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Six-Sigma And Lean Thinking in Healthcare: A Comprehensive Literature Review And Critical Assessment

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Abstract:

Purpose: This paper undertakes a comprehensive review of the literature on six-sigma and lean thinking in healthcare as the basis for critically evaluating current success in their deployment in the healthcare industry.

Design/methodology/approach: A reasonably exhaustive search of the literature was undertaken. This search targeted both research on six-sigma and lean thinking and specific research on six-sigma and lean thinking in healthcare.

Findings: Five conclusions emerge from the review. First, the measurable impact of six-sigma and lean thinking on the quality, cost, responsiveness and efficiency of healthcare organizations as evidenced by the results reported for improvement projects is modest, at best. Second, six-sigma and lean thinking improvement projects have targeted a very limited range of areas. There is no evidence of attempt to evaluate the extent to which these improvement were long lasting or permanent. Third, the improvement projects uncovered by our literature review generally leave untouched the core technologies, practices and methods of medical practice and delivery of healthcare. This means that none of the cases reported targeted or achieved the deep and permanent culture change that is the sine qua non of six-sigma and lean thinking implementation. Fourth, we uncovered no case of a healthcare organization that can be said to be prototypical six-sigma or lean thinking one of the calibre of Toyota Production System (TPS) or GE Capital. Finally, our research found no systematic attempt to build a theory of healthcare service delivery processes/operations. Such a theory is a pre-requisite to the systematic adaptation of six-sigma and lean thinking in these organizations.

Originality/value: First, this research has documented the state-of-the-art on the deployment of six-sigma and lean thinking in healthcare. Such documentation is the first step in any systematic effort to identify areas where progress has been made as well as avenues for further research. The review demonstrates that very little systematic deployment of six-sigma and lean thinking in healthcare has been achieved and that the field of research is fundamentally wide open. Second, the review provides rather conclusive evidence that pronouncements to the contrary, the broad applicability of six-sigma and lean thinking, as these paradigms were originally conceived of and as they are currently used to guide research in healthcare, is far from established. Third, the very weak results of research undertaken thus far speak rather forcefully to the need to make radical change in the six-sigma and lean thinking paradigms to make them applicable to healthcare organizations. Fourth, the identification of a need for a theory of healthcare organizations may prove to be significant for the deployment of six-sigma and lean thinking in healthcare.

Introduction

In the United States, healthcare costs are rising at a rate that is much higher than the core rate of inflation and is consuming an increasingly larger share of GDP. Of the thirty-one developed countries, members of the OECD, the US is the only one without universal healthcare insurance.

Nearly every serious report on the state of healthcare in the US paints an unfavourable picture. The Institute of Medicine report in 2000 estimated that as many as 98,000 deaths occur annually as a result of avoidable mistakes and errors, and that these errors and mistakes result in unnecessary healthcare costs of the order of $3.6 billion (Institute of Medicine, 2000). That report focused attention on healthcare quality and cost as an issue of national importance, and led to frenetic activity on the part of a number of healthcare organizations to look for solutions for what is obviously a critical quality problem. Many organizations settled on six-sigma/lean six-sigma. A follow-up study to the Institute of Medicine 2000 report released in 2010, showed that there was virtually no change in the fundamental findings of the 2000 report. These new data imply that few, if any, healthcare organizations are operating any where close to the six-sigma benchmark of 3.4 Defects per Million Opportunities (DPMO). There appears to have been no change in the measureable quality performance of the US healthcare delivery system and that it is still operating at the 2-3 sigma level.

Thus, twenty-six years after Motorola invented six-sigma and a fair number of manufacturing companies are approaching the six-sigma benchmark while a few service companies are progressing towards six-sigma quality, the healthcare system has been unable to use six-sigma methods to effect significant improvement in healthcare quality and cost. Through a comprehensive literature review, this paper will attempt to understand the reasons for this state-of-affairs.

WHAT IS LEAN THINKING/ SIX-SIGMA?

Lean Thinking:

As early as the late 1960s to early 1970s, it started to become clear to Western observers that for Japanese manufacturing, quality improvement is viewed as a critical driver of lower cost. That philosophy was operationalized the Toyota Production System, TPS. The handbook on TPS was first published in English in 1972, and its key elements were accurately documented in a series of publications by Taiichi Ohno (1988). The concepts and methods of TPS were referred to variously as Lean Systems, Lean Thinking or Lean Methods (Womack and Jones, 2003). It must be emphasized that although the Western conceptualization of TPS almost single-mindedly focuses on the efficiency, cost and time compression aspect of it, TPS is as much concerned about driving quality up through systematic defect removal as it is about driving efficiency up.

The perpetual pursuit of operational excellence is the distinctive characteristic of TPS. In TPS, Toyota found ways to nurture core competencies appropriate to the pursuit of operational excellence, to redefine and broaden its boundaries and to raise the bar of performance. Most importantly Toyota learnt to define, view and manage the pursuit of operational excellence as a crucial mission of competitive strategy (Wheelwright, 1981).

TPS created a new paradigm, that is, lean thinking, but the core idea of TPS, the relentless pursuit of efficiency, cost reduction and time compression in the production/operations and supply chain system as a key driver of long term competitive advantage, emerged at Ford Motor Company some fifty years prior, and that fact was underscored by none other than the father of TPS himself, Taiichi Ohno (Ohno, 1988). But the single-minded obsession with the efficiency, cost and time compression aspect of TPS by management thinkers means that management theory and practice missed, at the very onset of the Western adoption of lean thinking, what is a most crucial point. Quality and lean (efficiency) are entirely compatible, and maximum strategic advantage can be derived from both if they are explicitly managed to exploit synergy between the two (Etienne, 2005a, 2005b, 2009a). That concept is deeply embedded in Ford's vision of lean. (Ford and Crowther, 1926).

