Six Sigma Methodology Can Be Used to Improve Adherence for Antibiotic Prophylaxis In Patients Undergoing Noncardiac Surgery

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BACKGROUND: Six Sigma methodology is a data management process that can be used to achieve a goal of near perfection in process performance. An audit of 615 surgeries over 2 mo revealed only 38% of noncardiac patients admitted on the day of surgery at our institution received perioperative antimicrobial prophylaxis within the target interval of ≤60 min before incision.

METHODS: Six Sigma methodology was used to improve our process of timing of antimicrobial prophylaxis administration. A multidisciplinary team was assembled which identified seven process inputs by which patients receive antimicrobial prophylaxis. Interventions for improvement included reinforcement of use of preoperative antibiotic order forms, eliminating administration of antibiotics in the preoperative admission area, and sending appropriate antibiotics and IV tubing with the patient to the operating room. We concurrently developed a control plan to sustain this improvement using a recently deployed electronic anesthesia record keeping system using real-time measurement and reporting capabilities of antimicrobial prophylaxis administration. After defining the new process and undertaking a system-wide educational effort, implementation was begun with data collection and analysis occurring over the next 7 mo.

RESULTS: For the 8-mo postintervention interval, there was a significant improvement with 86% of 1716 surgical patients receiving their antibiotic prophylaxis within the specified time frame ($P < 0.01$). The time interval for antibiotic administration before surgical incision also decreased from a preintervention mean of 88 (CI 56–119 min) to 38 min (CI 25–51 min) ($P < 0.01$).

CONCLUSION: We conclude that Six Sigma methods were used to successfully improve our process for timing of perioperative antibiotic prophylaxis before surgical incision. An electronic anesthesia record keeping system is a useful tool to monitor this process improvement.

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It is estimated that 30%–40% of patients in the United States and the Netherlands, two countries with advanced evidence-based health care systems, do not receive the current standard of care based on available scientific evidence (1). Antibiotic prophylaxis for surgery is one example of an adherence gap in surgical infection prevention. Although evidence-based guidelines support the administration of antimicrobial prophylaxis within 60 min of surgical incision to prevent surgical site infections (SSI) (2,3), a recent (4) study reported that only 56% of Medicare patients undergoing major surgical procedures received antimicrobial prophylaxis within the appropriate time interval before surgical incision.

A process is the combination of people, equipment, materials, methods, and environment that produce an output or, simply stated, a particular way of doing something. The processes of delivery of health care (in this case antimicrobial prophylaxis) present both a challenge and an opportunity to improve the quality of care and ultimately patient outcomes. Understanding how these factors interact and affect processes is the key in process studies. The Six Sigma approach is a data-driven, quality improvement methodology developed by Motorola and enhanced by General Electric. The name "Six Sigma" refers to the six standard deviations in variable performance of a given process (approximately 3.4 in 1 million); the program is used to improve outcomes by reducing process variability.

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Six Sigma methodology has been used successfully in the health care setting, including implementation of evidence-based guidelines for reducing catheter-related bloodstream infections in a surgical intensive care unit as well as improving patient throughput (5–7). We report our experience with Six Sigma methodology to improve the process of timing of antimicrobial prophylaxis in patients undergoing noncardiac surgery at our institution.

METHODS

Background

At our institution, electronic data audits of timing of antimicrobial prophylaxis for the more than 5000 cardiac surgeries performed annually during the 2001–2005 year interval determined that more than 90% of cardiac surgical patients received prophylactic antimicrobials <60 min before incision. In contrast, an audit of patients undergoing noncardiac surgery and admitted through the same surgical admissions preoperative area in March and April 2005 revealed that only 38% of patients received antimicrobial prophylaxis ≤60 min before incision. These data illustrated an opportunity for improvement of our process. The institution subsequently partnered with 3M Six Sigma to improve antimicrobial prophylaxis administration adherence in noncardiac surgical patients.

