



# Lean Six Sigma for Intravenous Therapy Optimization: A Hospital Use of Lean Thinking to Improve Occlusion Management

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## Abstract

**Background:** Continual improvement is a necessary part of hospital culture. This occurs by identifying opportunities for improvement that influence efficiency while saving money.

**Methodology:** An investigation of intravenous device-related practices was performed by the nurses of the intravenous access team, pharmacy, and hospital operations at Hartford Hospital using Lean Six Sigma methodology. Central venous access device occlusion and tissue plasminogen activator variability was identified. Using observation, measurement of performance, and root cause analysis, the hospital's practices, policies, and equipment were evaluated for the process of occlusion management. The team utilized a Six Sigma strategy employing the elements define, measure, analyze, improve, and control, which is a disciplined, data-driven methodology that focuses on eliminating defects (waste). Interventions initiated based on the assessment performed by the team using the define, measure, analyze, improve, and control approach included replacement of negative displacement needleless connectors with antireflux needleless connectors and specialty team assessment before tissue plasminogen activator use.

**Results:** Over the course of the 26-month study, Hartford Hospital experienced a 69% total reduction in tissue plasminogen activator use representing a total 26-month savings of \$107,315. Other cost savings were reflected in areas of flushing, flushing disposables, and in a decrease in needleless connector consumption. Central line-associated bloodstream rates fell 36% following the intervention as an unexpected secondary gain, resulting in further savings related to treating this nonreimbursable hospital-acquired condition.

**Conclusions:** This study examined the influence of using Lean Thinking and Six Sigma methodology as a tool in saving hospital money, resulting in better patient outcomes.

**Keywords:** central venous catheter, cost savings, lean six sigma

## Introduction

Among the most frequent complications associated with central venous access devices (CVADs) is catheter occlusion, ranging from 3%-79%.<sup>1-4</sup> Thrombotic formations on a CVAD are a natural physiological process in response to the insertion of foreign material into the body. Immediately upon insertion of an intravenous (IV) catheter, cells attach to the surface forming a fibrin coating.<sup>5,6</sup> This body response occurs soon after insertion and may develop around and within a catheter at any

time during the IV treatment processes.<sup>7,8</sup> Intraluminal thrombotic catheter occlusion, a common noninfectious complication, is associated with negative outcomes of loss of patency (43%), device replacement (29%), device removal (14%), and hospital visits (15%) that all delay or disrupt the treatment process, slow a patient's progress toward therapeutic goals, and increase length of hospital stay and cost of care.<sup>1,2,9,10</sup>

Peripherally inserted central catheters (PICCs), a type of CVAD, have a higher incidence of occlusion than other chest-inserted central catheters potentially due to factors such as insertion into smaller peripheral veins, larger surface area, use of 3F-6F sizes with multiple lumens, and small catheter diameter.<sup>2,11-16</sup> Activities associated with PICCs for administration of IV medications and solutions require flushing, aspiration of blood, and connection and disconnection of needleless connectors (NCs) causing pressure changes within the catheter that result in venous blood cell deposits within the lumen of the

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catheter known as reflux. Reflux is associated with both mechanical and physiological pressure changes that force blood into the catheter lumen, leaving blood deposits contributing to the incidence of catheter occlusion.<sup>17,18</sup>

Reflux of blood into the terminal end of a catheter is a cause of catheter occlusion.<sup>19</sup> Patient movements, muscle flexing, and coughing all cause pressure changes and reflux within the catheter. As the catheter is manipulated, blood is intermittently pulled back into the catheter.<sup>19,20</sup> These deposits of blood on the catheter may be cleared, somewhat, with saline flushing.<sup>21-23</sup> When catheter lumen flushing is inadequate or blood protein deposits completely or partially block the terminal end of the catheter, these occlusions to the terminal end of the catheter may prevent blood sampling and the infusion of fluids.<sup>10,21,24,25</sup>