Six-Sigma:

Six-sigma research and implementation suffers from a severe problem of nomenclature. Some use six-sigma to refer to the DMAIC problem solving process adopted by six-sigma thinking from classical management theory and popularized by six-sigma pioneers (Motorola) and early adopters (GE) (Welch, 2001). In other cases, six-sigma refers to the unique team structure and definition and allocation of project management and execution responsibility adopted by Motorola. Still others use six-sigma to refer to any reasonable set of management actions that aim at continuously improving quality, reducing defects and costs on some sustainable basis, and which deploy any number of the set of quality analysis tools, quantitative or otherwise, borrowed by six-sigma from quality management and other technical disciplines. As used by that latter, six-sigma is not more than a new way of communicating classical quality management methods.

Very few view six-sigma holistically, as a complete set of statistical and qualitative concepts, fundamental tools of managerial analysis, and a problem-solving process driven by a philosophy of quality improvement, and all resting on a foundation of culture and values. In a holistic view of six-sigma, the foundational culture and values are paramount because they provide the energy to relentless drive defects out of the production process until the benchmark six-sigma metric of 3.4 DPMO is attained and surpassed (Etienne, 2002, 2005a, 2005b, 2008, 2009a, 2009b, 2010a, 2010b, 2011a, 2011b).

Six-Sigma: the Statistical Concept: It is a logical extension of Statistical Process Control, (SPC) which is rooted in the work of the early quality pioneers. The central idea behind SPC is that although variation is present in any process, it can be modeled using statistics and that such modeling is essential to understanding, control and reduction of variation (Shewart, 1931; Deming, 1982; Taguchi, 1986; Taguchi and Clausing, 1990).

Six-Sigma: Management Process: The second dimension of six-sigma is the management process through which the statistical concept and other supporting tools are deployed (Pyzdek, 1999; Etienne, 2002; 2005(a); 2005(b); Harry and Schroeder, 2000). Six-sigma is substantially about understanding and improvement of a process as a means of dramatically reducing defects.

The six-sigma management process includes some or all of the following aspects; 1. Core Principles through which a perpetual improvement process is created and maintained (Deming, 1982; Juran, 1986; Crosby, 1979; Taguchi, 1990) 2. Six-sigma improvement method, 'Define, Measure, Analyze, Improve and Control' (DMAIC) (Eckes, 2001; Harry and Schroeder,2000); 3. Eight steps to process improvement of Business Process Re-engineering (Eckes, 2001; Davenport, 1993; Hammer and Champy,1993); 4. Benchmarking process (Camp, 1989; Eckes,2001; Harry and Schroeder, 2000); 5. Six-sigma team deployment process (Eckes,2001; Mikel and Schroeder, 2000).

Six-sigma Improvement Tools and Techniques: Six-sigma has adopted all the proven tools of quality improvement. These include Pareto charts, cause and effect diagrams, Ishikawa diagrams, Failure Mode Effect and Criticality Analysis (FMECA), Quality Function Deployment (QFD), Poka-Yoke devices and Taguchi methods, the quality improvement story. (Shingo, 1986; Ohno, 1988).

Six-sigma: Foundation Culture and Values: The drive to push quality to benchmark levels is energized by a solid foundation of culture and values. These include 1. Deeply embedded Organization wide customer consciousness; 2. Passion for quality; 3. High value on human resources; 4. A perpetual search for improvement or Kaizen; 5. High value placed on experimentation and innovation; 6. Strong competitive spirit; 7. Deep, mutual trust woven into the organizational mindset; 8. Top management assuming leadership responsibility for quality improvement (Deming, 1982; Deming, 1986; Peters and Waterman, 1982; Peters, 1986; Etienne, 2002, 2005, 2008, 2009a, 2009b, 2010a, 2010b; Etienne-Hamilton, 1994).

The foundational culture and values of Six-Sigma have been heavily influenced by the works of Deming, Juran and Crosby, which collectively constitute the cornerstones of the TQM paradigm. The central thesis is that sustained quality improvement comes from a vigorous Policy Deployment process (Deming, 1982; Deming, 1986; Crosby, 1979; Ishikawa, 1986; Taguchi, 1986). Leading-edge companies deploy these principles through Quality Function Deployment, (QFD) culminating in Quality in Daily Work.

Lean Thinking and Six-Sigma:

Motorola explicitly invented six-sigma in an effort to reduce eliminate the huge quality advantage that the Japanese electronics manufacturers had achieved in the 1980s and which had decimated Motorola's market position. The company knew that the Japanese had a substantial and widening competitive advantage on both quality and cost, but it initially erroneously concluded that the cost advantage was due to lower Japanese labor cost. However, Motorola's initial single-minded focus on quality was the result of management thinking that even if the company had a labor cost disadvantage that would result in somewhat higher prices, the latter would be competitively defensible if quality superiority could be achieved. That thinking was also fed by the assumption, now recognized to be flawed, that higher quality can only be achieved through higher cost. So, initially, six-sigma at Motorola was not concerned about directly reducing cost, but about increasing quality measured as DPMO, to breakthrough levels.

Lean Thinking in Services:

The systematic transfer of lean thinking to the service industries started with the two seminal papers by Levitt (1972; 1976). He averred that manufacturing industries are far superior to services in efficiency because service managers manage their service delivery processes in ways that are inimical to the methods of highly efficient manufacturing. Levitt observed that the culture in many companies led managers to view service as servitude, a performance and an art-form which cannot be subjected to the scientific method. Judging the quality of service is an idiosyncratic process that is unpredictable (Levitt, 1972; 1976; Etienne, 1987; 2002a; 2002b; 2005a; 2005b; 2010; 2011).