Six Sigma Methodology Used

A 10-member multidisciplinary team consisting of physician process champions, nurses, a hospital epidemiologist, and an outcome administrator were assigned a 3M "black belt" mentor responsible for team building and overall project management. All team members subsequently underwent Six Sigma "green belt" training to learn the tools and concepts necessary to begin this performance improvement project (PIP) over a 2-mo period. DMAIC is a process that includes the following steps: Define (what is the process?); Measure (what is the root cause of the problem and how can it be measured?); Analyze (how can I understand the root cause [data driven]?); Improve (how can I make it better [remove the root cause]?); and Control (how can I ensure that the problem will not recur?).

The initial step was the development of a project charter that clearly defined the antibiotic administration process and the primary output to increase to 90% the number of patients receiving their antibiotic prophylaxis within 60 min before surgical incision. The scope of the project (patient population) was to include all patients undergoing orthopedic, colorectal, gynecologic, and vascular surgery at the main hospital who were being admitted on the day of surgery. These patient populations were selected for intervention because they are defined patient groups for the Centers for Medicare & Medicaid Services core measures reporting. In addition, the number of patients being admitted for each group on the day of surgery was determined to be significantly more than the number of inpatients, thus representing the largest number of patients to be affected by the scope of this PIP. The primary metric would be the percentage of patients receiving antibiotic prophylaxis ≤60 min before surgical incision and was determined by review of the anesthetic record by a single investigator (SV).

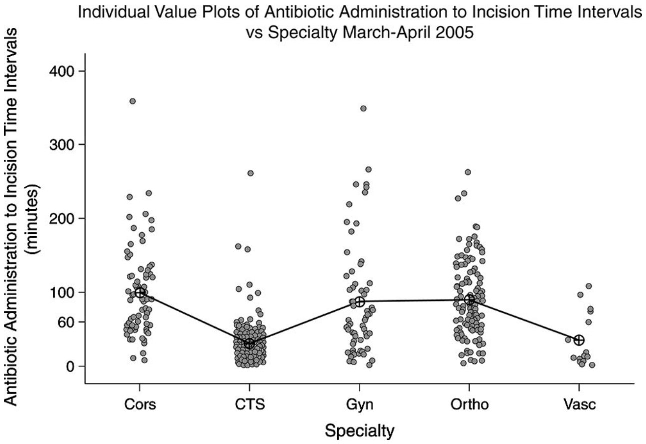

Figure 1. Dot plot of timing of antimicrobial prophylaxis for 318 noncardiac surgical patients stratified by subspecialty and 316 cardiothoracic surgical patients. Baseline data (March–April 2005). Cors = colorectal surgery; CTS = cardiothoracic surgery; Gyn = gynecology; Ortho = orthopedic surgery; Vasc = vascular surgery.

Baseline Data for Appropriate Timing of Antibiotic Prophylaxis in Surgery

An initial capabilities study was performed auditing 615 surgical procedures over an 8-wk period in March and April 2005. This included: 240 (39%) orthopedic; 191 (31%) colorectal; 121 (20%) gynecologic, and 63 (10%) vascular surgical procedures. Specifically, nursing documentation in the surgical admissions areas, as well as all anesthetic records of audited patients, were examined. Thus, all possible documentation opportunities for antibiotic prophylaxis administration were examined. The mean overall adherence to guidelines for antibiotic prophylaxis was only 38% and did not differ significantly by subspecialty (Fig. 1).

Process Mapping

The process map focused on sending the necessary antibiotic(s) with the patient from the surgical admissions preoperative area for administration in the operating room (OR) before surgical incision. A cause and effect matrix was used to help prioritize the critical process inputs that had the strongest relationship to the desired output of the process. Critical process inputs by which patients would receive prophylactic antibiotics included: available and completed preoperative antibiotic order forms; ordered antibiotic(s) obtained from the Pyxis™ machine and matched with the patient; patient sent to the OR with ordered antibiotic and IV tubing for administration;

