Appreciation of a Process Improvement: Leanining the Process of
Venous Thromboembolism Prophylaxis at Denver Health Medical Center

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February 16, 2014

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Nursing 525, Managing Clinical Effectiveness in Care Systems

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**Background**

The Triple Aim is a framework designed by the Institute for Healthcare Improvement (IHI) to optimize healthcare performance. This approach proposes to pursue three distinct objectives simultaneously within healthcare organizations and systems: "improving the patient experience of care (including quality and satisfaction); improving the health of populations; and reducing the per capita cost of health care" (IHI, 2014). With the assistance of the Triple Aim, Denver Health Medical Center (DHMC) has been successfully employing Lean principles to improve both nonclinical and clinical management processes since 2005 (Biffl et al., 2011).

DHMC, an affiliate hospital to Denver Health, that cares for one third of Denver's population annually and 37 percent of Denver's children, is a 525-bed safety-net hospital, one of the busiest hospitals in Colorado with more than 26,000 annual admissions (Denver Health, 2013). It is an Academic Level I Adult and a Pediatric Level II verified Trauma Center in Colorado by the American College of Surgeons (Denver Health, 2013). In this paper, a process improvement project that applied Lean principles to venous thromboembolism prophylaxis is thoughtfully appreciated and analyzed in-depth.

Venous thromboembolism (VTE), collectively deep vein thrombosis (DVT) and pulmonary embolism (PE), is a leading cause of morbidity and mortality in hospitalized patients, responsible for between 100,000 and 300,000 deaths annually in the United States (Mahan et al., 2012). Between 59% and 75% of all VTEs are hospital-acquired, and they are highly preventable in a range of between 18% to 65% of events (Mahan et al., 2012). Prevention of VTE is ranked as "the most highly rated patient safety practice" of 79 practices by the Agency for Healthcare
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Research and Quality (Biffl et al., 2011). The annual cost of hospital-acquired "preventable" VTEs alone is estimated between $11.9-$39.3 billion (Mahan et al., 2012). Furthermore, Centers for Medicare & Medicaid Services designated deep vein thrombosis and pulmonary embolism following total knee replacement and hip replacement as "hospital-acquired conditions (HAC),” and CMS has not reimbursed hospitals for the related costs since October 1, 2008 (CMS, 2012). Consequently, these two compelling factors forcefully moved healthcare organizations, including DHMC, to considerably improve VTE prophylactic clinical management.

Focus of the Improvement Project

In spite of significant resource allocation toward VTE prophylaxis measures in 2006 and 2007, DHMC suffered because of poor quality care. For the second quarter of 2008, DMHC had "the highest incidence of postoperative VTE among 74 University HealthSystems Consortium hospitals,” with 26.6 VTE rate per 1,000 surgical procedures (Biffl et al., 2011, pp. 100-102). In 2006 and 2007, low molecular weight heparin was the most costly item in the hospital's pharmacy budget, with $307,243 annual cost, and sequential compress devices also cost the hospital $160,872 annually, in addition to $31,816 annual cost for unfractionated heparin (Biffl et al., 2011, p. 100). Despite all these annual expenditures of approximately $500,000, the prophylaxis measures failed to demonstrate their effectiveness in preventing VTE incidents in the hospital.

The performance improvement reviews at DHMC discovered two fundamental problems that had caused such ineffectiveness and inefficiency. They discovered that VTE risk factors were not consistently assessed at the hospital. Also, there was a wide variation of selecting VTE prophylaxis measures among providers. Furthermore, the hospital's clinical guidelines for the VTE prophylactic measures were outdated and inadequate (Biffl et al., 2011, p. 100). The
reviews summarized a root problem as "inconsistent implementation of well-accepted guidelines" (Biffl et al., 2011, p. 100).

This inconsistent practice of prophylactic measures on VTEs has translated into a large sum of avoidable care cost. In a retrospective calculation, the success of the process improvement revealed that the hospital was unnecessarily wasting more than $15,000 per month constantly and recording a financial loss of more than $6 million over 28 months (Biffl et al., 2011, p. 99). These outcomes clearly articulate that there had been great room to reduce the cost of care for VTEs by employing the knowledge and practice that were already available and evidence-based.