Thus, creating lean systems required the implementation of four key ideas; 1. Define the service delivery task in terms of process parameters for performing customer requirements. 2. Standardize the service offering 3. Design the service task to reduce employee discretion 4. Automate the process to the maximum extent possible. Levitt had correctly surmised that efficiency/lean and quality are facets of the same mission. But, most service companies are still measuring quality at the level of errors or defects-per-hundred-opportunities (DPHO), while six-sigma aims for error rates that are less than 3.4 DPMO. Much of service quality exists in the customer's psyche and no one has as yet found a way to measure psychological phenomena to the precision of six-sigma (Etienne, 1987; 2002a; 2002b; 2005a; 2005b; 2011). This is an enormous challenge and the proliferation of research that purports to apply lean thinking and six-sigma concepts to services have not proposed credible ways to deal with it.

Lean Thinking in Healthcare: Spear provides the definitive statement on application of lean thinking to healthcare. He proposes that the capacity of a company to achieve operational excellence similar to TPS, depends on mastery of four organizational capabilities; 1. Work is designed as a series of ongoing experiments that immediately reveal problems; 2. Problems are addressed immediately through rapid experimentation; 3. Solutions are disseminated adaptively through collaborative experimentation; 4. People at all levels are taught to become experimentalists (Spear, 2005). This is the core of TPS and lean thinking. Spear avers that its application to healthcare can have dramatic impact on the efficiency and effectiveness of healthcare delivery and makes the case as follows; "The Centers for Disease Control (CDC) in the US cites estimates indicating that bloodstream infections arising from the insertion of a central line (an intravenous catheter) affect up to 250,000 patients a year in the United States, killing some 15% or more. The CDC puts the cost of additional care per infection in the tens of thousands of dollars. Yet, two dozen Pittsburgh hospitals have succeeded in cutting the incidence of central-line infections by more than 50%; some, in fact, have reduced them by more than 90%. Rolled out throughout the U.S., these improvements alone would save thousands of lives and billions of dollars." (Spear, 2005).

Spear provides more cases of dramatic improvements in healthcare that have come from the application of the TPS model, and concludes that they have direct impact on safety, quality, efficiency, reliability, and timeliness of health care. His conclusion lends further support to the position we stated previously; lean systems seek simultaneous improvement in cost, time and quality. Lean systems are also quality improvement systems.

SIX-SIGMA AND LEAN THINKING IN HEALTHCARE: A COMPREHENSIVE REVIEW OF THE LITERATURE

We have classified the literature covered by our review into ten (10) categories as follows: 1. Descriptive theoretical/conceptual papers; 2. Prescriptive theoretical/conceptual papers; Empirical papers that report on one or more of the following improvement projects: 3. Improving Operating Room (OR) throughput and turnaround times; 4. Improving emergency department (ED) throughput and turnaround times; 5. Reducing other turnaround times and patient wait times; 7. Implementing standards of and increasing adherence to best practice; 6. Reducing medication errors; 8. Reducing other errors, (medical laboratory); 9. Implementing best practice in non-medical departments (inventory control and Supply Chain Management (SCM); 10. Syntheses of broad sets of empirical papers. Categories 3 to 8 were also identified in Delliframe et al. (2010).

Descriptive theoretical/conceptual papers:

The research by Feng and Manuel (2008) and Antony et al. (2007) appear to be representative of that type of research. In a survey of healthcare organizations, Feng and Manuel report that of 56 respondents, 15 or 27% were 'practicing' six-sigma, meaning that they had undertaken some improvement projects using six-sigma methodology. The mean length of time since these organizations had started using some kind of six-sigma method was 4 years.

The percentage of the total workforce engaged in six-sigma ranged from 0.05% in the case of an organization with 15,000 employees, to 4.5% in the case of an organization with 400 employees. These numbers indicate that six-sigma expertise is quite low in these organizations, particularly because they were already classified as users. That same survey found that three general areas of improvement were targeted by six-sigma projects: cycle time reduction, process flow improvement and medical error reduction. Most projects within the participating hospitals last 4 to 7 months with variations due to problem scopes, availability of data and resources. The results also revealed that many of the initial projects undertaken in most of the hospitals provide smaller but quick wins such as streamlining referrals to admissions and other clogged processes. About 60% of the participating hospitals observed that management buy-in and their uncompromising commitment at the beginning of the initiative has been a major challenge. The hospitals which are currently not using Six Sigma responded that Six Sigma is primarily for the manufacturing world. Moreover, hospitals do not have a data-driven culture and so Six Sigma is not needed. Examination of later research shows very little change from this pattern. These papers also highlighted the Critical Success Factors (CSFs) for the successful deployment of Six Sigma in a hospital setting. These are: uncompromising management support and commitment, formation of Six Sigma infrastructure and training, selection of appropriate projects, effective communication at all levels, developing organizational readiness and effective leadership.

Prescriptive theoretically/conceptually oriented literature:

Papers by Antony and Banuelas (2002), Banuelas and Antony (2002), Benedetto (2003), Caldwell (2006), Carrigan and Kujawa (2006), De Souza (2009), Ettinger (2001), Fosdick and Uphoff (2007), James (2005) and Kumar and Steinbeck (2007) fall in this category. These research reports all take off from the premise that six-sigma/lean thinking is entirely applicable to the healthcare industry, even if some authors admit that adjustments need to be made to adapt these quality and efficiency management paradigms to the few particular exigencies of healthcare delivery organizations or systems. In general, the authors aver that because six-sigma has been successfully argued to be applicable to the service industries and that it has been successfully applied to some noteworthy service organizations, one can make at least a prima facie case that six-sigma/lean thinking apply to healthcare industries as well (Kannan, 2006). In some cases, they examine six-sigma/lean thinking problem solving and improvement methodologies such as the DMAIC logic and assert that there is nothing peculiar enough about healthcare organizations that would make them not applicable to these. In other cases, they examine a broad range of six-sigma/lean thinking improvement tools and assert that these are obviously applicable to healthcare organizations because there is no inherent reason to think otherwise.

