"All Bundled Out" - Application of Lean Six Sigma techniques to reduce workload impact during implementation of patient care bundles within critical care – A case study

Heather Woodward, IUPUI
Jamie El-Harit, SSFHS
Chris Vanni, SSFHS
Penny Scott, SSFHS

Abstract:

Within healthcare, clinical practice bundles have been used to implement standardized, nursing driven protocols resulting in standardized patient care and improved patient outcomes. Examples of these types of bundles include clinical practices shown through evidence based medicine to reduce occurrences of Ventilator Associated Pneumonia – VAP bundle; those shown to reduce the occurrences of central line infections – CL bundle; and those shown to significantly improve the outcomes of patients presenting with sepsis – Sepsis Bundle.

Unfortunately, as critical care units cycle through the implementation of multiple bundles without adjustment in workflow practices the result is often increased staff fatigue and a more stressful work environment – a phenomenon appropriately termed by critical care staff members as being 'All Bundled Out'.

This paper will describe the partnership between IUPUI faculty and Sisters of St. Francis Health Services (SSFHS) in application of Lean Six Sigma techniques. These techniques were adapted for use within healthcare and were applied to reduce the workflow impact and optimize implementation of nursing driven, clinical protocols used to implement intensive glucose control for ventilator patients within two critical care units. Additionally, this paper will discuss the strategies and methodologies used to sustain initial results during the 9 months following the initial protocol implementation.

Background:

In January, 2006, St. Margaret Mercy Hospital partnered with the Purdue School of Engineering and Technology at Indiana University Purdue University – Indianapolis (IUPUI) to apply Lean Six Sigma methodologies to reduce Intensive Care Unit (ICU) Length of Stay (LOS) within their Hammond and Dyer healthcare facilities.

The initial team was composed of quality managers, critical care nursing , nursing case managers, quality analysts, and a critical care educator. This team met during 16 weekly sessions of instruction in Lean Six Sigma tools as well as direct, practical application of tools directly to the process under investigation. These sessions were facilitated by

Industrial and Mechanical Engineering Technology faculty from Purdue Schools of Engineering and Technology at Indiana University-Purdue University at Indianapolis (IUPUI).

The analysis done by the initial project team indicated that primary failure modes for increased ICU LOS were 1) inefficient discharge processes for ventilator patients and 2) lack of compliance to evidence based clinical standards of care for treatment of ventilator patients. These standards of care included those related to reduction of ventilator associated pneumonia (VAP) and intensive glycemic control. An implementation strategy was proposed that included an in-depth investigation to identify operational barriers preventing compliance through the engagement of critical care nursing staff, respiratory therapy and case management. The initial project implementation was set for the Hammond St. Margaret Mercy campus.

Current evidence based research strongly supports the use of a “bundle” of four care practices to reduce the incidence of ventilator associated pneumonia (VAP). Those care practices include: 1) head of bed elevation greater than 30 degrees, unless medically contraindicated, 2) Peptic ulcer prophylaxis, 3) Deep vein thrombosis (DVT) prophylaxis and 4) daily sedation vacation and assessment of readiness to wean mechanical ventilation. These measures, when complied with 100% of the time during the care of a mechanically ventilated patient, can significantly reduce the incidence of VAP. VAP has been shown to increase ICU LOS, cost of treatment and patient mortality. In addition to these 4 care practices, intensive glycemic control has also been demonstrated to benefit the critically ill adult. In a 2001 Belgium study[1], Greet Van den Berghe and her associates showed statistical evidence supporting the implementation in surgical ICU patients. In this study those patients receiving intensive glucose control utilizing IV insulin were found to have a significant reduction in mean blood transfusions, and a significant reduction in acute renal failure. Because of the medical community’s reluctance to translate these findings to the medical ICU patient, Van den Berghe repeated her study in 2006 in a medical ICU. Although the findings on mortality were not as impressive in her 2001 study, the study showed that, in this patient population, the same co-morbidities were decreased[2].

Experimental Method:

<u>The Lean Six Sigma Methodology:</u>

The Six Sigma DMAIC Methodology was utilized for this investigation and is summarized below[3], [4]:

> *Define* a problem, set a goal striving for customer satisfaction and aligning business objectives.
>
> *Measure* the process by collecting relevant data to realize issues and for future comparison.

Analyze to verify connection and cause of problems.

Improve or the process by reducing variation, based upon the analysis.

Control the process and maintain the reduction of variation.