### Lean Six Sigma

Hartford Hospital in Hartford, Connecticut, is an 867-bed regional referral center and the largest Hospital in the Hartford Health System. Lean Thinking and Six Sigma are 2 process improvement methods the IV Team at Hartford Hospital implemented to improve infusion therapy practices. The Lean Six Sigma (LSS) process is used to implement positive change by identifying inefficiencies, variables, process defects, and waste.<sup>26-31</sup> Specifically, LSS is a quality improvement methodology that originated during the 1970s with the Toyota Motor Company and Toyota Production System.<sup>32</sup> Much of the Toyota Production System way of thinking is based on the work of W. Edwards Deming.<sup>33</sup> Deming taught, among other things, that managers should stop depending on mass inspection to achieve quality, and instead focus on improving the production process, protocols, practices, and building quality into the product in the first place. LSS strives to pinpoint quality processes that correct identified defects in a system. Simply put, LSS means using less to do more.

The Lean Thinking concept was used initially in our department to improve the management of occluded CVADs. The hospital chose to study CVAD occlusion management while working to promote savings in medications, supplies, and time. This process allowed identification of variables that influenced the way occlusions were managed (ie, assessment of catheter function) and implement corrective actions that improved patient delivery of treatment without administering unnecessary medications.

The LSS data-driven quality method at Hartford Hospital was specifically guided by a programmed approach: defining, measuring, analyzing, improving, and controlling (DMAIC).<sup>34-36</sup>

The DMAIC phases:

- **Define** opportunity for improvement, project goals, and patient requirements.
- **Measure** pharmacy and medical supply consumption, overall cost, and performance.
- **Analyze** the consumption data to determine root causes of variation and poor performance (defects).
- **Improve** process performance by addressing and eliminating the root causes.

- **Control** by building a system of checks and adjustments for ongoing improvement in the process, protocols, practices, products, and patient outcomes (5Ps) of IV therapy.

The Hartford IV Team and stakeholders incorporated investigation of the 5Ps of IV therapy for insertion and management of vascular access devices. This process used the 5Ps as a tool to assist in differentiating value-added actions from nonvalue-added actions. By using the 5Ps systematic approach, waste and variability became obvious and detectable.

The LSS program at Hartford continued with agreement from the stakeholders from the supply chain and IV Team and from pharmacy, all committed to performance improvement. Infusion treatment with catheters in our facility represents more than 90% of our acute care hospital patients and CVADs are in use in approximately 50% of intensive care patients. Evaluating CVAD occlusion in terms of catheter function, flushing, and reflux had the potential to speed treatment and reduce occlusion complications. Wasted time, money, medical supplies, and pharmaceuticals and medications as well as logistics and nursing costs were all components because they applied to reported events of occlusion. LSS focuses on reducing defects, variability, and waste in current hospital IV access device practices.

### Methods

The LSS methodology was used with the design indicated by the DMAIC process to define problems and goals, measure activities and supplies, analyze results, and devise improvement strategies based on analysis and control throughout the process. A team of clinicians trained in LSS evaluated procedures from October 2014 to December 2016 to identify problems, set goals to improve patient outcomes and reduce variability and waste resulting in long-term economic change. Goals and objectives for each patient outcome and the variability and waste sections were established for CVAD use, including heparin flushing, occlusion management, medication administration, CVAD replacement, and all associated supply costs.

### DMAIC Phases

The LSS framework for infusion therapy practices at our facility began with a set of value-added actions and improvements identified through the DMAIC process. The DMAIC method was applied over 26 months as described in [Tables 1–5](#). During the define phase ([Table 1](#)), products and patient outcomes were evaluated for IV therapy. A refined literature review delved into subjects of catheter patency; thrombotic occlusion; risks associated with tissue plasminogen activator (tPA) use; blood reflux; NCs; valves used in catheters and NCs; flush solution volume and frequency; and CVAD indications, appropriate use, and tip position.<sup>10,17,20-22,37-51</sup> The results of the literature review assisted in guiding the analysis process.<sup>52,53</sup> After defining key concepts and associated activities the process moved into the measurement phase.

The measure phase ([Table 2](#)) of DMAIC distinguishes specific goals that quantify practices and processes needing improvement. Measurement key areas included incidence of occlusion; drug use for occluded catheters; supply consumption

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