An example of this position is expressed as follows; "Health care systems have just begun to utilize lean methods, with reports of improvements just beginning to appear in the literature. We describe some of the basic philosophy and principles of lean production methods and how these concepts can be applied in the health care environment. We describe some of the early success stories and ongoing endeavors of lean production in various health care organizations. We believe the hospital is an ideal setting for use of the lean production method, which could significantly affect how health care is delivered to patients…. Hospitalists are primed to take action in delivering care of greater quality with more efficiency by applying these new principles in the hospital setting" (Kim, 2006). Yet, there is a vibrant debate within the medical communities themselves as to whether there is a sufficient degree of fit between the theoretical assumptions, methods and processes of six-sigma and lean methods and the quality, operational exigencies and cultural particularities of the typical healthcare delivery organization (Kassirer, 1998). And some are questioning whether lean thinking is applicable to services, much less to healthcare services (Seedon, 2003). Others see both opportunities and challenges for the application of six-sigma and lean methods in healthcare and counsel caution in efforts to undertake wholesale, uncritical adoption of six-sigma/lean six-sigma approaches by healthcare organizations (Natarajan, 2006;).

Antony et al. (2007) examined a set of six-sigma projects undertaken at eleven different hospital systems and the pattern of six-sigma projects appear to be similar to that identified by Feng and Manuel (2008) except that in one case, Charleston Area Medical Centre, the six-sigma project targeted Supply Chain Management for surgical supplies and resulted in reduced inventory levels and improved supplier relationships, activities that have traditionally been the focus of other improvement programs, and not that of six-sigma, methods.

Kumar and Steinback (2007) evaluated the theoretical feasibility of applying the DMAIC process through the design and improvement of a set of service blueprints, and identification of causes through cause-and-effect or Ishikawa diagrams, to reduce the incidence of medication errors to six-sigma levels in US hospitals. They assert that implementing the new service blueprint, buttressed by poka yoke devices, would likely result in improvement medication error rates to the six-sigma level, or 3.4 errors-per-million-opportunities (EPMO). Various estimates put current rates of medication errors at between 5.3% and 20.6% of administered doses, or between 1.26 sigma and 1.93 sigma.

The above papers tend to exaggerate the similarities between healthcare and other service organizations, while glossing over profound differences between services and manufacturing.

Literature Based on Empirical Evidence:

Improving Operating Room (OR) throughput and outcomes:

Some papers evaluated application of six-sigma methods to improve Operating Room outcomes (Does et al., 2009; Shukla et al., 2008; Thiele et al., 2008; Fairbanks, 2007; Griffin et al., 2007; Leslie et al., 2006; Adams et al., 2004; Cima et al, 2011; Welch, 2002). The six-sigma projects reported on typically identified some factors that drive OR throughput such as adherence to OR cleaning best practices, deployment of surgical masks and helmets, ambiguous staff assignments, and development of complete case charts. None examined the impact of six-sigma on core surgical methods. Thiele et al. (2008) evaluated a set of operating room practices in an effort to identify which of those would stand up to a rigorous analysis based on the six-sigma methodology. They conclude that there is no empirical data to support the use of either surgical or exhaust helmets during surgery and laminar airflow systems cannot be supported outside of spine surgery. Moreover, pre-warming for at least two hours prior to surgery, and forced air or resistive blanket warming during surgery should be employed routinely.

An ambitious initiative was launched in the Australia. (Ben-Tovim et al., 2008; O'Connell et al., 2008a; O'Connell et al., 2008b; MacLellan et al., 2008; Ben-Tovim et al., 2007). It covered ninety-six hospitals over three years. Improvement projects targeted both OR and ED care. The research reports, "in New South Wales, the number of patients that were waiting more than twelve months for planned surgery continued to increase from 1993 to 2004, reaching an acceptable number of 10,551 patients in January, 2005". Cancellation rates, where the wait was so long the patient decided to seek relief elsewhere, were 10-15% in some hospitals (MacLellan et al., 2008). "Occupancy rates were over 95% in many hospitals" and "many patients each day way being kept waiting on stretchers outside the ED for over an hour." In the years 2002-2005, ED patients who needed to be admitted to hospital and who experienced access block was of the order of 40-50% and approached 60% in some cases, although the target for New South Wales was 20%.

The clinical process redesign project implemented a number of changes, including process mapping, involving staff in the improvement process, involving patients to understand the problem from their perspective, that is, listening to the voice of the customer, questioning the status-quo, identifying typical patient journeys and creating patient-care families, where patients whose journeys share the same process steps are grouped together even if the specifics of their clinical case may differ, identifying the many disconnections and misalignments in the processes, implementing procedures to smooth the load before arrival at the hospitals, implementing solutions for patients who do not need admission through what is referred to as 'streaming', creating fast track zones, preventing unnecessary hospitalization for patients with conditions such as deep vein thrombosis, community acquired pneumonia, and cellulitis that could be safely managed using 'hospital in the home'(MacLellan et. Al. 2008).

Within two years, there was a 97% reduction in the number of category 1 patients whose surgery was overdue, from 5308 in January, 2005 to 135 in June, 2007. There was a 99% reduction in the number of patients who had waited more than 365 days for surgery, from 10,551 in January, 2005 to 84 patients in June, 2007. In 2007, EDs met the 20% target for patients who experienced access block, that is, the EDs were not able to admit patients who needed admission, for the first time since 1997. The number of deaths per 10,000 patients admitted fell significantly at Flinders Medical Centre, one or the hospitals participating in the clinical process redesign project.

