Using Lean Six Sigma Methodology to Improve a Mass Immunizations Process at the United States Naval Academy

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ABSTRACT Lean Six Sigma (LSS) is a process improvement methodology developed in the manufacturing industry to increase process efficiency while maintaining product quality. The efficacy of LSS application to the health care setting has not been adequately studied. This article presents a quality improvement project at the U.S. Naval Academy that uses LSS to improve the mass immunizations process for Midshipmen during in-processing. The process was standardized to give all vaccinations at one station instead of giving a different vaccination at each station. After project implementation, the average immunizations lead time decreased by 79% and staffing decreased by 10%. The process was shown to be in control with a capability index of 1.18 and performance index of 1.10, resulting in a defect rate of 0.04%. This project demonstrates that the LSS methodology can be applied successfully to the health care setting to make sustainable process improvements if used correctly and completely.

INTRODUCTION

In 2000, the Institute of Medicine first published a breakthrough synopsis of patient deaths as a result of medical errors.[1] The organization rallied the health care industry to create a safer and more efficient health care system[2] by pushing institutions to develop more sophisticated quality improvement projects. With the need for more advanced analytical tools, health care turned to the manufacturing industry.

The manufacturing industry developed multiple quality improvement frameworks to increase process efficiency while maintaining product quality. Two of the most common frameworks used today are the Six Sigma methodology and the Lean principle. In the 1980s, Motorola introduced the Six Sigma methodology that was later popularized by General Electric in the 1990s. Six Sigma allows users to improve product quality by determining the relationship between output and errors in process inputs.[3] The name comes from a statistical model of manufacturing where sigma refers to standard deviation of product variability. Six Sigma indicates low product variability resulting in a long-term defect level below 3.4 defects per million opportunities (DPMO).[4] The Lean principle is a framework revolving around waste elimination and process velocity optimization.[3] The Ford Motor Company popularized Lean in the 1960s.[5] Where Lean lacks statistical control and organizational infrastructure, Six Sigma is a complex method that does not emphasize process efficiency. Combining the two frameworks into the Lean Six Sigma (LSS) methodology created a business improvement framework that addresses both quality and speed.[4]

Health care started using these frameworks within their own organizations and had published 152 projects using Six Sigma and 46 projects using Lean by 2009. The effectiveness of these applications was uncertain because only 18 of the published studies provided significant evidence of success.[6] Organizations also tended to use different combinations of improvement methodologies,[7] thus making it difficult for others to follow and implement similar improvement projects. Health care organizations are reluctant to appropriate resources to this methodology without sufficient evidence to support the value and efficacy of LSS.[6]

In 2006, the Bureau of Medicine and Surgery of the U.S. Navy began training health care leaders and staff in LSS methodology by implementing Black Belt and Green Belt training programs. By 2009, the Bureau of Medicine and Surgery recognized LSS as the primary approach for performance improvement.[8] In November 2013, Naval Health Clinic Annapolis (NHCA) trained its first Green Belt to support NHCA's mission to optimize the health and readiness of the brigade of Midshipmen. The U.S. Naval Academy welcomes nearly 1,200 Midshipmen annually who all need vaccinations during their in-processing period. Midshipmen receive these vaccinations during a mass immunizations evolution on Indoctrination Day (I-Day).

Similar to other members of the U.S. Armed Forces, Midshipmen live in crowded quarters and have a higher occupational risk of exposure to bioterrorism and endemic illnesses.[9–11] Mass immunization programs have long been a routine component of military medical readiness since

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The views expressed in this article are those of the authors and do not reflect the official policy or position of the Department of the Navy, the Department of Defense, or the U.S. Government. Jitendrakumar Modi is a paid speaker and consultant for GSK and Novartis. All authors are U.S. Government employees.

doi: 10.7205/MILMED-D-15-00247

its first implementation in 1777 to immunize Continental Army trainees against smallpox. The Department of Defense requires specific vaccinations for its active duty population, which includes the Midshipmen. Midshipmen often need up to six different vaccinations, which increases the complexity of the process. The evolution required a significant amount of NHCA staff members in previous years. Midshipmen have voiced frustration with long waiting times, duplication of paperwork, and the reduced time available to complete other evolutions. Our project demonstrates the successful application of the LSS methodology to standardize and improve the immunizations process at the U.S. Naval Academy.