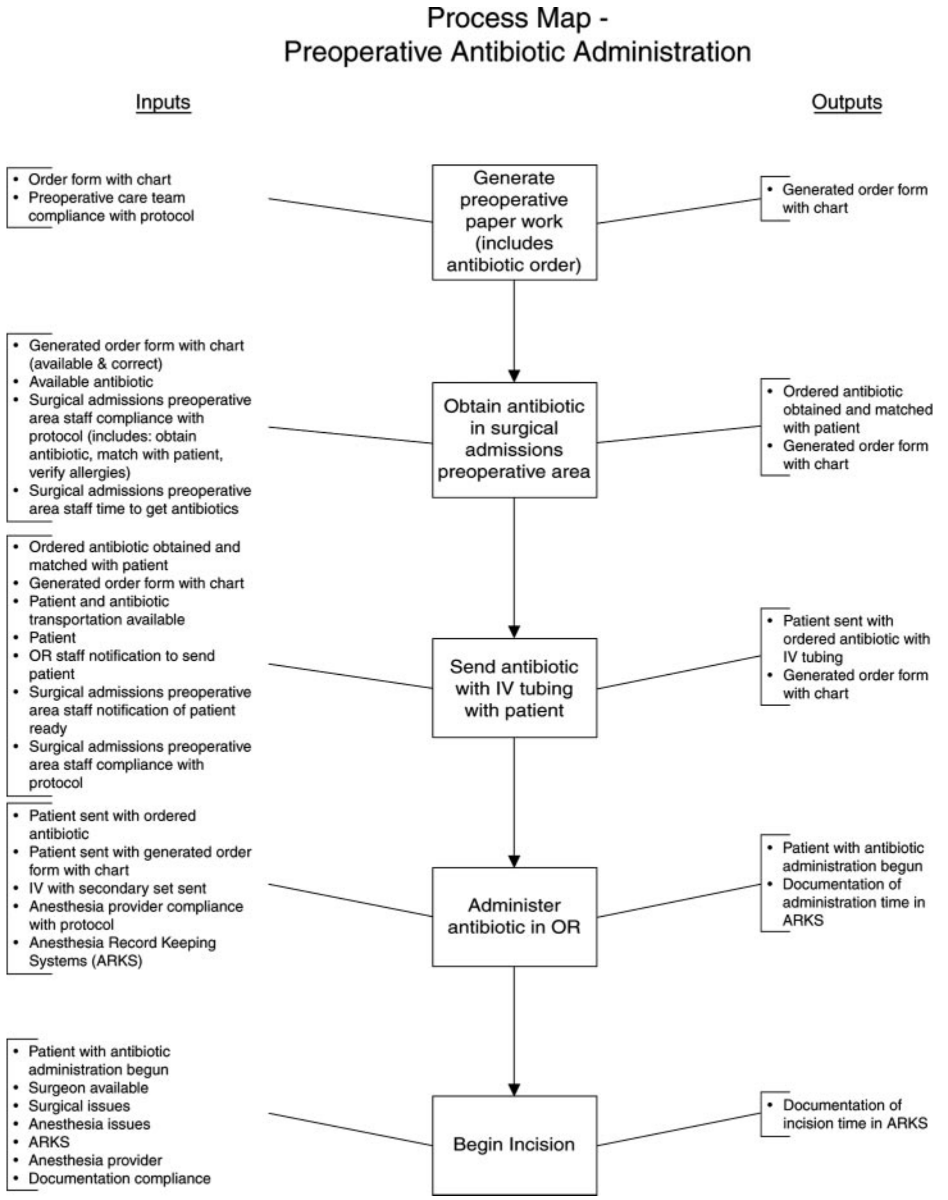

Figure 2. Flow diagram illustrating the process determined for antibiotic administration in the operating room ≤60 min of surgical incision.

and anesthesia personnel responsible for final confirmation and administration of antibiotic prophylaxis in the OR (Fig. 2). The project team also completed a failure mode and effects analysis to help prioritize the actions that should be taken that would have the most significant impact on the process.