Define Phase:

A project charter was completed by the project team that defined the business case, problem statement and goal statement for the project. The decision was made to limit the scope of this project to ICU ventilator patients. Cardiovascular surgical patients were not originally included in the project as they already had an order set addressing each of these care practices. A project team was created composed exclusively of front line critical nursing, respiratory therapy and case management staff. A compressed (5 week) training schedule was used to introduce and apply key Lean and Six Sigma concepts to the team members.

A Voice of the Customer (VOC) analysis was performed by interviewing other front line staff members not on the project team and asking four key questions:

1. What do you like about the existing ICU processes related to VAP, glycemic control and discharge planning?
2. What are the weaknesses within these processes?
3. What are the opportunities for improvement within these processes?
4. What could potentially threaten the success of this project team?

VOC analysis indicated that while staff members did recognize the importance of the VAP bundle with respect to providing quality patient care, they found the current work processes related to the VAP and glycemic control bundles unsatisfactory. Staff members cited availability of equipment and supplies as the primary barrier to VAP and glycemic control protocol compliance. Additionally, staff members cited lack of communication amongst care providers as a major barrier to appropriate ventilator weaning and a major component of delays in discharge processes.

Measure Phase:

Baseline measurement of compliance to VAP and glycemic control process indicated that the primary adherence failures occurred with respect to patient weaning from the ventilator (sedation vacation) and the ventilator patient head elevation at $>30^o$. Discharge delays were found to be largely as function of poor end of life and a lack of communication between medical staff, nursing and patient families, despite the existence of a palliative care program. Glycemic control was found to be very poor, with only 30% of ventilator patients within recommended guidelines.

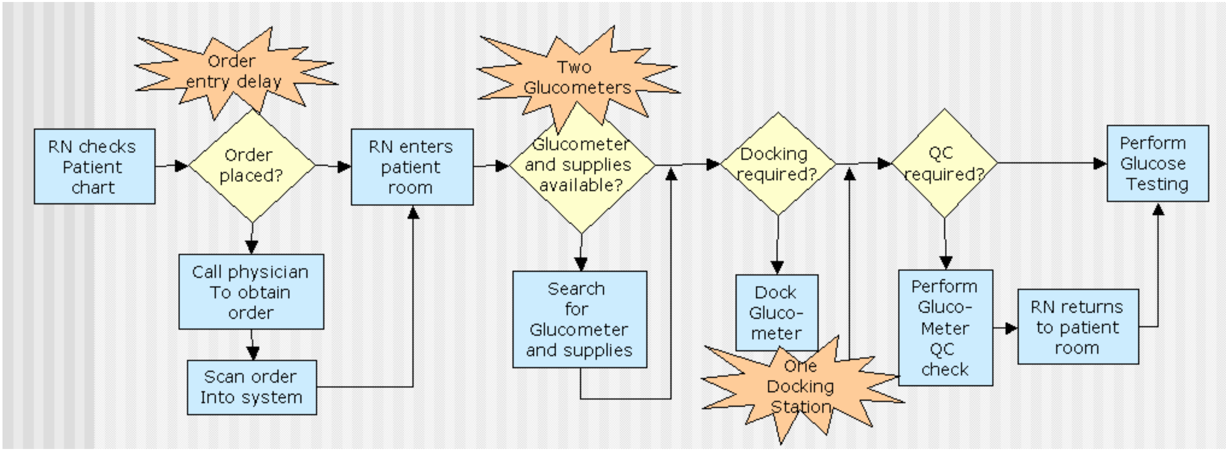

Figure 1. Process Flow Diagram for Glycemic Control Process

Process Observation Worksheet

Step #	Description	Distance	Clock Time	Task Time	Wait Time	Observations
		0	0			
1	RN checks patient chart		2:00	2:00		
2	Order Obtained?					
	- If No, call physician to obtain order, scan order					
3	RN enters patient room	20	2:30	0:30		
4	Glucometer and Supplies available?					
	- If no, then search for Glucometer and Supplies.	500	12:30	10:00		entered 4 rooms to find glucometer
5	Docking required?					
	- If Yes, then goto Docking station.					
6	QC? If Yes then find QC equipment.					
	- If Yes, then perform QC.					
	- RN Returns to patient room	20	13:00	1:30		
7	Perform Glucose testing	0	13:30	0:30		

Figure2. Example of process observation worksheet used during the process observation study to quantify impact of operational barriers for glycemic control