More significantly, the failure of implementing relevant VTE prophylaxis had been devastating both quality and safety of care experienced by patients. Until the improvement project began in 2008, a number of patients had been unnecessarily suffering "highly preventable" hospital-acquired VTEs at a rate of 26.6 per 1,000 surgical procedures (Biffl et al., 2011, p. 102). Some of those innocent vulnerable patients even lost their lives. Targeting these two objectives among the Triple Aim, ensuring quality and safety of patient care and reducing unnecessary costs, the VTE prevention process improvement was chartered.

**The Approach of the Improvement Project**

**Lean the VTE Prophylaxis Process**

After comprehensive performance reviews and analysis, the project team decided to "standardize and consistently implement risk assessment and evidence-based prophylaxis throughout the institution" by applying Lean principles and tools to VTE prophylaxis (Biffl et al., 2011, p. 100). The team hypothesized that reformation of the process could reduce the rate of VTE events as well as cost in the hospital. The decision to employ Lean transformation was a
natural choice for the hospital because by that time, between 2005 through 2006, DHMC had been successfully employing many Lean transformation initiatives across the hospital and experiencing a cumulative financial benefit of about $74 million (Biffl et al., 2011, p. 101).

For the Lean transformation of VTE prophylaxis processes, the project team utilized a number of Lean tools: outlining a process map, trystorming, developing the ideal state characteristics, elaborating a future state process map, employing standard work, tracking metrics, and using POKE YOKE (error proofing) and ANDON (stopping the process). By applying these important Lean tools, the project aimed to identify and eliminate (or significantly mitigate) the waste in the prophylaxis processes, which is the core of Lean transformation. To achieve such objectives, the project focused on "[developing] a standardized, housewide, evidence-based, computerized physician order entry (CPOE)---an embedded, easy-to-use, and easy-to-understand prophylaxis algorithm that would apply to adult non-obstetric patients admitted to the hospital" (Biffl et al., 2011, p. 101).

In order to guide the entire improvement project, the project team utilized the "9 block A3," a structured problem-solving and results-reporting tool in the Lean transformation (Biffl et al., 2011, p. 101). The 9 block A3 tool worked well in the transformation by enabling the project team to follow each transformation event through step-by-step and periodically monitor and report each step of the transformation process. The sequence of 9-block transformation is listed below:
During the block 7 implementation, the project team logically and reasonably focused on overcoming occurring challenges to facilitate a hospital-wide adoption. The project team worked with a medical informatics team to plant the standard VTE CPOE order set into the admission order set. Particularly, the joint team focused on making the embedded CPOE prophylaxis algorithm easy to understand and use for all diverse medical staff. In addition, the project team facilitated a successful adoption by leveraging a structured education program for clinical staff. Beginning with a presentation at the directors of service, meeting in late June 2008, the project team actively engaged in a 60-day education program for the clinical staff, including resident physicians, consisting of a dissemination of information about the impacts of hospital-acquired
VTEs, the need for changing practice patterns, the associated cost of prophylaxis to the hospital, and the departments' prophylactic utilization patterns. These highly structured education sessions were effective and promoted a wide adoption among the medical staff, creating a culture for the change. After building such consensus, the project team collaborated with the medical informatics team to integrate the VTE prophylactic algorithm into the admission order set in the CPOE system. This was a strong mechanism because it mandated all providers to assess their patient's risk of VTE and the order. A provider could not complete the admission order without addressing the VTE prophylaxis, thus this mechanism served as a first degree of POKE YOKE (error-proofing). In spite of the risk of potential resistance from the medical staff, this process went smoothly. The other strong mechanism that ensured a wide compliance of the standardized prophylaxis measures was ANDON (stopping the process at the point of defect identification). Any variance that was inconsistent with the approved clinical practice guideline was followed up with the clinical pharmacists contacting the ordering physician with the goal of changing the order. This ANDON increased the overall compliance over 97% from 85%-90% at pre-intervention (Biffl et al., 2011, p. 104).