Improvement Plan

The team interventions for improvement included reinforcement of use of standardized preoperative order forms, eliminating the administration of antibiotic prophylaxis in the surgical admissions preoperative area, and sending antibiotics with IV tubing to the OR. A 1-wk intensive educational effort immediately preceding project initiation and data collection was undertaken by the project team targeting all appropriate noncardiac staff surgeons and team members, all preoperative nursing staff, and all staff anesthesiologists, and anesthesia care providers to increase awareness and to alter previous attitudes toward antibiotic prophylaxis.

Antibiotic prophylaxis timing data were collected and analyzed after institution of the new antibiotic administration protocol starting in September of 2005 and continued through April of 2006.

Control Plan and the Anesthesia Record Keeping System (ARKS)

A control plan was developed to ensure that the improvements were sustained through routine measurement and reporting of the data. In 2005, an electronic anesthesia record keeping system (ARKS, GE Centricity™) was instituted throughout the main ORs in our institution. Customized data collected

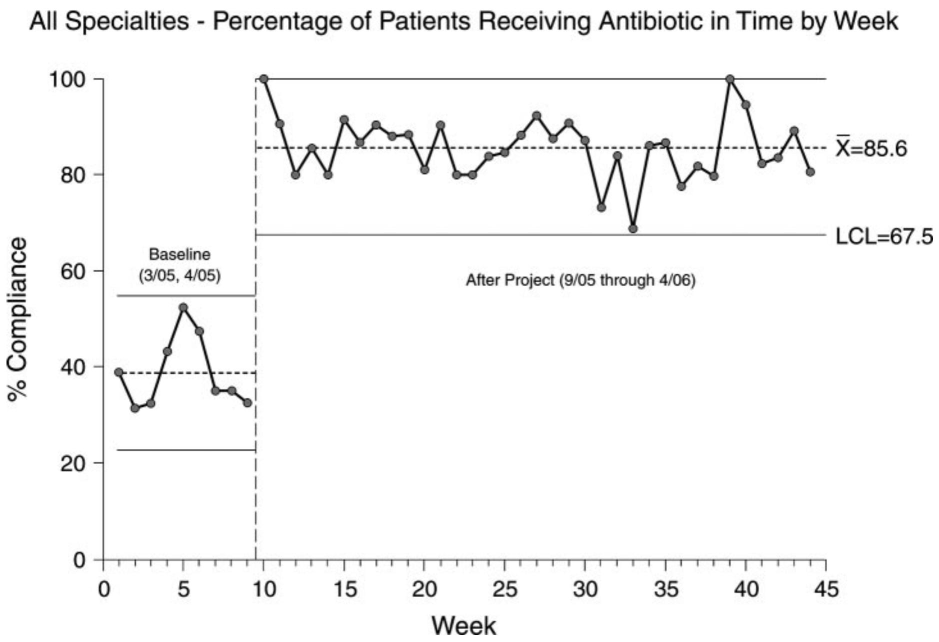

Figure 3. Statistical process control chart illustrating percentage of noncardiac surgical patients receiving antimicrobial prophylaxis $\leq$60 min before incision at baseline (March and April 2005) and after intervention (September 2005–April 2006) using Six Sigma methodology.

includes entry fields specific to the administration of type and timing of antibiotics, as well as the time of the surgical incision. In addition, ARKS uses several steps as a decision support tool to remind the anesthesia provider to administer the antibiotic(s) at the optimal time. Antibiotic administration is a specific step of documentation during the initial phase of anesthetic care in which ARKS acts as a reminder to administer antibiotic(s) before incision. A "data entry reminder" feature is implemented such that the anesthesia care giver is prompted through a flashing button to administer and document the antibiotic(s) given once the patient's case is activated within ARKS. The "data entry reminder" feature subsequently generates a second reminder to administer an additional dose of antibiotic if the last dose of antibiotic has been given more than 1 h before incision.

Statistics

Statistical process control methodology was used to compare baseline antibiotic administration data with data collected after institution of the new antibiotic administration protocol. Average antibiotic administration times and the percent of patients receiving antibiotics on time were graphed. The statistical software package used was MINITAB. The χ^2 test was used to compare the preintervention antibiotic administration rates with the postintervention rates. A P value of <0.05 was considered statistically significant.