METHODS

A Rapid Improvement Event, which uses Lean tools to reduce process complexity and Six Sigma tools to validate the outcomes, was initiated to deliver immunizations on I-Day. Multiple references have been published on the LSS tools and methodology,[4,12] and its application to this project is explained here.

Pre-Event

A team was commissioned, which included a Green Belt (J.M.), a command Master Black Belt (D.M.), and an LSS champion. Other team members included staff from the Primary Care, Emergency, and Occupational Health Departments. The team first created the project charter to outline the problem statement, expected mission benefits, expected financial benefits, and improvement goals using specified metrics. The team developed a rough sketch of the immunizations process using a SIPOC (suppliers-inputs-process-outputs-customers) diagram to visualize the entire immunizations process to ensure team members had the same understanding of all steps involved. The steps were further detailed through a process map, which was defined to start when the Midshipman checked in at the immunizations evolution and to end when the staff member finished checking all documentation at checkout.

Four metrics were identified to measure process efficiency. The primary goal was to reduce the average immunizations lead time, which is measured in minutes from the moment the Midshipman checked in to the immunization evolution until checkout. Secondary goals included reduction of total processing time for all Midshipmen, reduction of total labor hours, and reduction in number of stations with nonstandard work. Reduction of total labor hours was reported as a decrease in number of staff members required to work the evolution. Nonstandard work was defined to be a process that is completed differently every time and leads to a variation in results.

The team collected baseline I-Day data in 2012. Every tenth Midshipman after the first 200 Midshipmen was tracked from check-in to checkout to measure the immunizations lead time. The team surveyed these Midshipmen and all staff members to determine the voice of the customer.

Event

Using information collected from the pre-event phase, the LSS team utilized value stream analysis to identify the nonvalue-added steps and decrease process complexity through standardization. The team identified hidden factories that unknowingly required high levels of input, but produced very little output. The team also utilized a fishbone diagram and root cause analysis to identify areas of clutter where Lean tools could be used to reduce waste. Because the project occurred on a large scale and the consequences of failure would have been unacceptable, the team conducted a pilot study on a subgroup of Midshipmen on I-Day in 2013 to ensure smooth flow and safety of the new process.

Postevent

The new process was fully implemented on I-Day in 2014 with the same data collection. Mission benefits were reassessed. Financial benefits were reassessed using number of staff members required as a proxy.

Validate

Process control was calculated using capability indices that measure the probability (p) of an event occurring outside the upper and lower specification limits set at 30 minutes and 1 minute, respectively. We used significance levels of capability (Cp) > 1.33 and capability index (Cpk) > 1 to indicate a controlled process. We used the capability indices to calculate a corresponding sigma level and DPMO (Minitab Statistical Software; Minitab, State College, Pennsylvania). Upper and lower control limits were set at 3 standard deviations above and below the mean. The team recorded and archived all process documents and results. New standard operating procedures were created and documented for future cycles. The team presented project success to the command's Executive Steering Committee.

RESULTS

Baseline

The LSS team identified inefficiencies in the immunizations delivery as the root cause for processing delays. Expected mission benefits included cycle time reduction and increased operational readiness. The expected financial benefit was a reduction in total labor hours.

The original process consisted of 12 stations with individual vaccinations at each different station. After check-in and paperwork completion, the Midshipmen had to repeat a part of the process up to six times and take an average of 920 steps to complete the process. Baseline measurements from 2012 (Fig. 1) shows an average immunizations lead time of 54.78 minutes per Midshipman. Secondary metrics revealed a total processing time for all Midshipmen to be 6 hours, 96 staff members were required to work the evolution, and six stations were doing nonstandard

