Laboratory-driven Lean Sigma to prove critical to hospitals' future success under new healthcare reform law

By Patrick Maul

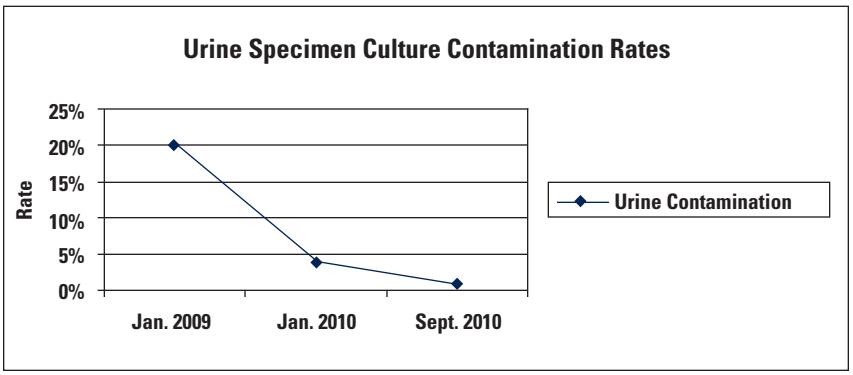
Many medical diagnostics manufacturers rely upon Lean and Six Sigma (Lean Sigma) methodologies to drive quality improvements and provide additional value to the healthcare institutions they serve. So, it is no surprise that their customers are now turning to Lean Sigma to help them achieve similar goals.

Case studies on the topic abound from emergency departments to critical care units to imaging services. Recent success stories demonstrate that clinical laboratories can apply Lean Sigma to enhance their operations and align with their institution's strategic objectives, which are likely centered on providing high-quality, cost-effective care.

Given the new healthcare reform law and the current economic climate, hospitals must find ways to increase revenue, enhance efficiency, lower operating expenses, and elevate patient care. Lean Sigma can be a powerful tool in these regards, helping institutions weather and take advantage of the U.S. healthcare system's tectonic shift from a reimbursement model that paid for services provided to one that rewards (or penalizes) institutions for quality care and efficiency.

For laboratory managers who embrace Lean Sigma principles and practices, some programs in the healthcare reform law may provide opportunities to help preserve and even grow hospital revenue. For example, catheter-associated urinary tract infections (CAUTIs) can cost hospitals dearly under recent changes in Medicare payment regulations.

The Centers for Medicare and Medicaid Services (CMS) consider CAUTIs to be "hospital-acquired conditions" and will not reimburse hospitals for the subsequent care resulting from them. In addition, hospitals with high CAUTI rates may see their Medicare reimbursement reduced under the *Affordable Care Act of 2010* (ACA), specifically the value-based purchasing (VBP) program that assesses hospitals' year-over-year infection rates and a provision that penalizes hospitals for ranking in the lowest quartile for hospital-acquired conditions. Finally, CAUTIs can hurt hospitals on another important VBP efficiency measure, "Medicare-spending-per-beneficiary," through increases in acuity, length of stay, antibiotic use, and additional diagnostic testing.



At the pilot's start in January 2009, the hospital's urine contamination rate exceeded 20 percent. After implementing standardized Lean Sigma processes, it fell to less than six percent in just 11 months. It declined to nearly one percent by September 2010 as these standardized processes gained greater acceptance.

At this point, you are probably wondering how the laboratory can play a role in reducing CAUTIs. It is actually quite logical.

The emphasis on reducing CAUTIs through financial carrots and sticks makes it very important for hospitals to identify patients quickly and accurately who are admitted with a pre-existing UTI. Yet urine sample contamination is a common occurrence in many institutions that often leads to test result delays, false positive results, inappropriate care, sample recollection/retesting, and unnecessary costs. This problem can make it difficult for hospitals to detect UTIs in general, as well as to understand the extent of their actual CAUTI problem and take necessary actions.

Like most patient specimen collection, urine sample contamination typically occurs outside the laboratory, and breakdowns in a hospital's overall preanalytical processes are often to blame. However, the effects are felt most intensely by the laboratory as doctors begin to lose confidence in the quality of test results and laboratory productivity decreases due to costly retesting.

These processes—especially when carried out in multiple locations by multiple stakeholders in multiple ways—leave room for costly variability that makes them ripe for standardization and improvement via Lean Sigma. Take the following case of a laboratory for a major healthcare facility in the northeast. It demonstrates how Lean Sigma can fix preanalytical processes both inside and outside of the laboratory and po-

sition an institution for continued success.

In 2009, this 375-bed acute care medical/surgical facility experienced urine contamination rates that exceeded 20 percent, with the Emergency Department (ED) and Critical Care Units having the highest rates. Sample quality problems raised continual questions about test results, which led to re-collection and retesting that wasted time, increased costs, and decreased patient and physician satisfaction. Working with BD Laboratory Consulting Services^{SM}, the hospital's laboratory and nursing professionals applied Lean strategies to improve urine specimen quality and improve test results.

The Team's first step was to conduct a root cause analysis, which turned up several issues from patient collection to the ED and Critical Care nurses' stations to the laboratory. In addition, urine collection processes and products were not standardized across the hospital. As a result of this analysis, a multidisciplinary Lean Sigma team developed a pilot program in the ED and Critical Care Units to determine where and how process and/or products changes could improve urine specimen quality.

The Team tested a standardized urine collection process in the ED, which involved using a closed sample collection and transport system and better educating patients on proper urine collection techniques. The hospital's Critical Care Unit also standardized urine collection from catheterized patients by using BD Vacutainer® Luer-Lok™ Access Devices, Urinanalysis Preservative Tubes, and Urine Culture and Sensitivity Preservative Tubes. The latter enabled the Team to modify the laboratory's specimen acceptance criteria and processing. Previously, the laboratory rejected samples more than an hour old, which forced many re-collections. Now, the laboratory could speed testing along since the specimens arrived in a test-ready form.

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The results were impressive. Through Lean Sigma, the hospital experienced the dramatic impact that the right processes and products can have on reducing urine sample contamination rates, improving patient outcomes, and generating substantial savings. With most urine contamination eliminated, the hospital could focus attention on patients with true positive results and help reduce the costs and complications associated with unnecessarily treating patients who received false positive results.

Eleven months after implementing standardized Lean Sigma processes, the hospital had reduced its urine contamination rate to less than six percent in the ED and Critical Care Unit. When it standardized these same Lean Sigma processes hospital-wide, the hospital further reduced urine contamination to less than one percent. During the pilot phase alone, BD estimates that the hospital saved $50,000 by switching from an open urine collection system that did not use preservatives to a closed one with preservatives for urinalysis and culture and sensitivity testing. The laboratory also became a key partner with clinicians in establishing treatment guidelines and hospital-wide best practices.

While this hospital's Lean Sigma work began prior to the passage of healthcare reform, the lessons learned and improvements could help position it for success under the new Medicare payment system that is increasingly focused on outcomes and efficiency. Besides restoring physician confidence in laboratory test results and giving hospital infection control professionals a reliable way to monitor CAUTI infection rates, the improvements in urine collection and lab processing will continue to help the ED improve throughput—another key metric that could drive reimbursement under the new healthcare reform law.

The lessons learned by this hospital and many others are important for healthcare leaders, who must balance an increased focus on patient safety, quality of care, and patient satisfaction in the face of shrinking budgets and increasing regulation amid an uncertain economic environment. With an understanding of this dynamic and how Lean Sigma can help institutions meet these challenges, laboratory managers can ensure that their departments are viewed as strategic assets that are critical to their facilities' long-term success. ☐

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