A few studies (Fillingham, 2007; Proudlove et al., 2008) have examined the experience of the NHS (UK) in the application of six-sigma and lean theories to the improvement of healthcare delivery processes in the UK. Fillingham (2007) focused specifically on the results achieved through implementation of lean projects at the Bolton Hospital Hospitals NHS Trust.

He reports the following dramatic results achieved over a 9-month period: 42% reduction in paperwork, better multi-disciplinary teamwork, 38% decrease in the time taken to get patients with a fractured hip into theatre, from 2.3 days to 1.7 days, faster recovery and lower demand on the rehabilitation ward, 33% reduction in the total length of stay, 36% reduction in mortality "resulting in a relative risk adjusted mortality rate of 105.5" although, as he noted, these improvements only decreased mortality to the national average. The question that remains unanswered is to what extent have six-sigma and lean principles been deployed by hospitals that are already achieving mortality rates that are better than the national average. The existing NHS culture was identified as a critical challenge to the deployment of six-sigma and lean thinking to the healthcare delivery process.

Van den Heuvel et al. and de Koning et al. report on the application of the Six-Sigma to healthcare at the 384-bed Red Cross Hospital, Netherlands. During Green Belt training, every participant was required to participate in at least one six-sigma project. The total savings realized by the hospital in 2004 were $1.4 million, or an average savings of $67,000 for twenty-one completed projects. One project that targeted starting times for the operating room, resulted in surgeries being started nine minutes earlier and resulted in net annual savings of greater than $273,000. Another project aimed at reducing the number of patients receiving IV Antibiotics resulted in only 157 patients receiving them in 2004 compared with 291 in 2002, resulting in annual savings of medication costs alone of $75,000. A third project which targeted the length of stay in delivery rooms reduced these from 11.9 hours to 3.4 hours, for total annual savings of $68,000 (Van den Heuvel et al., 2006; de Koning et al., 2006). In one case study, Does et al. (2009) looked at the factors that led to delays in start times for surgery. They conclude that while anesthesia technique and specialty are factors that influence that outcome, a poor planning and scheduling process were the most important factor influencing the delay of start times for surgery.

Improving emergency department (ED) throughput:

Some studies increasingly focus on the use of Six Sigma and lean methods to improve ED throughput by examining their impact on specific ED performance metrics such as patient balking assignment, re-routing and patient streaming, duration of patient stay, ED workload and capacity enhancement and patient satisfaction. These studies evaluated how six-sigma and lean methods increased ED performance by examining their impact on improvement in the factors that are thought to drive ED throughput. The various factors that were selected for study as drivers of ED throughput include case start time, patient balking, ambulance assignment, rerouting and patient streaming, duration of patient stay, room turnaround time, patient preparation time, methods for patient triage, turnaround time support services such as radiology and laboratory, including cardiac catheterization, scheduling methods (PUSH versus PULL) for ED, deployment of alternative care strategies that bypass the ED, implementation of methods of care that quickly relieve ED of patients that are no longer critical, registration and discharge procedures and patient satisfaction. On the whole, these studies showed some improvement in ED throughput. With the exception of Johnson et al. which investigated the impact of the six-sigma process, these studies focused exclusively on improvement in ED lean methods (Ben-Tovim et al., 2008; O'Connell et al., 2008a; O'Connell et al., 2008b; MacLellan et al., 2008; Ben-Tovim et al., 2007; Christianson et al., 2005; Dickson et al., 2008; Johnson et al., 2005; Kelly et al., 2007; MacFarlane and Eager, 1995).

Lazarus and Stamps (2002a, 2002b) adopt a very optimistic position on the potential impact of six-sigma in healthcare, and ED is one area of focus. After examining results of early efforts to deploy six-sigma at Charleston Area Medical Center, the COO of that organization declares that "Six-Sigma quality is more than a goal. It is a commitment woven deeply into the fabric of everything we do". Furthermore, the Six-Sigma corporate champion at Commonwealth Health Corporation declares; "The changes caused through Six-Sigma are awesome and exciting. Our CEO, as well as our senior leaders, is fully behind it. John Desmarais is full of passion. His commitment is tremendous". Similar positions were adopted elsewhere; Lazarus and Neely, 2003; Lazarus and Andell, 2006). To back up their positions, the authors provide the following specific results achieved by early six-sigma adopters; Commonwealth Health Corporation invested about $900,000 and reports improvements of $2.5 million; Charleston Area Medical Centre cut $163,410 out of $1.7 million of surgical equipment inventory and the company estimates that future cost avoidance will be $841,540; Scottsdale Healthcare reduced cycle time for bed control by 10%, increased Emergency Department (ED) throughput by 0.1 patients per hour and produced nearly $600,000 in incremental profits.

So confident was top management of Commonwealth Health Corporation of the expected impact of six-sigma on the performance of the organization that they asserted in their six-sigma vision that "By the year 2004, we will be proudly recognized by our employees, patients, clients, community, physicians and payers as the unquestioned leader in care and service, providing flawless quality never before achieved in the healthcare industry". Our literature search uncovered no published follow-up studies that report on the achievement of that stated ambition.

Reducing other turnaround times and patient wait times:

Long patient wait times are a major source of inefficiency, usually leading to inferior quality of care. They are a leading source of waste. Yet, the reduction of waiting times is exactly what the TPS has been very successful at achieving. It is therefore not surprising that research in the application of lean thinking in healthcare has focused on the reduction of waiting times (Wood, 2006; Pellicone and Martocci, 2006; Ben-Tovim et al., 2008; Bush et al., 2007; O'Connell et al., 2008a; O'Connell et al., 2008b; MacLellan et al., 2008; Ben-Tovim et al., 2007; Christianson et al., 2005; Dickson et al., 2008; Johnson et al., 2005; Kelly et al., 2007; MacFarlane and Eager, 1995). The following research deal specifically with the problem of reducing waiting time (Bush et al., 2007; Jackson and Woeste, 2008; Kim et al., 2009; Chand and Musitano, 2011).