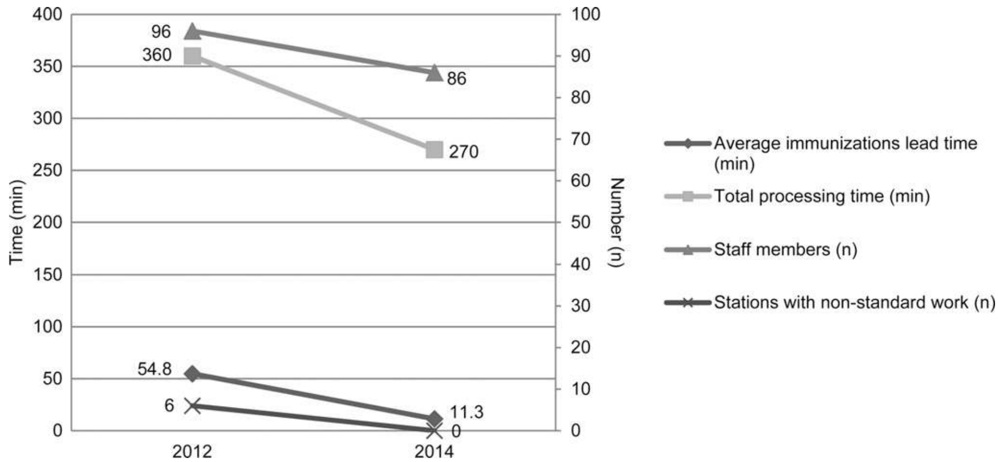

FIGURE 1. Comparison of baseline (2012 I-Day) and postimplementation (2014 I-Day) metrics.

work. Improvement goals were set at less than 30 minutes lead time, less than 5 hours total time, decrease to 86 staff members, and no stations with nonstandard work, respectively.

The value stream map revealed a hidden factory caused by having too many immunization stations (Fig. 2). Root cause analysis revealed additional issues such as lack of standard instructions, inadequately oriented staff, Midshipmen confusion with movement through the evolution, and staff members' confusion on where to get supplies. Because staff members did not receive training beforehand, each station was set up according to personal preference. The variation in vaccine delivery made it difficult for shift turnover and coordination of supplies. Midshipmen were frustrated with the amount of time waiting in multiple lines and the redundancy of information repeated at each station.

Implementation

The patient flow and process map were redesigned (Fig. 3) to create a one-way linear flow so that all six vaccinations were given at one station. The team rebuilt the immunization station using 5S (sort-straighten-scrub-standardize-sustain). All supplies were placed in one box with checklists issued to each station. Visual management reinforced the new flow with physical barriers and use of arrows. A large sign placed at the first station explained all the required paperwork. Education on immunizations was also delivered at this time. Prohibition of other reading materials ensured full attention from the Midshipmen.

The team created standard operating procedures on station setup, vaccine delivery, and protocol for replenishing supplies. All staff members received training before working at their stations.

Improvements

During its first implementation on I-Day 2014, the new linear process consisted of 5 lines and decreased the number of steps down to 226 (75% improvement).

The average immunizations lead time per Midshipman decreased to 11.3 minutes (79% improvement) (Fig. 1). Secondary metrics showed a decrease in total processing lead time for all Midshipmen to 4.5 hours (25% improvement), a decrease in staff members assigned to work the evolution to 86 (10% improvement), and a decrease in the number of stations with nonstandard work to 0 (100% improvement).

Validation

A capability histogram showed that all time points fell within the specification limits of 1 and 30 minutes (Fig. 4). The data points were calculated to be statistically significantly different from a normal distribution (p = 0.029), but visualization of the histogram revealed an appropriate distribution. The difference was attributed to a single outlier data point, and consultation with our command Black Belt determined that a normal capability model was still appropriate. The process had a Cp of 1.66 and Cpk of 1.18. This would equate to a DPMO of 475.9, corresponding to a defect rate of 0.04%. The individual control chart (Fig. 5) shows only 1 data point above the upper control limit at 22.4 minutes, which was attributed to an adverse reaction that required additional medical attention.

