APPLICATION OF SIX SIGMA TO REDUCE MEDICAL ERRORS

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INTRODUCTION

Medication administration and laboratory processing/results reporting are examples of complex systems in healthcare that are known to be error prone. At Froedtert Hospital in Milwaukee, Wisconsin, errors with IV medication drips and laboratory processing and results reporting were well documented. The purpose of this paper is to describe our initial experience utilizing the Six Sigma methodology to reduce medication and laboratory errors and improve patient safety in a tertiary care hospital affiliated with an academic medical center. The specific long-term project goal is to determine whether this error reduction methodology can be successfully applied in healthcare to improve patient safety.

BACKGROUND

Errors in healthcare result in part from poorly designed complex systems. [(1)] Six Sigma is an error reduction methodology that has been successfully applied in industry, most notably at General Electric and Motorola. [(2)] It represents both a management discipline and a standardized approach to problem solving and process optimization. When used as a metric, Six Sigma technically means having no more than 3.4 defects per million opportunities in any process, product or service. Six Sigma is so named because its powerful tools provide a proven methodology of reducing error rates to the amount that would fall under a bell curve six standard deviations (or sigmas) from the mean. The goal is to redesign a given process to Six Sigma specifications to insure that the process is 99.99975% error free. The likelihood of an error occurring in a process with Six Sigma would be 3.4 per million opportunities. This measure is thought to be overly ambitious for the personnel intensive process in healthcare but eminently adaptable with somewhat less optimistic objectives. [(3)] Six Sigma uses basic tools to reduce error through quantitative methods of benchmarking, design of experiments and analysis of variation. It requires specially trained project leaders known as “black belts” to direct teams in project execution. The improvement process consists of four macrophases. These are: measure performance and determine defect levels; analyze data and perform root cause analysis; improve the number of defects; and, control the process to insure improvements are sustained. [(4)]

As described in the report of the National Academy of Sciences/Institute of Medicine, medication errors are a substantial source of preventable errors in hospitals.[(5-8)] The report states that “medication-related error has been studied extensively because it is one of the most common types of errors, substantial numbers of individuals are affected and it accounts for a sizable increase in health care costs.” [(9)] Medication errors fit Ferraco and Spaeth’s definition of a high risk process as “any healthcare delivery activity that: has a high probability of error; occurs with sufficient frequency; and, would result in severe patient injury if an error were made.” [(10)]

Medication incidents at Froedtert Hospital are consistent with this definition of a high-risk process. Additionally, errors in ordering, transporting, analyzing and reporting clinical laboratory tests was known to be a significant source of error at Froedtert Hospital. It is for these reasons that these two areas were targeted for initial study of errors in the hospital.

PILOT PROJECTS

In the interest of improving patient safety, a consortium was created by four Milwaukee based organizations committed to the development of an approach to reduce errors and improve patient safety. The consortium members consist of the Medical College of Wisconsin, Froedtert Memorial Lutheran Hospital, the American Society for Quality and SecurTrac, a company formed specifically to develop technologies to improve patient safety. The consortium is currently addressing three major efforts; improved identification and reporting of healthcare errors, deployment of the Six Sigma methodology to reduce errors, and testing and implementation of technical solutions to improve patient safety. At the center of this approach is the effort to determine whether the Six Sigma error reduction methodology can be successfully applied in healthcare.

Using Six Sigma methods and selected statistical tools, Froedtert Hospital's processes for medication delivery were evaluated with the goal of designing an approach that would decrease the likelihood of errors. The design employed the classic Six Sigma process steps. A multidisciplinary group of physicians, nurses, pharmacists and administrators identified medication delivery by continuous IV infusions as a process subject to substantial error. Continuous IV infusions are used in many clinical settings and errors of this nature can impact severely on patient well being. Initially, the focus was on five specific IV medications. Soon it was realized that the number was too small to permit quantification of error rates. The scope of the project was expanded to 22 medications delivered by continuous IV infusion. Team members developed a Process Map (Figure 1) to delineate each step in the procedure for continuous IV medication infusion. The Process Map revealed nine steps: (1) physician order; (2) order review; (3) pharmacist order entry; (4) dose preparation; (5) dose dispensing; (6) infusion rate calculation; (7) IV pump set up; (8) pump programming; and (9) pump monitoring. Each of the steps was subjected to a Failure Modes and Effect Analysis (FMEA) and scored on a scale of 1 to 10 for three categories; frequency of occurrence, detectability and severity. The scores were multiplied together to yield a Risk Priority Number (RPN) for each step. Eighteen months of retrospective medication error reports were reviewed to provide additional data for the RPN calculation. This review confirmed the FMEA results that IV rate calculations and IV pump set up were the two most error prone steps in the IV infusion process. Initial efforts to delineate and reduce errors focused on these two steps.