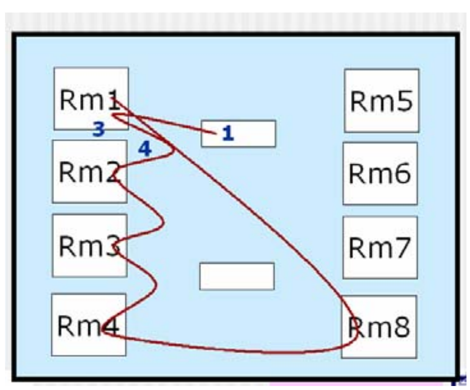

Figure 3. Example of spaghetti diagram created during the process observation study for glycemic control

As a result of the baseline data collected, a decision was made to focus the project team on optimizing ventilator weaning, glycemic control, discharge processes. A process flow map of the discharge processes, glycemic control process and the ventilator weaning processes were created. Operational barriers highlighted during the Voice of the Customer exercise as well as those from team members were annotated on the process maps. An example of the process map created for the glycemic control process is shown in Figure 1.

Results and Discussion:

Analyze Phase:

Multiple direct process observation studies were conducted by team members using process observation worksheets and spaghetti diagrams were to quantitatively assess the impact of the primary operational barriers. Examples of process observation worksheets and spaghetti diagrams for the glycemic control process are shown in Figures 2 and 3.

The primary operational barrier for patient weaning was found to be delays in order placement for patient weaning, which often extended beyond 24 hours. Additionally, variability in physician to physician practice with respect to preferred weaning algorithms was found. Direct process observation also determined that the majority of bed scales on the critical care unit beds were located on the bed frame, underneath the mattress and were not easily readable unless the staff member bent down to be at eye level with the scale.

The primary operational barriers to the intensive glucose control were found to be 1) availability of glucometer and glucometer supplies, 2) delays in starting IVs, and 3) Insulin drip availability. On average, the time to locate one of the two glucometers on the unit was 11 minutes. The spaghetti diagram shown in Figure 3 shows the path of the critical care nurse as she roams from room to room searching for the glucometer and glucometer supplies.

Improve Phase:

Multiple solutions were generated to reduce or eliminate the impact of operational barriers. Each solution was evaluated on the basis of cost, likelihood of success, and ease of implementation. With respect the discharge processes, a palliative care champion and palliative care education program was implemented to improve patient, family and staff awareness of end of life options.

To improve compliance to the VAP bundle, physician champions were enlisted to improve the current weaning protocols to include additional algorithms created to accommodate more aggressive weaning schedule. Visual tools were applied to improve visibility of bed. To improve glucose control processes, additional glucometers were purchased and placed within holders on the walls on the nursing stations and areas were designated for placement of incoming IVs. Glucometer QC checks were designated for night shifts and additional docking stations were added. Additionally, in-line blood sampling kits were purchased to enable glucose checks directly from central and arterial lines.

Control Phase – Pilot Implementation:

Pilot implementation was conducted using a staggered implementation strategy, utilizing small, incremental tests of change following a 2/1/2006 kick-off. Process improvements were introduced gradually, over a 2-week period, and daily process outputs monitored to validate positive impact. Compliance to VAP bundle and intensive glycemic control protocols were monitored on a daily basis using a daily goals sheet completed by the charge nurse. Additionally, process outputs were communicated throughout the unit on a daily basis through posting on large control charts placed on the unit.

Discharge delays, readmissions, and inappropriate admissions were monitored though completion of an ICU discharge status form during daily meetings of patient care multi-disciplinary teams.

Graphs of the results from the pilot phase as compared to pre-pilot results are shown in Figure 4a-4c. Initial results up to 8 weeks following the pilot implementation are excellent as shown in the figures. Based on these results, the control measurement plan was switched from a daily to a monthly basis.

