. One main focus of GHS is to standardize healthcare delivery. While this may sound contradictory to providing personal care on an individual-to-individual basis, it actually is directly in line with this concept. In fact, GHS would like to standardize the method by which personal care is delivered. Providing a more predictable experience for their patients will likely lead too many benefits, including improved patient satisfaction.

DESIGN FOR SIX SIGMA PROJECT APPROACH

While no two process improvement projects are the same, the methodology by which a project is executed can be standardized. GHS and Clemson have adopted the Design for Six Sigma (DFSS) approach across all projects. Not only is a proven approach being used to ensure each project has accountability and continues to be pursued only based on its likelihood of success, but DFSS provides a template for each project that helps all persons involved understand and be aware of the current status and progress within each effort.

DFSS employs an improvement framework using DMAIC or Define-Measure-Analyze-Improve-Control (See Figure 1). We discuss each step in the improvement process in more detail next. It is a very adaptable framework that allows for improving existing processes and products. A second framework that focuses on the development of new processes and products is called DMADV or Define-Measure-Analyze-Design-Verify. While the focus will be on introducing DMAIC, an example of using DMADV is shown in Section 3 on one of the project efforts.
DEFINE

In this first phase, the project stakeholders and team members must decide if a business case exists for the project. The project should clearly state the potential impact of the project on customers, profits, and its relationship to business strategies. Another key factor is the problem statement – detailing (when) the problem has been seen, (what) is the problem, what is the (magnitude) of the problem and what is the (impact or consequence) of the problem.

Without a clear goals statement, with achievable results and measurable targets, a project can begin to flounder immediately. Often a project has immediate buy-in from several parties, but then great ideas only seem to get discussed in meetings, with little or no action being taken. With DFSS, the team members must provide these details in order to successfully complete the Design Phase.

It is also important to state any barriers to remove or lessons learned to date so that project risk can be assessed, and the likelihood for success can be continually updated and hopefully increased.

MEASURE

It is at this key juncture that extensive data analysis is necessary to understand what the current state of the process truly looks like. For example, has a value stream or process map been completed to better understand the process and problem, and
where in the process the root causes might reside? Has the measurement system been checked for repeatability and reproducibility, potentially including the training of data collectors? Data collection is a real issue on each and every project. Knowing when to use historical data or to acquire new/updated information from the existing system will influence the data analysis. All team members must believe in the analytical approach, and this is the opportunity for members of the team to demonstrate that the analysis being carried out is based on a valid representation of the underlying process.

It is important to understand the satisfaction level of the customer (whether it is staff, doctors, or patients), and to be aware of any large gaps between current performance and the customer requirements.

**ANALYZE**

In the Analyze project phase, this is typically where potential root causes to the problem are identified. As individual root causes are discussed and studied, they can be eliminated from consideration, thus reducing our potential root cause list.

There must be a mechanism for identifying the root cause to output relationship. By collecting the correct data in the Measure phase, the team can be better prepared to conduct the right data mining analysis in hopes of estimating the impact of root causes on key outputs. This will ultimately lead to the prioritizing of specific root causes.

**IMPROVE (OR DESIGN)**

The Improve phase is dedicated to carrying out the testing of one or more improvement opportunities in the process. Such improvements can be implemented in the real system or in a simulated system, with the latter option offering the opportunity to test several competing scenarios and to select only the best for implementation in the real system.

**CONTROL (OR VERIFY)**

Lastly, the Control phase provides a framework for measuring how well the process improvements are being maintained. It also opens the door to continuous improvement, since the project stakeholders periodically revisit the current state and are more aware of the possibility for further system changes. It is important to understand the satisfaction level of the customer (whether it is staff, doctors, or patients), and to be aware of any large gaps between current performance and the customer requirements.
ROOT CAUSES, ERROR REPORTING, AND COMMUNICATION – A HUMAN FACTORS APPROACH

In this section, we review several concurrent research efforts between GHS and Clemson that all have one common thread – applying human factors principles in process improvement. Each research effort is presented below.

ROOT CAUSE ANALYSIS PROCESS DEVELOPMENT

The driving issue for this work was that GHS, like many other healthcare providers, has non-systemic and sometimes ineffective means for understanding the true “root causes” of sentinel events (the Joint Commission defines a sentinel event as “an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof”, Joint Commission, 2010). This means that many of their intervention efforts to improve patient safety are local and often only graze the surface, and thereby do not address the root causes of the problems.

HOW TO ADDRESS THIS?