During the block 8 process (Confirmed State), the project team measured if the improvement initiative was successful by tracking the selected outcome measure metrics: 1) low molecular weight heparin, unfractionated heparin, and sequential compression devices per 1,000 patient days; 2) monthly pharmacologic venous thromboembolism prophylaxis expense; 3) percentage of low molecular weight heparin orders following the algorithm; 4) AHRQ (Agency for Healthcare Research and Quality) Patient Safety Indicator: Postoperative VTE Rate per 1,000 Surgeries; 5) VTE prophylactic expense per quarter; and 6) financial impact of reducing hospital-acquired VTEs (Biffl et al., 2011, p. 104).
Results of Leanin

The result of the rapid improvement event was a success. The compliance to the approved standardized clinical practice guideline approached 100% within six months of implementation. One year after implementation, the use of LMWH fell more than 60% below baseline, and the use of sequential compression devices decreased by almost 30%. More importantly, the rate of VTE events decreased from “an average of 25.0 ± 4.2 per 1,000 inpatient hospital days for January 2008 through May 2008 to 8.2 ± 5.5 for June 2008 through September 2010” (Biffl et al., 2011, p. 105). Financially, this successful improvement resulted in approximately $425,000 in direct cost savings, exceeding $15,000 per month with the increased use of unfractionated heparin, and more than $6.2 million in cumulative cost savings associated with fewer hospital-acquired VTEs since the implementation (Biffl et al., 2011, p. 105).

Limitations

In spite of the success, there are a few limitations. First of all, the project team should have considered in-depth entrenchment of the standardized prophylaxis and compliance in the long-term. Although, the project team is "hoping" to see the firm establishment of the standardized prophylaxis over time, it may not take place due to two underlining problems embedded in the healthcare system. By nature, as the project team anticipated, the practices of physicians can result in variation because physicians usually apply their own knowledge, clinical experience, and judgment in providing care to patients (Kresse in Biffl et al., 2011, p. 106). Such autonomy of physicians may have to be sacrificed by the standardized automatic algorithm, "forcing" them just to endorse pre-set orders. Thus, this structural problem is a tough barrier for the long-term establishment of the standardized VTE prophylaxis algorithm.

Secondly, there is a great rate of turnover by rotating residents at DHMC, where residents
are frontline care providers. Repeatedly, the residents, educated and compliant to the standardized VTE prophylaxis, leave the hospital, and new groups of residents come as they rotate clinical sites. This is a great concern for the long-term prospect of the improvement agenda that even the project team was concerned about. They called for "[requiring] ongoing vigilance and continuous reminders and reeducation" (Biffl et al., 2011, p. 106).

The third limitation for the improvement procedure was a skewed emphasis on certain groups of clinicians. The improvement process mainly focused on physicians and pharmacists as the main vehicles to implement the VTE prophylaxis, although participation of other stakeholders is important for success. For example, in a similar improvement process at the Saint Francis Hospital (SFH) in Oklahoma, in 2007, the improvement leveraged the role of nurses without "forcing" physicians to standardization by the CPOE system. (Gray & Razmus, 2012). In a multidisciplinary effort, the SFH project team developed an "electronic trigger" incorporated in the admission orders in the CPOE system, promoting nurses to initiate clinical communication with attending physicians for VTE prophylaxis. This approach resulted in a significant reduction of VTE events in the hospital by 31.6% from 123 in 2008 to 87 in 2010 (Gray & Razmus, 2012). The approach is sustainable in the long-term because the main driver of improvement was embedded in the traditional workflow of clinicians. Evidently, the project team at DHMC could have utilized other clinicians and hospital staff, in addition to physicians and pharmacists, to maximize the improvement.

**Lesson Learned**

Over the course of the improvement, the project team learned specifically about processes contributing to a high incidence of hospital-acquired VTEs and gained insights into developing solutions to minimize the frequency of the incidents. During the Block 4 Gap
Analysis, the project team identified all potential barriers hindering optimal outcome in preventing hospital-acquired VTEs. All of the potential barriers were categorized into four groups: “materials,” “people,” “method,” and “machine” (Biffl et al., 2011, p. 103). The project team gained insight on all these identified factors, converged to a single fundamental problem of inconsistent implementation of well-accepted guidelines on VTE prophylactic measures. Most importantly, over the course of this successful application of Lean methodology in VTE prevention, the project team learned practically how to apply Lean principles in "actual clinical" cases. Standing on this firm foundation, the project team expects to apply Lean methodology in other clinical management processes. DHMC has even emerged as a strong adapter and advocate of Lean principles in healthcare (Denver Health, 2014).

**Contributing Factors to Success**

A comprehensive review of the VTE process improvement at DHMC identifies three critical factors contributing to the success of the improvement: expertise and experience in applying Lean principles in healthcare settings, a systematic implementation approach, and strong support from the administration.