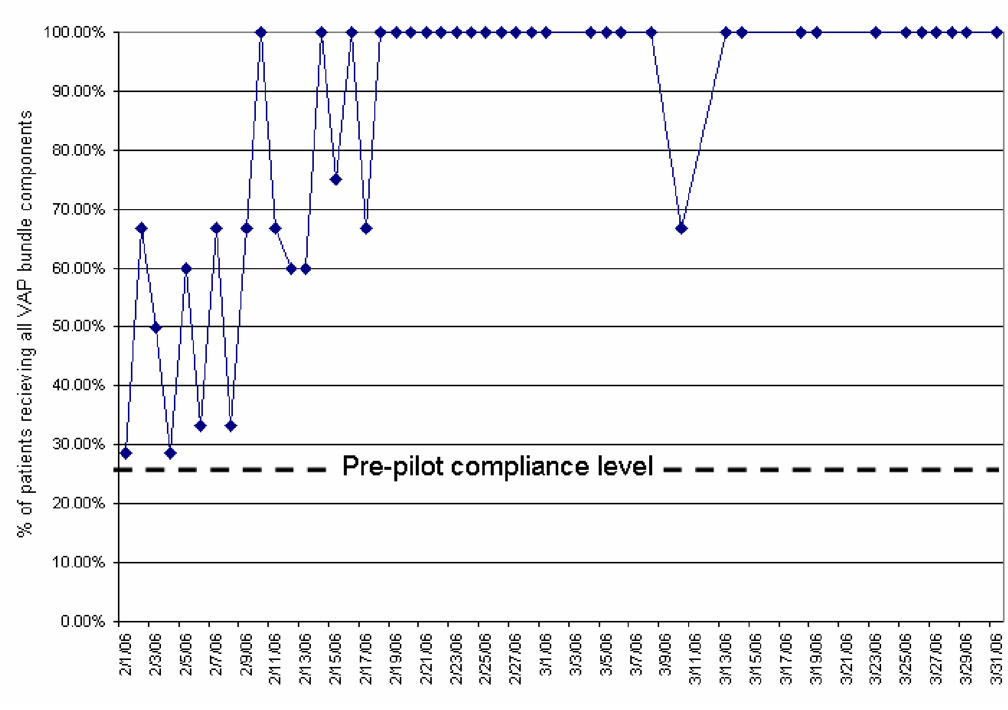

Figure 4a. % of patients receiving all components of VAP bundle, implementation pilot, 2/1-3/31/2006