Bush et al. (2007) undertook one of the few studies on the application of lean methods that used a control group that could allow for strong conclusions to be drawn on the impact of the deployment of lean methods on healthcare delivery throughput. The goal of their study was to evaluate the impact of six-sigma tools and lean methods on the improvement of patient access at an outpatient clinic in a hospital residency program. They implemented six-sigma and lean methods in the obstetrics/gynecology clinic and after implementation, compared that clinics productivity with that of a comparable internal medicine clinic of the same hospital where no six-sigma and lean methods were deployed. Productivity from both groups was assessed from January 1 to December 31, 2005. After implementation of the six-sigma tools and lean methods were implemented in OB/GYN, productivity of the OB/GYN clinic and that of the internal medicine group was tracked and measured for one full year, from January 1 to December 31, 2006.

The results were dramatic. Wait times for new obstetrical visits decreased from 38 to 8 days. Patient time spent in the clinic dropped from 3.2 to 1.5 hours. Initial gynecologic visits increased from 453 to 850, or 87%. Return gynecology visits increased from 1,392 to 2,311 per year, or 66%. Initial obstetrical visits increased from 520 to 808, or 55%. Repeat obstetrical visits increased from 2,239 to 3,243, or 45%. Average patient satisfaction scores measured on a 10-point scale increased from 5.75 to 8.54, or 49%. The gross revenue of the clinic increased by 73% for the first six months of 2006 compared with the previous year. The control group, the internal medicine clinic registered no change in the same vital metrics that were used to measure change in performance before and after the implementation of six-sigma and lean methods (Bush et al., 2007).

Deckard et al. (2010) report on the application of DMAIC to improve the referral process at the Jackson Health System, a primary care organization in Miami. The study focused on two specialty clinics, genitourinary (GU) and gynecology (GYN). Deployment of DMAIC resulted in improved timeliness and efficiency. Total process time was reduced by 23 days or 38% in GU and by 100 days or 74% in GYN. Kim et al. (2009) report on a study of the implementation of the six-sigma DMAIC process to reduce waiting times at the outpatient phlebotomy department in a South Korea's Kyungpook National University Hospital. Prior to the deployment of six-sigma methods waiting times were so long and measurement of the process revealed that it was performing at the level of 2.61 sigma. Using fishbone diagrams and an assortment of six-sigma tools, the dominant causes of long wait times were isolated and analyzed and improvements to the process were implemented. After the improvements, the number of patients waiting more than five (5) minutes decreased significantly and the sigma performance of the process increased to 3.00 sigma in December, 2007 and to 3.35 sigma in July, 2008.

Similarly favorable results were obtained by Jackson and Woeste (2008) in a study of the phlebotomy department of the Trinity Clinic, Tyler Texas. By deploying DMAIC and lean methods to eliminate non-value adding activities, the wait times that were less than or equal to 30 minutes before the improvement project decreased to less than or equal to 15 minutes after the improvement and during the pilot. It appears that wait times were being sustained at less than or equal to 12 minutes on a more long term basis. Six-sigma and lean methods have also been deployed to maximize the capacity, and thus improve turnaround times, of magnetic resonance imaging facilities (Chan et al., 2005), radiography (Chen et al., 2005), to produce faster test results (Godin, et al., 2005),

Improving communication and documentation of preliminary and final radiology reports (Gorman et al., 2007), maximize productivity in a cardiac catheterization laboratory (LeBlanc et al., 2004), improve the histopathology section of an anatomical pathology laboratory (Raab et al., 2008).

A study by Kang et al. (2005) that reports on the implementation of six-sigma and lean methods to improve downtime of the PACS at Kyunghee University Hospital is the most detailed and technically robust analysis of the application of six-sigma in healthcare that we came across in our review. The aim of the study was to attempt to achieve a level of zero defects in the PACS, a computerized replacement for traditional radiologic film, while simultaneously reducing resource requirements. According to the authors, "the issue of quality management has become important because a poorly performing PACS causes operational problems not only for the radiology department, but also for the hospital as a whole. Therefore, maintaining the quality of the PACS is critical to maintaining the quality of the hospital itself."

Using maintenance data of the system, they determined that between January 1, 2002 and December 31, 2002, approximately 294,000 studies were performed comprising 4.2 million images, and the number of reported defects was 434, including both system errors and images. They then proceeded to measure the current sigma of the various components of the system. PCs and monitors were operating at 5.2676 and 5.6745 sigma, respectively. The sigma of the network was 4.3362, while that of the gateway was 4.701. Using a number of six-sigma and lean tools, the authors built a cause and effect diagram, process flow and pareto charts that separated the vital few from the trivial many causes of defects. The PACS checkup timetable was revised to reflect the current sigma performance of each element of the system, the resource requirements of each element and its impact on the sigma level. The improvement program focused on defects that have a large impact on sigma performance. An education program was instituted for new employees and they decreased routine checkups on elements that failed less often, while increasing these checkups on items that failed more often. Six months after implementation of the improvement program, overall resource requirements were reduced to 79% of their pre-six-sigma levels, while quality improved. Unfortunately, the authors did not provide updated sigma measures for the various elements of the system after the implementation of the six-sigma improvement program.