Since we know that the majority of unsafe events involve human error on some level, we wanted to introduce a method for root cause analysis which focuses on the human operator and those factors that influence his/her behavior. The Human Factors Analysis and Classification System (HFACS) is a framework that allows investigators to evaluate accidents and incidents across all levels of the event including, the unsafe acts themselves, the preconditions for unsafe acts, unsafe supervision and organizational influences (Wiegmann and Shappell 2003). This framework has shown tremendous success in helping to manage safety in a number of different domains (i.e. Wiegmann and Shappell 2001, Broach and Dollar 2002, Reinach and Viale 2006), but only preliminary work had been done to explore the use of this approach in the healthcare industry (ElBardissi et al. 2007). This work aimed to bridge the gap by using HFACS as a foundation on which to improve the root cause analysis process within GHS.

RESEARCH METHODOLOGY AND RESULTS THUS FAR

The methodology used to conduct this work started by defining the problem at hand. Next, archival data (e.g. documentation of past sentinel events) was evaluated for contributing and leading causal factors using the HFACS framework. To do this, expert HFACS analysts reviewed each incident case together and reached consensus as to the causal factors present. The data was compiled and analyzed to determine leading causal factors and trends in human error.
Thus far, preliminary analysis has been conducted and high-level trends have been identified. The next steps will involve using these findings to refine the process for conducting root cause analyses of sentinel events.

**MEDICATION SAFETY REPORTING SYSTEM**

GHS maintains a number of data bases that can potentially provide information about the causes, frequency, location, and severity of adverse drug events. An adverse drug event is defined as an injury resulting from the use of a drug. These data bases, however, are not coordinated. This makes it difficult to detect trends in the data or opportunities for improvement of patient safety. The goal of this project is to identify, collect, and organize useful medication event information so that it may be used to systemically reduce the frequency of adverse drug events.

This project is currently in the Define phase. We have interviewed stakeholders and observed hospital processes to elicit stakeholder needs. We have observed general agreement among stakeholders that we should place initial emphasis on adverse drug events that involve high-risk medications. A detailed process map of the use of warfarin in anticoagulation therapy has been developed and reviewed by GHS. It is through this process map that Clemson and GHS can collectively assess what is right and what is wrong with the current method of administering warfarin.

Anticoagulation therapy is most commonly involved in the treatment and care of atrial fibrillation, deep vein thrombosis, pulmonary embolism, and mechanical heart valve implants. Warfarin, an orally administered anticoagulant, requires complex dosing, careful monitoring, and consistent patient compliance. We will use the process map to identify metrics to measure that are relevant to adverse warfarin events. After process map evaluation, the following key project milestones will be addressed. First, a process for collecting the data necessary to calculate these metrics will be developed. At the same time, this methodology will also include a procedure for organizing the data and the continual tracking of these metrics. The resulting information will be used by the hospital to support decision making to improve patient safety. This is a closed loop process in that in addition to making improvements to administering high-risk medication, improvements to the design of the data collection methodology can be implemented. This DFSS approach allows the process for reviewing data and information to improve and adjust to the actual system.

**LABOR AND DELIVERY TEAM COMMUNICATION AND COORDINATION**

Critical to the performance of high reliability organizations are a series of processes and initiatives to optimize teamwork, communication, and care coordination in critical settings. The Joint Commission has identified communication and teamwork as significant root causes contributing to nationally reported sentinel
events. Previous analysis within GHS has identified concerns related to teamwork and communication within the Greenville Memorial Hospital (GMH) Labor and Delivery setting placing patient safety potentially at risk. Nationally, in a number of other industries, the importance of effective team coordination manifested by optimal communication and teamwork has been demonstrated to substantially improve organizational performance and safety.

**KEY OBJECTIVES**

There is strong desire on the part of GHS and Labor and Delivery leadership to optimize teamwork and communication within this setting. A secondary desire is to learn how to optimize teamwork and communication in a critical setting and then transfer this knowledge to other critical settings within the hospital system. Key objectives to achieve from this effort include:

1. Identify the root causes of less than optimal communication and teamwork within the GMH Labor and Delivery Unit.
2. Identify appropriate metrics to monitor / measure quality labor and delivery processes and outcomes.
3. Identify, develop, and implement corrective actions to culture and processes within the GMH Labor and Delivery Unit to optimize communication and teamwork.
4. Develop a methodology to transfer learning from this pilot study to all other critical settings within GHS to optimize communication and teamwork within and across units.

This work will address open-ended questions about the process of team communication and coordination in dynamic, time-critical, high-risk settings with the aim of ultimately reducing medical errors and improving patient safety within healthcare. As in the other efforts in Section 3, the researchers here are utilizing engineering and human factors techniques and drawing upon principles for team coordination in other similar settings (NASA, aviation and air traffic control, etc.) Subsequently, healthcare-specific advances to this body of research are anticipated through this work.