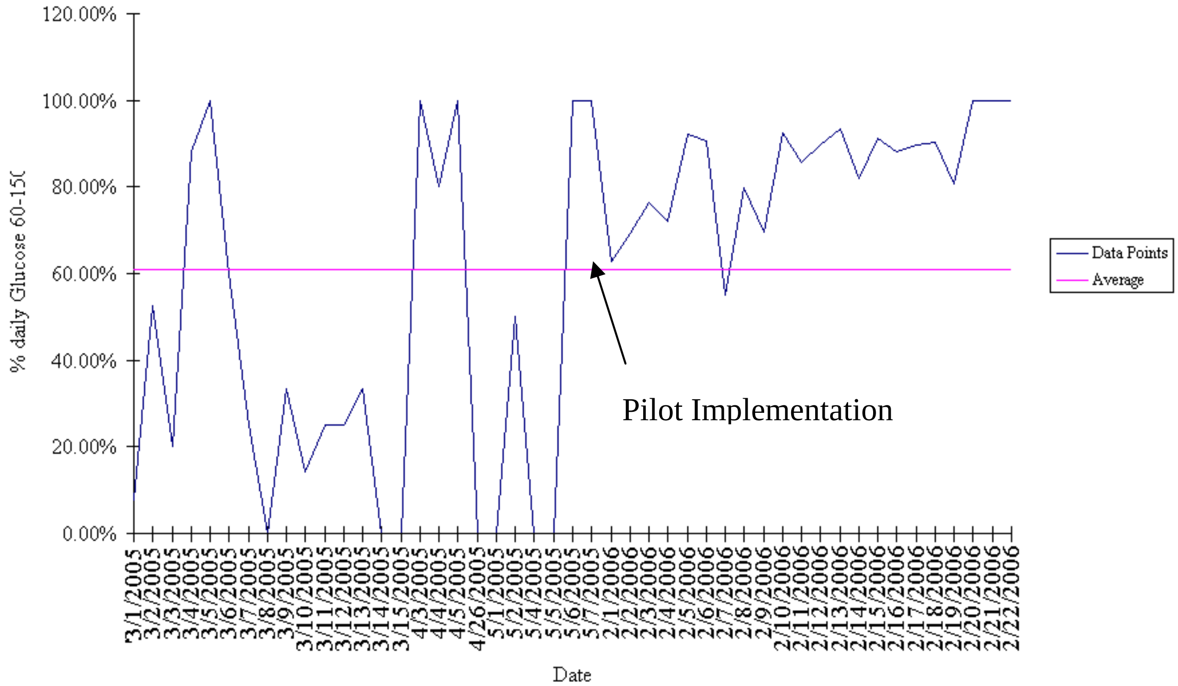

Figure 4b. % of patient daily glucose within 60-150 range, pre/post pilot

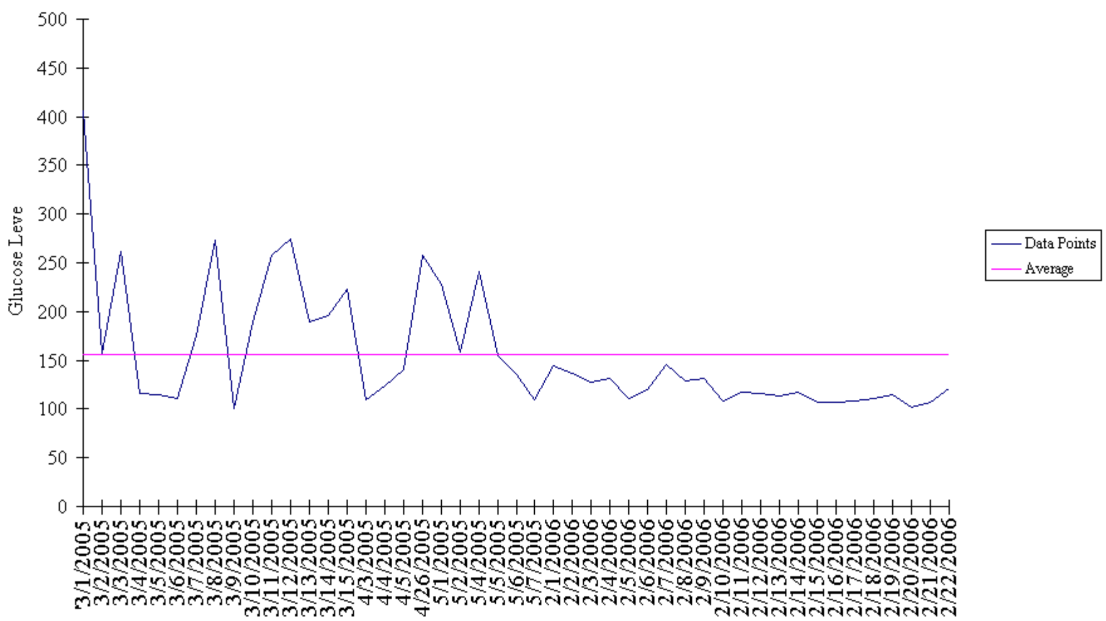

Figure 4c. Average Daily Glucose Levels pre/post pilot

Control Phase – Full Implementation:

After the initial two month success of this pilot, the project team decided to reduce process monitoring from daily monitoring and feedback by the charge nurse to monthly summarized reports compiled by the quality managers. As noted in Figure 5a, compliance to the bundle elements started to decrease almost immediately. It is important to note that before the use of Lean Six Sigma at St. Margaret Mercy, the decrease in compliance would be the case with any nursing and medical practice change that was implemented -- as if the physicians and nurses were "riding the wave" until it was not the flavor of the month any longer and they could go back to their original practices.

In this case, although the decrease in bundle compliance was noted in week 18, a change in unit management also occurred during this timeframe, delaying appropriate escalation and response until week 22. At this time, the project team was reconvened, additional failure modes were identified, action plans were implemented and daily monitoring restarted in week 27. Note the gradual increase in compliance as the daily monitoring was re-introduced and escalation and response processes refined. Currently the process in under weekly process monitoring, with daily feedback re-introduced if weekly metrics fall below 85% compliance.