Reducing medication errors:

Reduction in medication errors emerged as a favorite area of research (Castle et al., 2005; Esimai, 2005; Buck, 2001; Chan, 2004; Chassin, 2008; Christianson et al., 2005; Philips, et al. (2001). According to one researcher, medication errors fit Ferraco and Spaeth's definition of a high-risk process because it has a high probability of error, occurs with sufficient frequency and would result in severe patient injury (Buck, 2001). He describes one of the first and analytically rigorous efforts to apply the six-sigma process to reduce these errors by a consortium of four Milwaukee-based organizations. The project established a multidisciplinary team that quickly identified Continuous IV infusions involving twenty-two medications as a process that was subject to substantial error. The team deployed a number of six-sigma tools such as process mapping to identify the nine steps in the process and computed a Risk Priority Number, RPN, for each, using Failure Modes Effect and Analysis (FMEA). "Subsequent analysis of historical data revealed that IV rate calculation and IV pump setup were the two most prone to error in the IV infusion process" (Buck, 2001). The critical source of error was variability in the process caused by absence of clear standards. These standards were created to reduce process variation. A two-week audit of historical data with 124 data points was used to categorize IV infusion errors by level of discrepancy. Thirty (30) days after adherence to these standards, significant reduction in errors occurred. Level 1 discrepancies fell from 47.4% to 14%, Level 2 from 21.1% to 11.8% and Level 3 from 15.8% to 2.9%.

Esimai (2005) reports on a project to use lean six-sigma to reduce medication errors at a medium-sized hospital. The error rate prior to the lean six-sigma initiative was 0.33% or 3,300 per million opportunities and ten error types were identified, some potentially fatal. Leadership of the project was conferred to a project team. The hospital's quality improvement department had already developed process maps of the pharmacy order entry (OE) and nursing medication administration record (MAR) processes. In an attempt to isolate flaws in these processes, the team reviewed current practices and the actual sequences of operations using these process maps as standard.

Error reduction solutions envisaged and implemented included the institution of high performance standards through training and supervision, computerization of the physician order management system and the forging of agreement on the part of unit-based pharmacists on the standard times for medication administration. The results were dramatic. There was across-the-board reduction in pharmacist errors, some of the order of 83%. Non-pharmacy errors continued to be high, but these also experienced a 50% reduction, while the total error rate decreased from 0.33% to 0.14%. Labor cost savings of $550,000 were realized after five months for an annualized savings of $1.32 million. The research also reports an increase in patient satisfaction and improved employee morale, although no data to substantiate these latter claims was provided.

Reducing other errors (medical laboratory):

Gras and Philippe (2007) reviewed some studies of six-sigma methodology to improve medical laboratories. Boone reported that 93% of the errors in clinical laboratories are linked to the pre- or post-analytical phase (Boone, 1993). Plebani noted that most errors are due to pre-analytical factors which accounted for 46%-68.2% of total errors (Plebani, 2006; Kalra, 2004). According to Gras and Philippe, this is an important reason that early efforts to apply six-sigma in healthcare focused on medical laboratories. The first paper on quantification of laboratory processes on the six-sigma scale was published in 2009 (Nevalainen et al., 2009), comparing quality indicators for three laboratories expressed as variance and in DPMO. Two major findings of were; 1. Expression of quality indicators by variance seemed good in many cases, while the same results expressed in parts-per-million performed differently compared to non-laboratory industries: 2. Historical quality assurance programs did not seem to enhance quality across the total testing process.

Simmons (2002), reported results of a six-sigma project aimed at reducing turnaround time and loss of specimens during their transportation to the laboratory at Froedtert Memorial Lutheran Hospital in Wisconsin. Application of six-sigma methods and working in close collaboration with the vendor of the pneumatic transportation system resulted in a 20% reduction in travel time, a 7.5 minute reduction in turnaround time and a 35% reduction in errors.

Riebling et al. (2004) launched a six-sigma project to reduce access errors at North Shore-Long Island Jewish Health System laboratory, which had a chronic problem of errors in entering patient data, ordering tests and labeling samples. A multi-disciplinary team was assembled to lead the six-sigma project, aiming to reduce defects by 50% and increase staff productivity. Applying DMAIC to the accession department improved its performance from 3.9 to 4.2 sigma, resulting in a savings of $339,000/year and increased benefit. Performance continued to improve and reached 4.5 sigma or 1,387 DPMO in 2004.

Implementing standards and increasing adherence to best practice:

Eldridge et al. (2006) examined the impact of applying DMAIC to improve compliance to Centers for Disease Control (CDC's) Guidelines for Hand Hygiene involving ten required hand hygiene practices in a healthcare setting at four ICUs in three Veterans Administration Medical Centers. Over a nine-month period, observed compliance increased from 47% to 80%, based on over 4,000 observations, while mass of Alcohol-Based Hand Rubs (ABHRs) in the three intensive care units increased by 97%, 94% and 70%. They conclude that the six-sigma process was effective for organizing the knowledge, opinions and actions of a group of professionals to implement the CDC's evidence-based hand hygiene practices at the 4 ICUs studied.

DuPree et al. (2009) focused on improving patient satisfaction with pain management at Mount Sinai Hospital, a tertiary academic facility in New York City. The study involved using DMAIC in various elements of the pain management process to see whether patient satisfaction expressed through surveys, would improve. The hospital already conducted in-patient satisfaction surveys. They report that overall satisfaction with pain management ratings increased from 37% to 54%. Both units studied surpassed the preset goal of at least 50% responses rated as excellent by patients. Other studies have investigated adherence to best practice related to the reduction of inappropriate use of blood products (Neri et al., 2008), breast milk administration (Drenckpohl et al., 2007), use of intravenous antibiotics (Van den Heuvel et al., 2006), standardization of medication use and the reduction of hypoglycemic events (Johnson et al., 2005), and the use of aspirin, beta-blockers and angiotensin enzyme inhibitors (Elberfeld et al., 2004). Six-sigma methods improved adherence to best practice in the areas investigated. While these studies set out to investigate the deployment of six-sigma tools to improve the quality of care and not necessarily to cut costs, some of them did find that cost reduction did occur as well.