DISCUSSION

This project demonstrates the effective application of the LSS methodology to engage a multidisciplinary team to improve a medical care delivery process. The team discovered that lack of standardization led to untrained staff members, long hours spent waiting in line, and redundancy of information given. The LSS methodology provided the tools necessary to standardize the immunizations process and reorganized the process from 12 to 5 stations. The team was able to reduce the immunizations lead time by 79% and decrease staffing by 10%. Although these results did not reach Six Sigma level, they reached just below Four Sigma with a defect rate of 0.04%, translating to less than one Midshipman per year

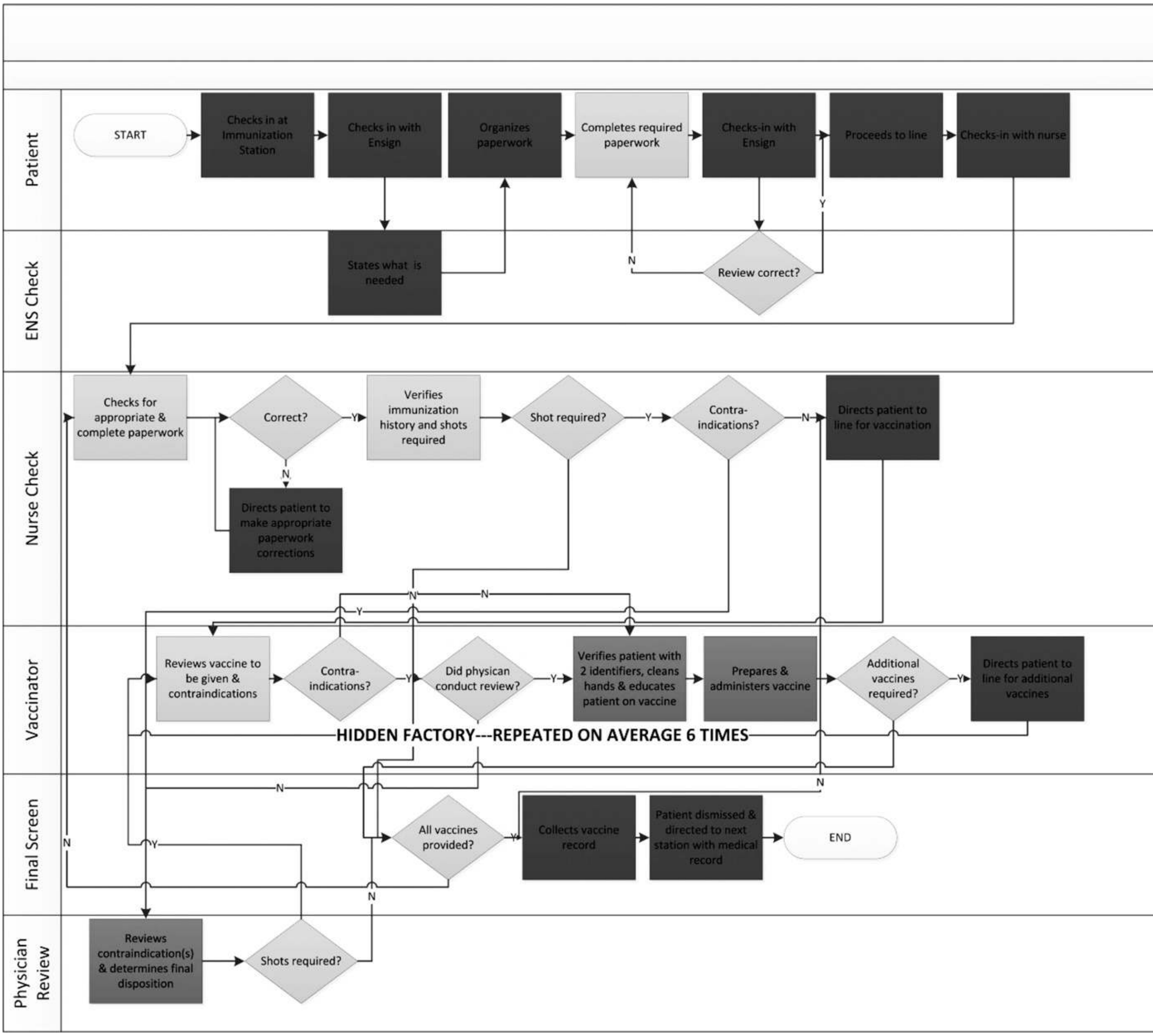

FIGURE 2. Baseline process map with overlying value stream analysis (dark gray = nonvalue-added step, gray = value-added step, light gray = nonvalue-added but necessary step).

who would take longer than 20 minutes to complete the immunizations evolution. In the health care industry, this is a clinically acceptable outcome.