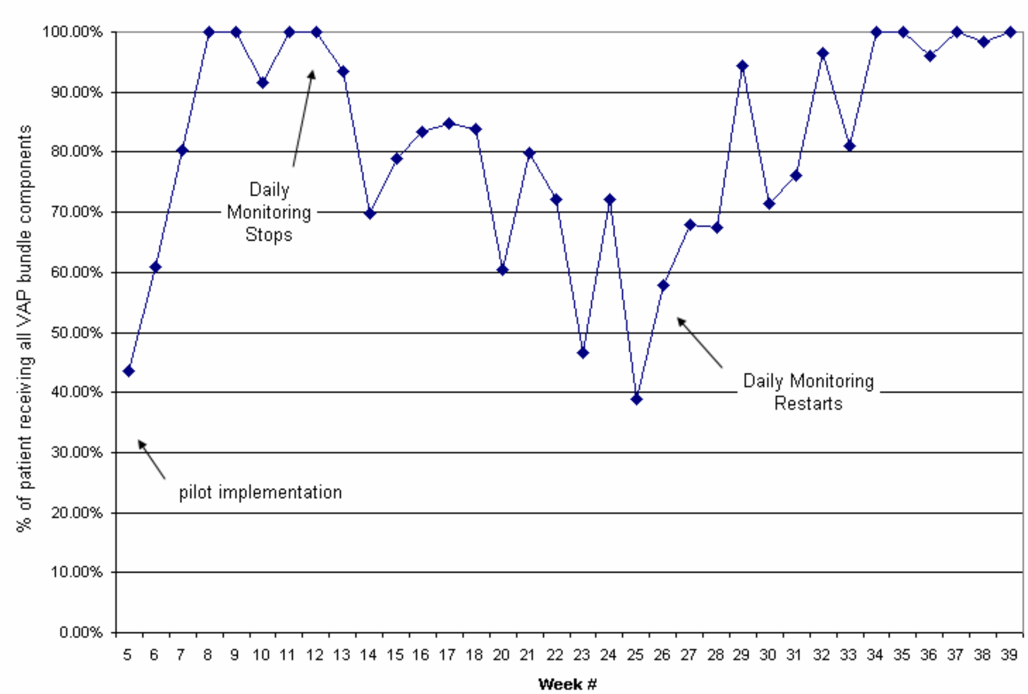

Figure 5a. % of patients receiving all components of VAP bundle by week, 2/1-9/1/2006

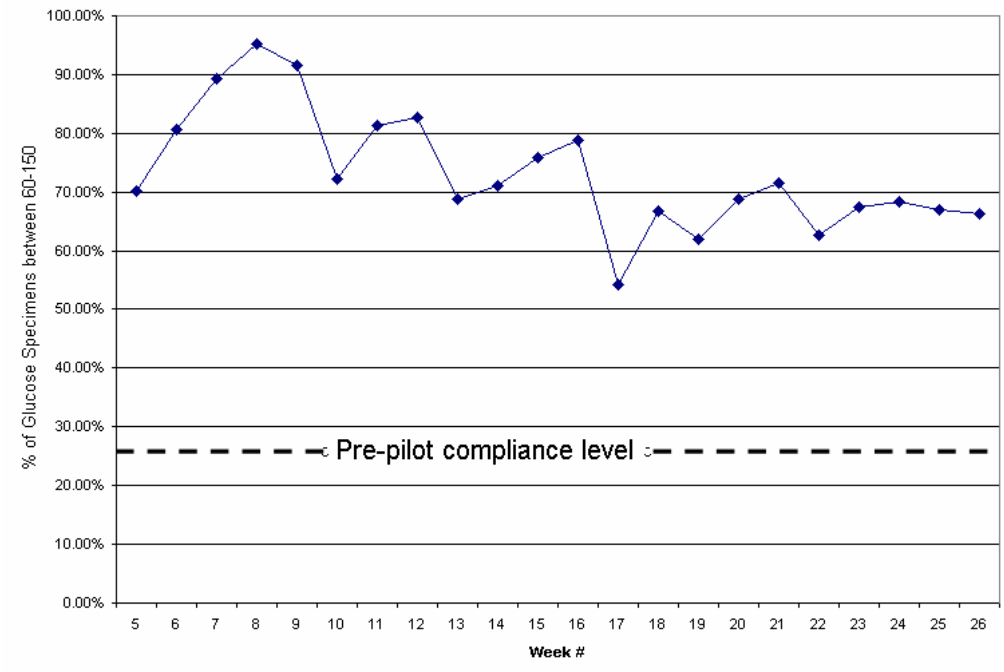

Figure 5b. % of glucose specimens within guidelines by week,
2/1-6/30/2006

Figure 5b shows the % of glucose specimens reporting within the required range during and following the implementation pilot . Interestingly, the sharp decrease in VAP protocol compliance is reflected in a more moderate decrease in glycemic control process performance in week 12. Also note that although the process performance does decrease from initial pilot results, the process gradually stabilizes at 70% of specimens within required range.

