Diversity and Inclusion Committee

Applied Without Insight, Lean Six Sigma Adversely Affects ED Flow and Health Care Quality

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Hospitals, insurers, and corporate group practices have used Lean Six Sigma methodology for years to improve patient safety and financial performance, with an increasing emphasis in recent years on simply maximizing revenue. However, applied without the required attention to ways in which health care differs from other service industries, the approach can undermine the value it proposes to capitalize on: the health of the patient. Application of Lean Six Sigma concepts to the delivery of medical care requires deeper insight and customization of these concepts or the goal of improved health outcomes will not be realized.

The term Lean Six Sigma combines two, well-known, business improvement principals aimed at performance: lean manufacturing (taken from the Toyota Production System), to remove waste and inefficiency, and Six Sigma (taken from Motorola and GE), to reduce variation and error. Some aspects of Six Sigma, a way to measure and reduce defects in the manufacturing, were directly transferable to reduction of errors and improving consistency in medical operations such as the ordering and administration of medications. The well-known landmark Institute of Medicine report of 1999, "To Err is Human: Building a Safer Health System," described the dire need for approaches to improve accuracy when performing straightforward tasks such as physician orders and delivery of medications. Reducing errors using checks and balances pioneered in Six Sigma, including confirming correct surgical sites, urgently needed addressing and saved lives almost overnight. Not surprisingly, these changes improved satisfaction as outcomes improved immediately.

However, Lean Six Sigma business strategies aimed at increasing revenue by improving production require more consideration to apply safely in health care. Any series of activities can be analyzed in the interest of increasing measurable steps to improve production and flow. This concept can be applied in a clear-cut manner when the goal is the sale of physical products or other uncomplicated services. But there are fundamental differences not shared by other industries in health care. For instance, higher sales and consumer expenditures do not correlate favorably health outcomes or patient satisfaction when measured in context. Health care business leaders, often focus disproportionately on metrics such as speed and quantity to gauge the success of operations which may lead to critical errors when applied to health care delivery.

Emergency physicians seeing patients, rather than managing operations, typically prioritize focus on health outcomes and prudent utilization of scarce resources. Although, they may be financially incentivized to increase production to a lesser extent than managers, they recognize markers of performance other than patient turnover. They understand the relationship between patients and health is unlike any other customer product relationship. However, these clinicians also introduce variation into process improvement measures. I suspect the internal conflict this dynamic causes is a significant contributor to what has erroneously been termed "physician burnout," and a source of waste antithetical to Lean Six principals.

Lean Six Sigma can be applied more usefully to improve health given a more considered approach. Currently, the focus on short-term returns, like immediate customer satisfaction based on attention to environment and entertainment (TV in every patient room), food and liberal use of narcotic pain medication as primary measures of performance, is a risky proposition applied indiscriminately. Care quality, when weighted too heavily towards a patient's comfort, rather than more focused on clinical effect, is not only wasteful, but irresponsible. Quality medical care requires that clinical interpretation and professional judgment supersede the immediate subjective preferences of patients as consumers. Moreover, the role of clinicians is not equivalent to salesman in other industries: as educators their opinion needs to be valued more highly in the context of the goal. If hearsay suggests clear coat does not protect your vehicle and you should forego the option, this does not equate to recommendations regarding vaccination. The issue of vaccines being flawed due to an unproven association with behavioral illness requires educated physicians, nurses and researchers to keep the world's population safe by valuing the time required to clarify the issue. This difference must be recognized and factored into applications of Lean Six to health care.

Caution must be taken to balance the business goal of improving the quarterly bottom line against long-term health outcomes. There is a risk in paying incentives to physicians and others in leadership interpreting Lean Six Sigma in unsophisticated ways. For example, equating patient satisfaction with speed of care and then prioritize it over clinical judgment, is a deeply flawed approach. Research increasingly supports that, current high satisfaction ratings from patients most often require they receive health care in excess of that provided the rest of the population. This leads to overmedication and avoidable hospitalizations which not only result in higher cost but poorer outcomes.[1] It represents a massive conflict of interest and should be reason enough to re-evaluate our current

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unexamined approach. Alarmingly, more satisfied patients suffer death at a higher rate than their less satisfied counterparts. By tying compensation to the wrong patient satisfaction indicators, our health care system is not only failing to realize the stated goal of improving patient safety and health, it is violating a primary tenet of medical care: "first do no harm."