RESULTS

The percentage of patients receiving antimicrobial prophylaxis within 60 min of incision improved from a baseline of 38% for 615 surveyed surgical procedures before process improvement was undertaken to 86% for 1716 surveyed surgical procedures in the postintervention period ($P < 0.001$) (Fig. 3). The time interval for antibiotic administration before surgical incision decreased from a preintervention mean of 88 (CI 56–119 min) to 38 min (CI 25–51 min) ($P < 0.01$) (Fig. 4).

Notably, there was variation in the observed improvements among the surgical subspecialties (Fig. 5). Significant improvements in adherence to timing of antimicrobial prophylaxis were documented in 688 orthopedic (37%–87%; $P < 0.01$), 535 colorectal (31%–89%; $P < 0.01$), and 313 gynecologic surgeries (43%–92%; $P < 0.01$). However, no significant change in vascular surgery ($n = 180$) adherence to antibiotic timing was observed (67%–61%; $P = 0.6$). The overall rate of ARKS use among all four surgical subspecialties during the 8-mo study period was 98%.

DISCUSSION

We have recently used Six Sigma methodology to greatly improve the timing of preoperative prophylactic antibiotic dosing within the recommended 60-min period of surgical incision at our institution. After analysis of many procedural steps, communications, and personnel involved in this process, the mechanism by which antibiotics were chosen, ordered, delivered, and administered was restructured through standardization of preoperative order forms and methodology. This resulted in an overall reduced mean time between preoperative antibiotic administration and surgical incision from 88 to 38 min, although this improvement was not uniformly seen among all four surgical specialties. There was also a significant increase in the percentage of patients receiving appropriately timed antimicrobial prophylaxis

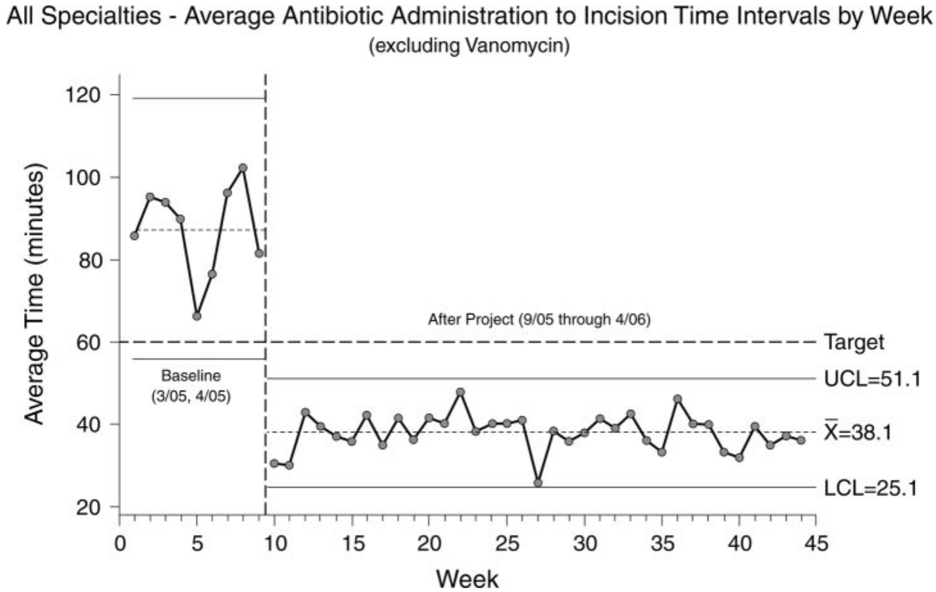

Figure 4. Statistical process control chart illustrating mean antimicrobial prophylaxis intervals from administration to incision among noncardiac surgical patients at baseline (March–April 2005) and after intervention (September 2005–April 2006) using Six Sigma methodology.