Additional investigation found that specimens not within range were primarily those for patients upon initial admission into the study unit, as elevated glucose levels may continue for several hours after patient admission while control is established. Rather than requiring more aggressive response by nursing to stabilizing recently admitted patients and risk hypoglycemic events, the project team opted to change the process output metric to the % of ICU patients with median patient glucose values between 80 mg/dl and 150 mg/dl.

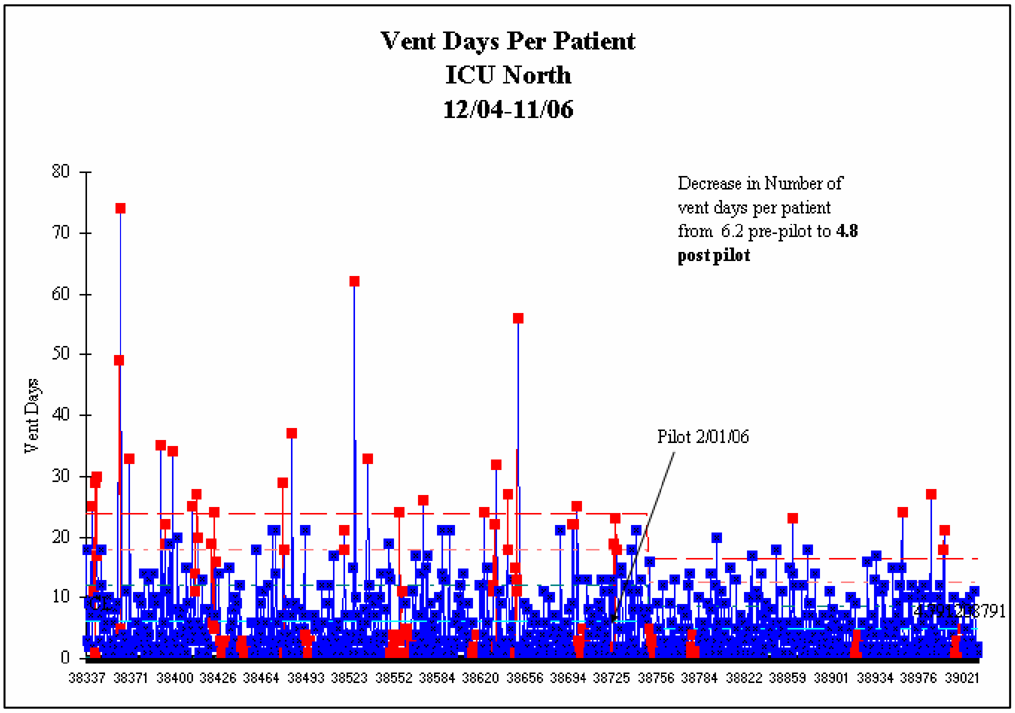

Figure 6a. St. Margaret Mercy North - # of Vent Days per patient pre/post implementation 11/04-11/06