First, the improvement was successful because the project team had already possessed an expertise in applying Lean principles to healthcare settings, which was gained from extensive experience. Since 2005, DHMC had been applying the Lean principles to transform the institution in order to thrive in the long-term. In this strategy, the hospital's management approached Lean principles that had proven their effectiveness in other industries. By carefully applying Lean principles in over 250 improvements in administrative and support processes, the DHMC had seen "consistent and positive results," which encouraged staff to contemplate the idea of implementing the proven Lean principles into actual "clinical" management processes
(Biffl et al., 2011, p. 101). One of first such efforts was this project, "Leaning the process of venous thromboembolism prophylaxis." Without such a rich and in-depth expertise in Lean transformation, this project would not have been even discussed. Besides the expertise, the rich history of Lean application resulted in invaluable human resources ready for any Lean transformation, more than 250 Lean-trained employees, including 28 physician leaders as Lean Black Belts (Biffl et al., 2011, p. 101). Through this expertise, DHMC was already enjoying a financial benefit of approximately $75 million by the time of the project’s initiation (Biffl et al., 2011, p. 101). There was soon a "culture" believing in Lean principles across the institution. The proven expertise and resources in Lean transformation were prerequisite to the success of the project.

The second contributing factor to the success of the project was a highly systematic implementation approach. Throughout the 9 Block A3 improvement process, the project team had demonstrated its highly reasonable and systemic implementation skills; for example, analyzing the problems, developing effective solutions, and designing the comprehensive implementation plan and its strong execution while constantly providing timely feedback to all participating stakeholders. In particular, during the completion of the implementation plans, the project team extensively engaged in highly structured education sessions for all levels of stakeholders. They regularly presented the concept of a standardized approach to VTE prophylaxis and implementation updates to governing directors, attending physicians, residents, the nursing staff, the clinical pharmacy staff, and the administration. In the structured education sessions, the project team discussed the impacts of hospital-acquired VTEs, the need for changing practice patterns, and the associated cost of prophylaxis to the hospital. These topics were truly relevant and strong enough to effectuate the change. Moreover, the project team
successfully collaborated with various stakeholders. For instance, the project team collaborated with the medical informatics team to develop the VTE prophylaxis admission order embedded in the CPOE system. The project team thoughtfully presented the medical informatics team with a plan for the development of an algorithm that is easy to understand and easy to use in order to ensure strong adoption among providers. Furthermore, the project team thoughtfully planned and administrated the implementation. For example, the implementation utilized additional two Lean tools, POKE YOKE and ANDON, in order to ensure nearly 100% of compliance for the standardized prophylactic measures. This systematic approach made it possible for the project to succeed.

The third and most important factor was the strong commitment and support from the administration and management of DHMC. While the former two factors were crucial, without support from the administration, success of this project would not have been possible. The strong support from the administration for this VTE Lean transformation, as well as a hospital-wide Lean transformation, was best demonstrated in the allocation of resources necessary for Lean transformation. In order to provide training, planning, and facilitation of Lean events, the hospital administration put a core team of seven full-time "Lean facilitators" in place, in addition to hiring a Sensei, a Lean teacher with previous Lean implementation experience (Biffl et al., 2011, p. 101). These internal experts in Lean provided a leadership role for multiple Lean teams throughout the improvement processes by helping each team identify and eliminate waste from specific processes. The strongest support from the administration was confirmed in endorsing the project team's plan and implementation of "standardizing" VTE prophylaxis measures for the entire health system, which impact was huge and permanent. Constructing and executing hospital-wide, standardized VTE prophylaxis measures, requiring all providers to address the
VTE prophylactic measures, were possible only under the strong commitment and support from the administration. Such strong support enabled the project to overcome barriers and articulate concerns throughout the life of the project. In fact, this initiative of employing Lean principles in clinical management processes was from the administration; at the third year of Lean transformation at DHMC, the chief medical officer advocated the concept of applying Lean principles into clinical settings (Biffl et al., 2011, p. 100). As the project team acknowledged, support from the administration was indispensable for the success of the VTE prophylaxis process improvement (Biffl et al., 2011, p. 108).

**Conclusion**

Hospital-acquired VTEs should vanish both for vulnerable patients and healthcare providers. The VTE prophylaxis process improvement project at DHMC has demonstrated that a significant and sustainable improvement of VTE prophylaxis management is possible, providing healthcare organizations with an applicable success model and approach. The highly systematic multidisciplinary planning and implementation, specifically rooted in the Lean principles, is the key to success of the project.
References