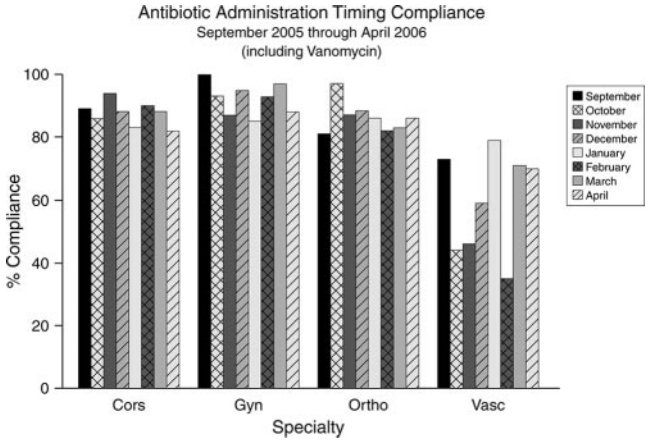

Figure 5. Adherence to antimicrobial prophylaxis target interval (≤60 min before incision) for noncardiac surgical patients stratified by surgical subspecialty after intervention (September 2005–April 2006).

from 38% preintervention to 86% postintervention. As stated earlier, the patient populations analyzed were chosen specifically because surgical antibiotic prophylaxis is one of the Centers for Medicare & Medicaid Services core measures for these groups. Governmental and private sector initiatives to improve quality of patient care, with increasing pressure for voluntary reporting of outcomes by health care organizations, will likely play a significant role in the evolving "pay for performance" model.

Unfortunately, in this analysis, antibiotic administration adherence rates were not achieved equally for the four surgical subspecialties analyzed. Of note, ARKS use was similar for all studied surgical specialties; however, for many vascular surgery cases the intended antimicrobial prophylaxis administration target time was not routinely being met. We subsequently discovered that antibiotics were being given early in these vascular cases either before or during placement of invasive hemodynamic monitors and patient positioning before surgical incision. Thus, an antibiotic redosing warning indicator has now been added to the ARKS display to alert anesthesia caregivers that antibiotic administration occurred outside the appropriate timeframe. In addition, a similar warning is also displayed intraoperatively during surgical cases of more than 3 h duration to alert personnel of the potential need to redose prophylactic antibiotics. The continued use of these automated reminders within ARKS is anticipated to both improve and extend the benefits of adherence to antibiotic dosing guidelines beyond the initial educational phase of quality improvement efforts for all surgical services.

There are several limitations to this study including the generalizability of our process. The Cleveland Clinic is fortunate to operate with a closed medical staff model which promotes cooperation and communication at all levels in the organization. Furthermore, ARKS was co-developed with GE Medical Systems, allowing for a high level of in-house information technology support to be brought to bear in solving this clinical problem. Although we chose to use Six Sigma methodology, there are clearly other ways providers can address patient safety and efficiency issues when undertaking PIPs. Lingard et al. (8) studied the use of a preoperative checklist by OR personnel to improve communication, which is often a barrier to effecting change. Although the results of that pilot study were encouraging, the number of trials using the checklist was small ($n = 18$) and the sustainability of the observed improved communication was not determined. Alternatively, Awad et al. (9) used medical team training and crew resource management principles to improve communication among

OR personnel to create a safer environment with one of the objectives being whether guidelines for prophylactic antibiotic administration would be adhered to appropriately. They found that communication improved between anesthesiologists and surgeons after training and that prophylactic antibiotic administration also improved significantly. Unfortunately, these antibiotic data were not statistically validated and the methodology for antibiotic administration data collection both before and after training was not presented. Lastly, whether or not these results are sustainable is also not discussed by the authors.