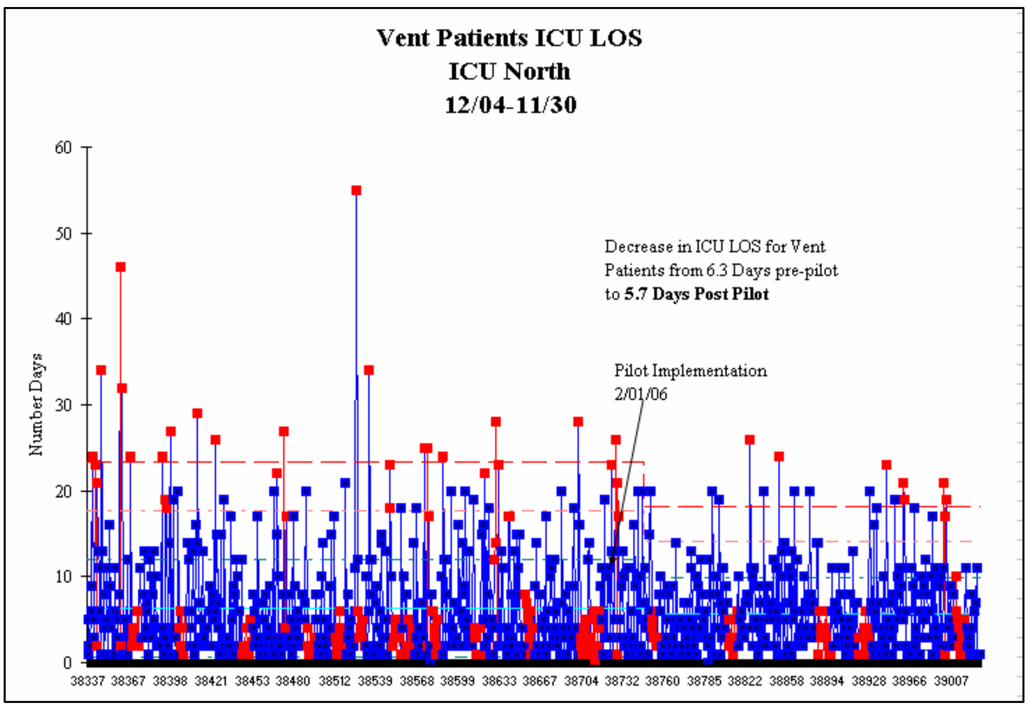

Figure 6b. St. Margaret Mercy North – ICU LOS per patient pre/post implementation, 12/04-11/06

Link to Patient Outcomes:

Patient outcomes such as VAP infection rate, ICU LOS and number of vent days per patient were also monitored to validate the positive impact of improvements in protocol compliance against patient outcomes. Within the study group, there have been no cases of Ventilator Associated Pneumonia since the 2/1/2006 implementation date a significant decrease from an average of 1 case per month in the 6 months prior to implementation.

Additionally, as shown in Figure 6a-6b, the number of patient vent days has decreased from an average of 6.2 in the 18 months immediately prior to the study implementation to 4.8 following the implementation. The ICU LOS has shown a corresponding decrease from 6.3 to 5.7 days following the intervention.

Project Transition:

Following the success of the project at the St. Margaret Mercy in Hammond, Indiana, the project was transitioned to St. Margaret Mercy Hospital in Dyer, Indiana.

A compressed (5 week) training schedule was also used to train teams composed of front line staff members in Lean Six Sigma tools in the Dyer hospital. Although the ST. MARGARET MERCY Hammond project was presented as part of this training, the Define, Measure and Analysis phases of the DMAIC process were conducted in the Dyer hospital to determine failure modes and develop solutions for KPOVs/KPIVs highlighted during the project sessions. In each case, failure modes unique to the Dyer campus were highlighted and solutions implemented to reduce or eliminate impact. Implementation within the 2nd critical care unit occurred in August of 2006. Compliance to both the VAP and glycemic control protocols has been very high and sustained at the Dyer campus and vent days have decreased from 5.0 to 3.8 days post pilot.

Lessons Learned:

A strong and constant presence in the unit during implementation to foster education and assist staff in these practice changes is imperative to a successful project. During the first 6 weeks of implementation the project leader was involved in education, fostering communication between the members of the multi-disciplinary team, making noted revisions to order sets based on staff input and providing daily feedback with respect to compliance against VAP and intensive glucose protocols. Unfortunately, the transition from of project ownership from the project leader was not seamless, and this was reflected in the decrease process performance in weeks 8-15.

In order for the cultural transformation to occur, middle and upper-management support and involvement is key. Lastly, in order for a true practice change to occur, the staff has to believe it is necessary and that they are empowered to make changes to remove operational barriers and improve processes. Constant education and reinforcement of changes is necessary, as is regular (daily) monitoring of control plan metrics. After the staff saw decreases in the unit's VAP rate and ICU LOS and make the link between protocol compliance and better patient outcomes, compliance against all protocols increased.

Conclusions:

We have successfully applied Lean Six Sigma methodologies to optimize operational processes associated with ventilator associated pneumonia (VAP) and intensive glycemic control protocols. As a result of these improvements, compliance against protocols has significantly improved within the critical care units in the two St. Margaret Mercy Hospitals in Hammond and Dyer, Indiana. These results have been sustained over time and have been linked to improved patient outcomes including VAP infection rates, patient vent days and ICU LOS.

---

[1] Van den Berghe et al. Intensive Insulin Therapy in Critically Ill Patients NEJM 2001; 345: 1359 - 67.
[2] Van den Berghe et al. Outcome benefit of intensive insulin therapy in the critically ill: Insulin dose versus glycemic control. Critical Care Medicine. 2003;31(2):359–366.
[3] Caldwell C. *Lean-Six Sigma: tools for rapid cycle cost reduction*.. Healthc Financ Manage. 2006 Oct;60(10):96-8.
[4] Daley AT. *Pro: lean six sigma revolutionizing health care of tomorrow*.. Clin Leadersh Manag Rev. 2006 Sep 26;20(5):E2.