Since it was not known how often errors went unrecognized or unreported, an audit to determine whether the prescribed dose rate matched the actual infusion rate was conducted. Two weeks of audit data were collected and the resulting 124 data points were rated on a discrepancy scale of 1 to 3 (1=<1 ml/hr discrepancy, 2=1-5 ml/hr discrepancy, 3=>5ml/hr discrepancy). Ten of the audits were rated at level 2 and four were rated at level 3. Root cause analysis was employed to determine the cause of the discrepancies. Work was then begun to impact the accuracy of infusion rates.

Using Six Sigma methods and statistical tools, we also examined the hospital's clinical laboratory process. Key elements in the acquisition, laboratory analysis and reporting of patient specimens were: (1) physician order; (2) order entry; (3) matching the order to the patient; (4) collecting the specimen; (5) labeling the specimen; (6) transporting the specimen; (7) analyzing the specimen;

(8) reporting the results; and, (9) entering the results into the patient's chart. Each of these steps is subject to error. Applying Six Sigma analysis, the steps subject to the most errors were identified. These were order entry by the unit clerical staff, transportation of the specimens to the lab and analysis of specimens in the lab. To identify, define and reduce these errors, a laboratory error reduction task force was established which included members from administration, lab, nursing, clerical staff, information systems and quality management. The task force first developed a Six Sigma Process Map (Figure 2) so that all members could appreciate the complexity and vulnerability of the entire process. The Process Map provided the task force with the tools to analyze the clinical laboratory problem in depth. The FMEA technique was employed to arrive at a Risk Priority Number (RPN) so that steps in the laboratory analysis process could be prioritized in terms of their vulnerability to error. Again, order entry, transportation and analysis of specimens was identified. Statistical tools were employed to evaluate the laboratory process further, including correlation and regression, analysis of variables, confidence intervals and hypothesis testing.

Our analysis of medication delivery by IV infusions served as a good example of deployment of Six Sigma methodology to reduce error and improve patient safety in a healthcare setting. Significant variability in the ordering and processing of IV drips was identified. Lack of standardization in many steps of the process posed the greatest risk for system failure. Those with the highest degree of variability and the greatest chance for error were as follows: (1), MD ordering practices (i.e., lack of standardization in medication description, dosage, concentration, etc.); (2) IV drip preparation (lack of standardization by pharmacy and nursing of IV bag concentrations; and, (3) RN labeling and documentation of IV concentrations. In these three areas, standards were created by a multidisciplinary task force to reduce variation. Specific interventions included implementation of standardized physician order sheets, a policy requiring preparation of all IV medications in a standard concentration and use of color-coded labels when nonstandard concentrations were in use.

Thirty days after implementation, measurable improvement was evident. Level 1 discrepancies fell from 47.4% to 14%. Level 2 discrepancies fell from 21.1% to 11.8% and level 3 discrepancies fell from 15.8% to 2.9%. Though far from achieving six sigma control, substantial efforts continue to move toward that goal.

The laboratory project proved to be more complex. It was evident early on that the scope of this complex, multifactoral system was too broad for an initial effort. The project was broken down into smaller individual steps of the larger process. Once refocused, the appointed task force identified opportunities to reduce variation in select steps of the laboratory process. Alternate means of identifying specimens, changes in the approach to "point of care" laboratory analysis, decentralization of some laboratory tests and a revised system to order and process stat lab tests was put into place. Effectiveness monitoring continues as does measurement of sustainable error reductions. These efforts marked the beginning of a long laboratory redesign process aimed at driving out error, reducing turnaround time and improving patient safety.

CONCLUSION

In conclusion, it is apparent that the application of the Six Sigma error reduction methodology is extremely powerful in identifying, quantifying and controlling complex hospital systems. Profound organizational commitment and extensive staff training is necessary to effect and sustain lasting improvements. Project selection is key requiring projects with a clearly defined scope until appropriate experience and expertise has been acquired with the Six Sigma process and tools. Future plans include training of additional blackbelts, continued project work to

improve patient safety and consideration of a formal partnership with industry to draw on their successful Six Sigma experience with error reduction.

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