The need for Lean Six Sigma methodology to be clinically informed by trained ethical leaders could not be more urgent. Process and quality improvement by identification using root cause analysis (RCA) helps reduce medical errors quickly and efficiently. However, losing levels of sophistication in medical assessment in order to simplify a process and increase turnover may both increase revenue and harm patients. We should be sensitive to the fact that continuous quality improvement (CQI) can easily stray from the primary goal of realizing improved health outcomes. For example, what happens when CQI analysis of a case is tainted by the desire to support an initiative that is financially favorable to the operation?[2]

Unexpected deaths typically trigger departmental chart review as part of CQI with the goal to uncover RCA. But what if the cause of death is unclear and leadership is interested in finding justification for increase in use of trauma consult services? Consider the following fictional example. Hospital trauma services are struggling to justify maintenance of Level 1 services and have pushed emergency services leadership to reduce under-triage to less than 1% and recommend 100% consultation on all trauma cases along with pan-scanning with CT. Higher utilization of services, would, after all, improve revenue and appear to increase safety. We can all imagine a case such as this: A patient presents to the emergency department alert and oriented but with mild lethargy immediately following a head injury and denies other injuries. No other injuries are found or documented on physical exam. Initial CT of the head and C-spine show no evidence of acute trauma, however Neurology is consulted immediately and explain mild alteration in mental status as due to concussive injury. The patient is transferred to the floor but becomes increasingly confused, lapses into coma, aspirates and has a cardiac arrest. After a prolonged resuscitation attempt, including extensive chest compressions, there is no spontaneous return of pulses. A middle manager in charge of CQI reviewing the case a couple of weeks later concludes based on the autopsy report including evidence of chest injury that the critical error occurred at presentation: failure to recognize traumatic chest injury and call for surgical trauma team evaluation of the chest. This, in turn, results in justification for pushing an agenda aimed at higher rates of trauma surgery consultation for chest trauma. The critical error in the RCA: the chest trauma is temporally out of sequence as it was actually caused by the resuscitation attempt rather than injury prior to arrival. Clearly, objectivity was compromised by confounding factor of external agenda.

Several factors, in fact, contributed to the incorrect assessment in this sample case. They include a hierarchical structure of leadership that put management agenda ahead of careful analysis of timeline, insufficient knowledge of medical care and perhaps the relative inexperience of the safety officer. The erroneous conclusion that the trauma team would have caught the chest injury and saved the patient's life is both wrong and misses the opportunity to educate the neurology team on the need for more aggressive evaluation of traumatic brain injury (TBI).[3] Correctly identifying the presentation of TBI might have resulted in recognizing required emergent MRI, intubation and ICU admission earlier in the patient's course. The case also illustrates a real observation made by other medical professionals about migrating practices from other safety critical industries to health care: the underlying principle must be customized to the level of sophistication required to explain the outcome. Application of RCA to CQI requires consideration of the danger of allowing external agendas to cloud the judgment of managers.

As for applications of business processes more focused on Lean concepts from manufacturing and production, the devil is in the details. Improving throughput and eliminating wasted time required for processing patient care, such as at patient registration, can decrease time to patient bed placement and reduce time to physician encounter with patients. However, what happens when the staff becomes more beholden to patient tracking boards and focus on identifying and addressing time stamps rather than patient needs? In fact, we all know staff learns to game electronic tracking systems to appear to be performing at the required level. Some clinicians, click on a patient icons significantly before seeing a patient, or charge nurses place patients in a room virtually that are still in triage. The tracker can become a fictional representation of reality and not represent actual ED flow, while hiding inefficiencies and waste they were created to eliminate.

Early patient testing and evaluation can expedite flow when the method is applied selectively and wisely. However, operations cannot be streamlined when upfront testing is applied blindly. Instead of decreased throughput times, flow is decreased due to over-utilization. Selective point of care testing, on the other hand, is useful to this end. Testing all patients liberally without a clear indication backs up scarce resources and slows the overall time required for safe efficient care. Responsible leadership balances such initiatives with what provides advantage for all stakeholders, rather than thoughtlessly push indiscriminate testing of all patients. Middle managers incentivized to follow protocols, unquestioningly focused on meeting bonus metrics, rather motivated by protecting all stakeholders, threaten to destroy the industry if not the profession. No priority should pre-empt the patient's best interests in a drive for remuneration for performance if for no other reason than it increases risk and adds, rather than removes, inefficiency and waste to the system.

Patient flow is often targeted for Lean method application without full consideration of the goal. Increased throughput efficiency brings patients to the point of requiring hospital admission, but where do patients go when inpatient beds are not available? This is a long recognized problem throughout U.S. hospitals, but is underappreciated cause of health inequity. Frequently, limited ability to hire staff takes precedence over actual hospital bed availability. In the case of safety net hospitals, economic constraints limit the ability to address bottlenecks, leading to increased patient hold times. Often reduction in wait times on the front end in the waiting room triage is all that is addressed in the ED, while the so called blocked back door is allowed to persist. Some hospitals attempt to create a work-around such as creating a holding area in an ED Annex, but run up against the same limitations in bed availability on the in-patient floors: nurse staffing. These constraints negatively impact safety net hospitals disproportionately as they have tighter budgetary constraints. Beyond that, often the same hospitals are overburdened by hospitals closings,

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as will be the case in the DC Metro area this year with the closing of Providence Hospital. A universal application of Lean concepts would consider the critical need to make patient admission to the hospital a pre-eminent concern rather than push the burden towards holding areas that would meet criteria for emergency services performance but not be the best interests of patients.