**RESEARCH / EDUCATIONAL OUTPUTS**

This research will focus on all functions that occur within GMH’s Labor and Delivery Department, including all care handoffs with other units, but will exclude the tracking of patient and baby once inside the other unit. The project will involve all clinicians, staff, and support personnel that are responsible for delivery of care to
patients on the unit. In keeping with the DMAIC process outlined in Section 2, noteworthy tasks that will be addressed in this research include:

- Development and delivery of metrics to monitor process and outcome quality.
- Development of a high level process flow map for activities of care within the unit.
- Measurement and analysis of the current culture and process of communication and teamwork on the unit.
- Analysis of potential and actual failure points and root causes for less than optimal communication and teamwork on the unit.
- Review and recommendation of potential solutions to address failure points and optimize communication and teamwork on the unit.
- Development and implementation of a plan to improve communication and teamwork on the unit.
- Assessment of the plan’s effectiveness and the development of monitoring processes.
- Development of a methodology to transfer learning to other critical settings within GHS.

Outputs from this research will yield contributions to the local and national healthcare community as well as to the body of research that makes up systems engineering and quality improvement.

HEALTHCARE DELIVERY IN SURGICAL UNITS – A SYSTEMS MODELING APPROACH

INCREASING FIRST CASE, ON-TIME STARTS

First cases of the day are elective surgeries that are scheduled to start at 8:00 am, with patient arrivals between 5:30 am and 6:30 am. At Greenville Memorial Hospital (GMH), cases are considered on time if the actual incision time is no more than 10 minutes after the scheduled incision time. Very few hospitals track on time starts based on such a strict measure. First case delay has been identified as a contributor to surgical cancellations, overtime, and dissatisfaction for patients, staff and surgeons. GHS and Clemson University are tasked with identifying the root causes of late starts and finding mitigating strategies. As inputs to these models, data has been collected by shadowing patients and hospital staff. After undergoing reliability testing with Minitab, a hospital database has been mined for historical data and then passed to the simulation model, permitting extensive testing of current and alternative policies. Considering all cases throughout the day, there is a significant increase in late starts from the first to the second case of the day,
indicating that an improvement in first case on-time starts would have a direct benefit to reducing subsequent late starts.

**PATIENT PROCESS IN PRE-OP**

Figure 2 represents the process flow that each outpatient encounters. Similar to most perioperative settings, the flow is not sequential for all tasks that need to be completed. Prior to requiring a Pre-op RN for completing the operation prep process, the patient may require lab work, a visit to the business office, or a separate triage by a triage nurse. Once the Pre-op RN has completed her/his tasks, additional resources interact with the patient before being ready to move to the OR.

The boxes in dark blue represent critical tasks or resources that are required for every patient. Note that triage can always be performed by the Pre-op RN. Based on the data collected during the project, patients are not leaving Pre-op early enough to ensure 85% on-time starts. There are three components of the Pre-op process that can have a significant effect on delivering the patient to the OR. Clemson and GHS considered specific improvements within these three components as follows:

1. Suggest appropriate scheduled patient arrival times to Pre-op.
2. Experiment with various process changes in Pre-op (focusing on the triage and RN prep time functions)
3. Predict when specific OR resources (certified registered nurse anesthetist or CRNA, anesthesiologist, and surgeon) must arrive in order for patients to leave Pre-op on time.

Historical data indicates that higher acuity level patients require longer in the OR prior to incision. GHS currently plans for this by appropriately staggering the arrivals of patients to Pre-op, with higher acuity patients arriving earlier than lower acuity patients (see Figure 3).
In order to evaluate the various alternatives, a detailed discrete event simulation model was developed using Rockwell Software’s Arena simulation tool. Clemson used historical data, as well as actual patient and resource observations, to represent the actual process and validate the model for accuracy.

**SOLUTIONS AND RECOMMENDATIONS**

Surprisingly, the patient arrival time had little effect on the efficiency with which patients were prepped and ready to move to the OR. There is simply a natural spreading of patient arrivals based on personal choice of each patient on when to arrive. This prevented the crowding or bunching of arrivals at any one time.

While several improvements were attempted within Pre-op, the limiting factor appears to be how the resources external to Pre-op are notified and respond to patients being ready in Pre-op. The project helped GHS realize the importance of having a well-defined trigger mechanism to alert the surgeon or anesthesiologist that they are now needed. By improving this key line of communication, GHS stands to gain 20-30 minutes in patient waiting time and, ultimately, reduce the number of procedures that are starting late.