The LSS methodology is becoming an increasingly popular strategy for improving health care processes and outcomes, but many health care organizations have a difficult time translating this manufacturing improvement process to the health care setting. Several literature searches surveying Lean and Six Sigma articles in health care found few projects that completely used all the tools or reported the Six Sigma level.[6,13] Our project contributes significantly to the current knowledge because it shows a statistically significant improvement with thorough application of the LSS methodology. A key aspect of our success was the narrow scope of our project. Setting attainable goals allowed the team to have realistic expectations and make sustainable changes.

Limitations

The two biggest limitations to this study are the human factor and the small sample size. Nearly 1,200 Midshipmen went through the immunizations station, but only 49 data points were taken. This caused the single outlier to have an impact on the normal distribution of the data set. However, this highlights a significant limitation in the application of LSS to the health care setting. Contrary to manufacturing processes, substituting humans as the product often introduces

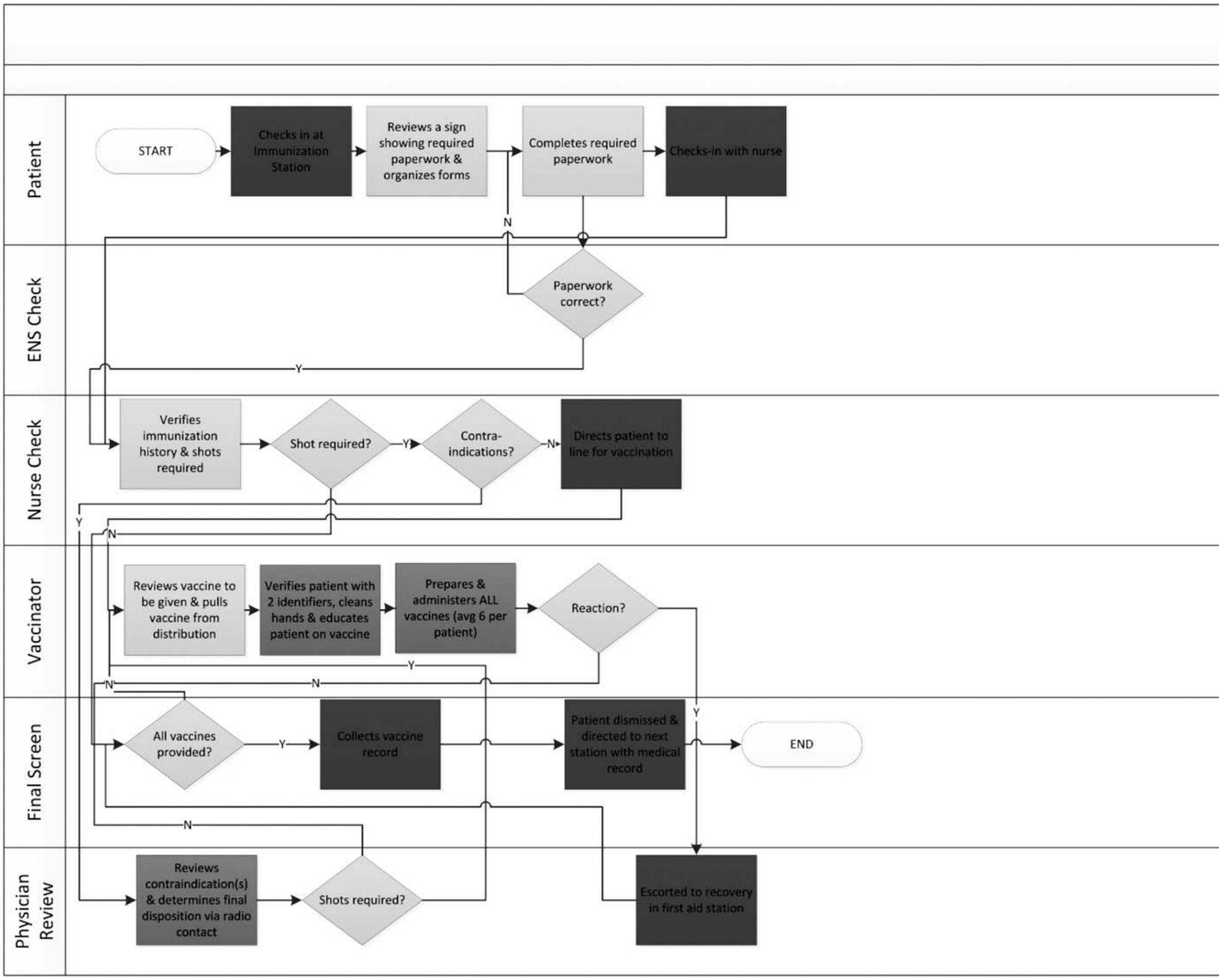

FIGURE 3. Postimplementation process map with overlying value stream analysis (dark gray = nonvalue-added step, gray = value-added step, light gray = nonvalue-added but necessary step).

uncontrollable biological factors. In this study, the outlier was due to an adverse reaction to the vaccine, which is essentially unpredictable[14] and not caused by an error in vaccine delivery. Because adverse reactions are unavoidable in large-scale processes such as this one, we included