Next, Lean Six Sigma methodology is frequently applied by leadership to doing more with less. Management often makes the case that the quickest and best way to reduce cost is by requiring increased productivity while simultaneously decreasing salaries. As administrators are rewarded with bonuses for achieving these benchmarks, employees, in this case physicians and nurses, are essentially incentivized to price themselves out of a job, also increasing the stress burden referred to a as burnout. In fact, when work force supply and demand equation is favorable to management, it does lead to lower cost. However, less experienced, less qualified clinicians deteriorate the quality of the product. This is, of course, not in the best interest of patients as consumers. Moreover, inexperienced clinicians would be less likely to challenge leadership, reducing internal oversight. An extension of this case might be made for increasing non-physician and non-nurse clinicians penetration and entice them to practice beyond their scope or experience. While these providers can expedite routine care of low level complexity, it would be inconsistent with reaching for ideal Lean Six Sigma performance levels to introduce more potential error into the system. Insisting lower-salaried caretakers evaluate increasingly medically complex cases is counter to the ultimate goal when Lean Six is applied wisely and should at minimum require transparency regarding level of quality.

Lean Six Sigma applied to health care in an informed manner requires practically experienced clinicians with undivided attention to the goal of achieving health in the best interest of patients. If a trained medical professional sees no indication for testing or consultation, using an untoward outcome to justify the increased utilization of those services, will bankrupt the system and still not help patients. A similar case can be made for any intervention with no proof to support their efficacy over time. The oversimplified objective to increase revenue by defaulting to defensive practice adds cost without benefit and will eventually deteriorate the value of service. We can easily imagine the conflict of interest caused by creating fear of reprisals to require clinicians to use needless services as a condition for continued employment. Physicians and nurses know that one incomplete chart in a patient with a poor outcome can be used against them, particularly if that professional tends to advocate for patients and invest time in unrecognized added value activities. Who better to recognize value than experience clinicians working in the trenches?

Health care corporations that continue not to adequately value patient contact time are missing an important opportunity. At one time the physician-patient and nurse-patient relationship was an unquestioned value, and the engendered trust generated satisfied patient customers more often. Prudent health care leaders should require that clinicians be valued for the quality of contact with patients. As noted above, that quality of care should be based on more than patient satisfaction. The Lean Six Sigma Tool known as DMAIC (Define, Measure, Analyze, Improve and Control) is commonly used for data-driven improvement and could be applied to value the quality of patient contact time and outcomes, over reproducibility and revenue cycles. This certainly merits discussion if only to highlight the competing interests of various stakeholders in the equation and what should be the ultimate objective of a health care system: improving health.

Limitation of physician or nurse activities for health care delivery may reduce variance, but it may simultaneously reduce autonomy and incentive to advocate for what is in the best interest of patients. We may fail to identify new causes of poor outcomes and accurate root causes of poor health states. Such steps would not be expected to have an immediate impact on improving the bottom line, but as actual health states improve, patient consumers can be expected to correlate the result of care with a higher value provider. Protocols used to enhance reproducibility may be out-competed by an allowance for professional judgment to protect the best interests of the individual. They may well begin to appreciate an organization that is willing to deviate from protocol and offer patients a higher value at a lower cost. As physicians have less flexibility to advocate on behalf of their patients, there is less attention given to the efficacy of expensive procedures or alternative interventions. The needs of economically disadvantaged patients, especially those struggling with mental disease or drug addiction, are often not factored into the equation, under the assumption that "no margin, no mission." There is no excuse for taking a more considered approach to tailoring care to needs of the entire spectrum of the population.

A final consideration to broadly applying Lean Six Sigma across the health care industry without a global considered approach: negative impact on health inequities. There is an ever-increasing chasm growing between billing and collections limited by payer mix of a particular catchment area for a hospital largely determines ability to drive revenue as the system is conceived now. As technology, services, interventions, usage and billing increase along with revenues for private services, the ability of underinsured populations and public insurers to cover costs is increasingly impossible. The economic competitive advantage the methodology offers to large, affluent for-profit hospitals and health care systems, deteriorates competition as fewer hospitals whose mission it is to serve the underinsured can stay afloat. Prudent application of these methodologies would allow all the entire health care system to remain competitive, as quality would be based on outcomes and value lower cost care.

All of these considerations are why it is a much more complex proposition to apply Six Sigma principles when the "product" is the health state of a human being. An unbending, formulaic approach to becoming Lean and unconsidered implementation of Six Sigma method is not in the best interest of patients. We must recognize the universe of difference between manufacture of even the most complicated of machines versus the delivery of health care. A great deal can be remedied by valuing the resource that are trained medical professionals that have direct contact with patients and reward their ability to connect what should be the goal of the operation: patients' best interests. If the trend towards rigid oversimplification of the methods is not modified, we can expect to continue to reap short term financial reward along with professional burnout and poorer health outcomes until the system ultimately fails. We will see quarterly earnings rise only until then, while in the long term goal, human health and the beauty of what was once a noble enterprise will continue to deteriorate. ●

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- Open positions: At-Large Board Member (five positions) and Young Physicians Section Director

www.aaem.org/elections

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www.aaemrsa.org/about/leadership/elections

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www.aaem.org/CCMS

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