This project is in the final phase, with the improvements in Pre-op and to the communication method between resources still being tested.
IMPROVING OPERATING ROOM AND SCHEDULED BLOCK UTILIZATION

Of all projects currently underway between Clemson and GHS, the OR and block utilization project has the potential for the most significant revenue generation for the hospital, as the issue is one of using available resources as efficiently as possible. Through this effort, GHS could not only improve access to OR time for surgeons and surgical groups, but also increase its profitability through the ability to schedule more cases and not leave ORs staffed but idle.

The fundamental question in OR and block scheduling is whether or not a surgeon should be given a reserved time on specific days (i.e., a block) for performing surgeries.

BLOCK ASSIGNMENTS AND ALLOCATION

Block times are assigned to individual surgeons, surgery groups or services, and surgeons can assign a case to their block if they can finish the surgery within the block. Typically, facilities determine a surgical group’s share of available block time using formulas based on OR utilization, a contribution margin, or some other performance metric (Dexter et al., 2002). Once each group’s share of time has been calculated, a method must be found for fitting each group’s allocated OR time into the surgical master schedule. This involves assigning specific ORs on specific days (Blake et al., 2002). Blake describes a hospital’s experience using integer programming to solve the problem of developing a consistent schedule that minimizes the shortfall between each group’s target and actual assignment of OR time (Blake et al., 2002).

While block booking solved this issue by reducing variability and allocating more predictable demand to specific surgeons, it does not allow block times to be filled by other surgeons or services which can increase the idle OR times (Charnetski, 1984; Ozkarahan, 2000). That is why most of the hospitals use a combination of open booking and block booking approaches in which the block is reserved for the block owner(s) until a certain time prior to operation or release time which depends on the service types and hospital policies (In some type of surgeries like plastic surgery, blocks are released ten days prior to the date where some others are released two days prior to the date). At this point the released times could be used by every surgeon and service on a first come first serve basis or under some other policies (Dexter et al., 1999). Some other hospitals schedule a proportion of their ORs according to open booking and use block booking to schedule the balance of
their ORs (Gupta, 2007). Cardoen et al. (2009) provides an excellent review of how mathematical programming models have been used to solve operating room planning and scheduling problems.

BEST PRACTICES IN BLOCK AND OPEN SCHEDULING

Dexter and Traub (2002) describes a method of assigning time to the groups/services/surgeons that maximizes efficiency. Using past data that tracks the number of surgery hours used on the same day of week over several months, the user can assess how many blocks would be most appropriate if this group continued to provide a similar level of business in the future.

In addition to the above approach, Blake et al. (2002) proposes using a more equitable method among all case specialists. Blake et al. (2002) and Santibáñez et al. (2007) developed mixed integer programming models for assigning blocks to the surgeons/services, using several specific criteria. In particular, they examined how to assign ORs by day of week to specific surgical groups in order to attain pre-specified group time allocations.

Industry experience suggests anywhere between 75%-85% utilization is an appropriate target, considering that room turnover and idle time at the end of the day are common components of OR time (Dexter, 2003). Each facility has a different approach, but one common theme is that blocks are assigned quickly when a surgeon or surgical group continues to have significantly higher case hours than block time assigned.

BLOCK RELEASE STRATEGIES

After decisions have been made to assign blocks to surgeons and surgical groups, equally important policy decisions must be made to determine when unused block time should be released. Dexter et al. (2003) discusses several methods that could be used to release blocks when there are requests that could not be satisfied. In a system that wants to maximize efficiency, releasing block times should only be done if there are cases waiting to be added to the schedule. This tends to be a little harder to manage with multiple staff manipulating the schedule, and in practice many hospitals have specific time for releasing blocks (Shaneberger, 2003). Some hospitals won’t count the released times toward unutilized times of the surgeon/service/group, if they have been released early enough.

NEXT STEPS

The next step in this project is to compile historical data that can indicate how far in advance surgeons requested case time, along with the details of each case. This will
help Clemson develop a decision support tool (using simulation) that can provide utilization, and perhaps even profitability, estimates based on various block allocations. Clemson is also investigating an integer programming-based approach that would use GHS-driven objectives for improved efficiency to set a block (and release) schedule for perioperative Services.

CONCLUSIONS

It is no surprise that healthcare research spans many disciplines, as has been documented in this discussion. From human factors to communication to simulation to mathematical modeling, an abundance of engineering-based tools can be directly applied to the needs of healthcare professionals. Still, for the project sponsor (in this case GHS), navigating the tools unique to each project can be a challenge. This is why GHS has chosen to use the DMAIC project approach that provides a standard method for evaluating and assessing progress across all efforts. Without the combination of introducing skills unique to each healthcare issue and managing the complete set of research projects under a proven accountability tracking system, GHS would not be able to achieve the successes already noticed within the departments involved in the various process improvement efforts already.

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