those events in our process map and kept that data point in our analysis to create the most accurate interpretation of our results. Collecting more data points may have mitigated this human factor, created a more normal distribution, and resulted in a higher sigma level of control.

Another limitation is the lack of a control group. Randomized controlled trials of a medical delivery service can be difficult to execute because of increased complexity. Our study was particularly transparent to our customers, and greater dissatisfaction would be generated if one group clearly experienced decreased waiting times compared to the other group. It would also be difficult to execute an interrupted time series study because of this event's infrequent occurrence.

As with all LSS projects, our staff members are possibly subjected to the Hawthorne effect of performing better when they know they are being assessed. However, by collecting data points during every cycle and openly discussing the results, staff members will be motivated to perform well every time.

Future Opportunities

LSS projects offer the benefit of continuous assessment and improvement after each iteration. We already see several opportunities to refine this process for future I-Days. Most notably, the number of staff members should continue to decline as our process remains under control. Although we suspect the number of staff members could have been reduced further than 10%, we did not want to overreach

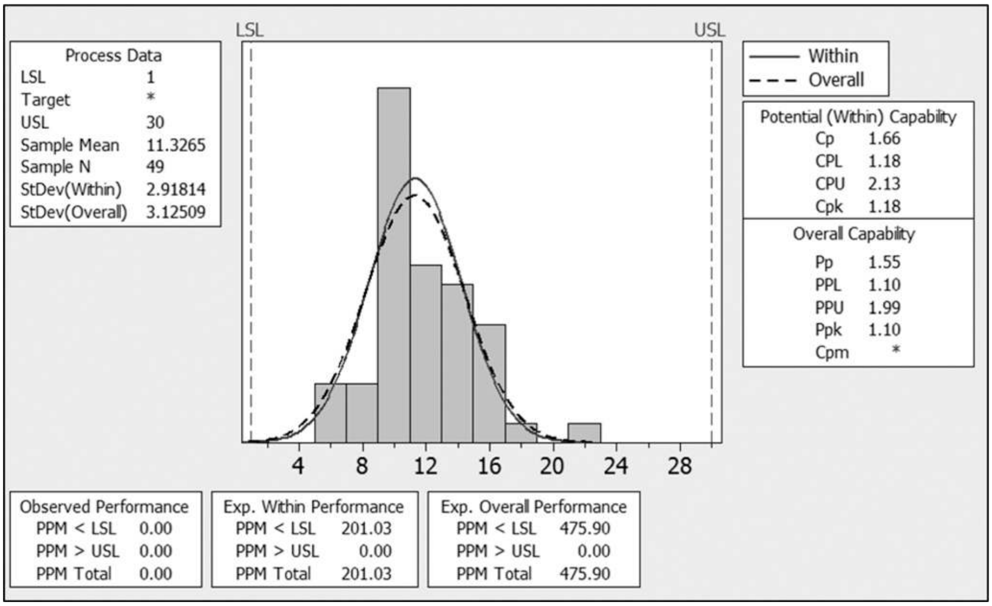

FIGURE 4. Capability histogram of postimplementation immunizations lead time per Midshipman. LSL = lower specification limit (1); USL = upper specification limit (30); Cp = 1.7; Cpk = 1.2; PPM = parts per million (475.9), which is equivalent to DPMO.