Another issue raised by undertaking this PIP is why patients cared for in our cardiothoracic ORs received appropriate antibiotic prophylaxis both before and during the study's baseline time interval. Importantly, both the cardiothoracic group and their established data collection methods differ from the general ORs in several significant ways. First, standardized and defined protocols for administering antibiotic prophylaxis for cardiothoracic patients were previously agreed upon, something that had not been done for the other 10 surgical departments. Second, surveillance of cardiothoracic infection rates is both an internal and external review process and is closely monitored and scrutinized. Third, a process for measuring and reporting antibiotic administration prophylaxis was already in place within the cardiothoracic surgery registry database. Finally, the cardiothoracic operating rooms ($n = 11$) are a more controlled environment compared to the main operating rooms ($n = 59$) at our institution with significantly less variability among both surgical and anesthesia personnel. Thus, as a result of the significantly greater number of anesthesia providers found in the main operating rooms, justification for using an active electronic reminder with ARKS to reduce antibiotic administration variability can be made.

In this article, we present adherence results for prophylactic antibiotic administration that have been sustained for 9 mo after initiation of this PIP. It is unlikely that simply educating all personnel involved before the start of postintervention data collection, on the importance of this issue alone, would have had a sustainable impact because we are a teaching institution with both anesthesia and surgical residents constantly rotating among clinical services. Thus, the impact of ARKS on personnel performance for antibiotic administration is likely an important part of actively changing and maintaining alterations in behavior. In the review article by Grimshaw et al. (10), a multifaceted approach for altering provider behavior was found to be most successful. Such an approach would include providing education (including materials on new or revised patient care guidelines); the use of reminders (including electronic); and audit and feedback mechanisms (either written or verbal) to monitor behavior. Interestingly, the most successful multifaceted approaches were found to be those that included an analysis of potential barriers to success. The use of Six Sigma methodology allowed us to use all the above components for a multifaceted approach after Six Sigma failure mode analysis was conducted, while statistical process control methodology allowed for the postintervention monitoring and feedback to determine if the process remains in control. In addition, ARKS provides an active reminder (as opposed to a passive paper reminder) for maintaining adherence for antibiotic administration. Finally, data similar to what are presented herein, as well as more detailed data analysis have been provided and continue to be provided as feedback to all stakeholders and participants in this process. Whether or not ARKS alone would have allowed us to maintain this sustained process improvement is not known.

We are unable at this time to link the improved process with long-term outcome, such as reduced SSI rates, because prospective surveillance for SSIs are performed for only cardiac, neurosurgical, and orthopedic (implants) procedures at our institution. However, with the recent implementation of the American College of Surgeons National Surgical Quality Improvement Program in May 2005, improved documentation of SSIs for targeted surgical procedures will be forthcoming by the end of 2007.

Importantly, the costs associated with undertaking a project such as this are low when compared with the savings realized through adhering to evidence-based patient care guidelines and recommendations, such as those concerning appropriate timing of antibiotic prophylaxis. Evidence-based guidelines arose from the seminal article by Classen et al., in a prospective study of 2847 patients at a large community hospital (11), found that variation in surgical antibiotic prophylaxis timing was linked to postoperative SSI. Administration of prophylactic antibiotics in the 2 h before incision resulted in the lowest SSI rate. Patients who received prophylactic antibiotics <3 h after incision and more than 3 h after incision had postoperative SSI rates of three times and five times greater, respectively, than those patients receiving their antibiotics before incision. That study clearly highlighted the importance of antibiotic timing and that infection risk increases for SSI as time passes after incision. Subsequently, Kirkland et al. (12) investigated morbidity and mortality, as well as costs associated with SSIs, in a 415-bed community hospital using 255 patient pairs (infected versus noninfected) matched for age, procedure, infection risk index, surgical date, and surgeon. They found that the total excess length of hospitalization attributable to SSI was 12 (CI 95, 10–12) days per patient while the relative risk of death from SSI was 2.2 (CI 95, 1.1–4.5). Finally, the authors extrapolated their finding at that time to the entire United States, stating that "SSI are responsible for approximately 20,000 in-hospital deaths and cost hospitals over $3 billion each year for inpatient care alone" highlighting the economic importance of addressing this issue.

In summary, Six Sigma methods were used to successfully improve our process for timing of perioperative antibiotic prophylaxis before surgical incision. In addition, ARKS is being used to provide ongoing real-time data for analysis to aid in monitoring this process.

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