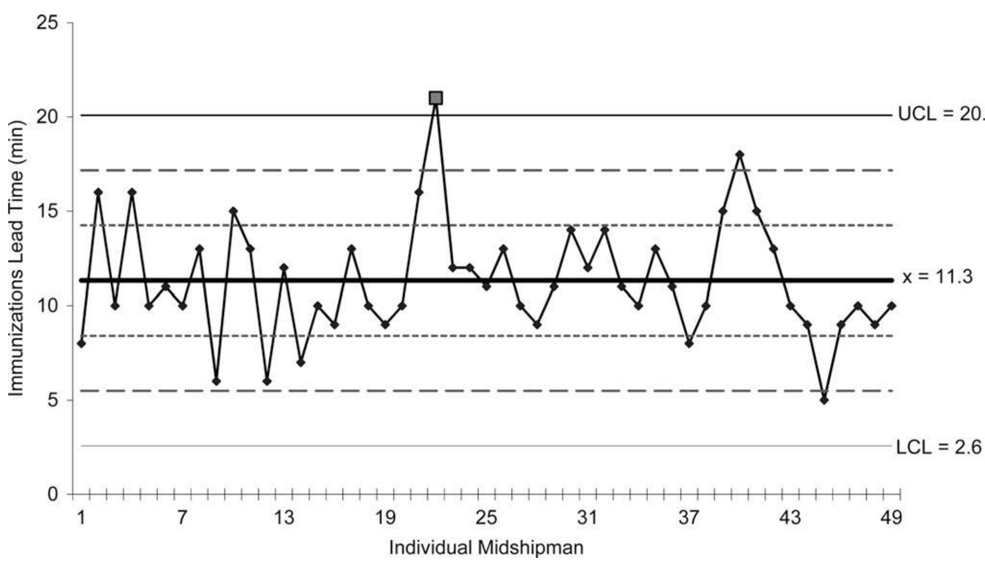

FIGURE 5. Postimplementation control chart showing individual immunizations lead time per Midshipman. UCL = upper control limit (20.08), LCL = lower control limit (2.6), x = average (11.3).

our goals and compromise patient safety. Now that we have demonstrated success in full implementation of the new process, additional adjustments can be made for future iterations. It would also be interesting to create a separate time model for Midshipmen who experience adverse reactions, which would require a much greater sample size.

This methodology requires more time and cost investment than other quality improvement strategies because of its extensive training of Green and Black Belts. Cost savings would be difficult to measure because of the undefined number of projects that each Green and Black Belt might complete, but a cost-benefit analysis showing positive net benefits would support increased use of this methodology.

The success of our study could be applied to other mass immunization settings, such as at military recruiting commands, and it would be interesting to see if similar improvements could be achieved. This methodology itself could be applied to almost any other health care delivery process. Previous studies have addressed issues such as delays in operating theater starting times,[3] reducing hospital readmissions,[15] and reducing emergency room waiting times.[16]

CONCLUSION

This study successfully utilized the tools and strategy from LSS methodology to identify and improve the root causes of inefficiency in a mass immunizations process. It led to a 79% decrease in the average lead immunizations time. LSS methodology can be effectively applied to the health care setting to make sustainable changes if used correctly and completely.

ACKNOWLEDGMENTS

The authors would like to thank the Lean Six Sigma Project Champion CDR Pamela Krahl, MC USN. The authors would also like to thank the team members for their participation in project design and implementation: Cindy Williams, RN, BSN; Sherri Davis; and HN Tyler Page.

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