Implementing best practice in inventory control and SCM:

Expansion of six-sigma to manage healthcare inventory and supply chains is emerging. Banchs et al. (2010) report results of a study of six-sigma to manage OR materials supply chain at a Spanish hospital. They deployed the DMAIC process, SIPOC diagrams, pareto charts, cross-functional process flow diagrams, project teams, value stream mapping, clear and measurable performance metrics. Implementation of improvements in SCM processes, Kanban, JIT, and standardization of ordering process produced a reduction of 20% inventory, 25% in storage space, and 21% in total inventory cost. Workflow improved substantially and first-case set-up time decreased by 30%. Antony et al. (2007) report on Clarkson Area Medical Centre that applied lean methods to reduce inventory levels and improve supplier relationships, with savings of over $500,000.

Syntheses of broad sets of empirical papers:

Spear (2005a) is representative of these papers. Work by Thomerson (2001), Lazarus and Stamps (2002a; 2002b), report on Commonwealth Health Corporation, one of the first to implement six-sigma assisted by GE consultants GE. By 2002, Commonwealth had invested $900,000 on its six-sigma projects, generating savings $2.5 million. Following Commonwealth, other healthcare organizations introduced six-sigma and have reportedly achieved better results (Sehwail and DeYoung, 2003). Mount Carmel Health System is reported to have realized savings of $3.1 million, while Charleston Area Medical Center achieved savings of $841,000 (Lazarus and Stamps, 2002b). Although these are initial efforts at six-sigma implementation, the reported savings are modest compared to the scale of these organizations, 7,300 employees for Mount Carmel and 919 beds in the case of Charleston Area Medical Center.

Proudlove et al. assessed the NHS six-sigma and lean initiatives from a theoretical viewpoint, identifying key lessons learned. They conclude that the NHS experience confirms that there are a number of challenges in applying six-sigma in complex, messy organizations like those that comprise the NHS. The use of a structured methodology or roadmap, the discipline of the early stages of the six-sigma methodology, and guidance on how to apply the sequence of six-sigma improvement tools would enhance success of NHS initiatives. They differentiate between six-sigma and lean and propose that the lessons learned in efforts to deploy six-sigma would be transferable to lean initiatives. They maintain a clear distinction between six-sigma and lean, although they admit that some cross learning between the two is likely. Their evaluation is that considerable potential exists for the deployment of lean within NHS organizations, but they aver that the critical hurdle is not the techniques of lean, but the implementation process.

Lazarus and Butler (2001) present preliminary evidence of the usefulness of six-sigma in healthcare delivery improvement from three case studies, Mount Carmel Health, Virtua Health (Southern New Jersey/Philadelphia) and Southdale Healthcare's (SHC) Osborn campus, At the time of their investigation, 44 full-time employees at Mount Carmel had been trained on six-sigma and 52 projects were in different stages of implementation. Although no results were reported for Virtua and SHC, Management at Virtua "has been very pleased with the results" of six-sigma projects undertaken. They assert that while six-sigma tools are more effective when deployed in conjunction with long term quality improvement strategies, six-sigma tools are better used to achieve improvement through short term projects. They conclude that six-sigma tools, particularly when deployed through powerful computing technology, lead to better decision-making through more careful analysis and are more effective in helping managers arrive at optimal solutions rather than those that are 'good enough'.

Barriers/Challenges to Six-Sigma/Lean Implementation in Healthcare:

As we discuss subsequently, much of the current evidence is weak, partial and limited only to certain segments of healthcare delivery organizations. Because of the empirical, methodological and theoretical weaknesses of current research, one cannot say categorically how broad deep and sustainable an impact six-sigma will eventually have on healthcare delivery systems or whether that impact will approach the experience of six-sigma/lean six-sigma in manufacturing or even other service industries. These latter industries have been experimenting with and implementing six-sigma/lean six-sigma for better of twenty years and they still are very far from being the type of six-sigma or lean organization that even remotely approaches the prototypical cases that exist in manufacturing or even service industries.

Progress in adopting six-sigma/lean in healthcare is slow. The evidence proffered in support of the thesis that six-sigma as originally designed is highly adaptable to healthcare organizations is weak. There are some strong barriers and tough challenges to implementing six-sigma in service industries and in healthcare organizations. These include: 1. The Manufacturing Origins of Six-Sigma; 2. Adoption of six-sigma by service companies viewed as technology transfer, a very slow process from manufacturing to services; 3. The Six-sigma emphasis on factual quality versus the prevalence of perceptual quality in services; 4. Process orientation in manufacturing versus human resource orientation in services; 5. The quality measurement challenge of six-sigma caused by the prevalence of perceptual quality; 6. The human touch quality dimension of service that comes from the need for empathy and deep down customer care, both of which are tough to measure; 7. Non-evidentiality and perishability; 8. Absence of a TQM Legacy leading to weak foundational TQM Values and Principles and absence of deployment of a broad range of TQM Tools and techniques (xxxxxxx, 2005; 2002a; 2002b).

Some barriers are specific to healthcare organizations. First is the existence of a large number of autonomous professions that are the guardians and arbiters of what constitutes sound quality practice for their respective professions. It is very difficult to align core medical, pharmacy and nursing practice with six-sigma quality methods without influencing the respective professional bodies. Second, input variability requires process flexibility which is anathema to TPS and lean thinking. Third, there is the perception nurtured by traditional medical practice that lean means cutting corners and sacrificing quality care. The old adage says, 'cheap thing no good, good thing no cheap'.

Fourth, some jurisdictions now realize that lean six-sigma may require redefining professional boundaries, where a pharmacist or nurse diagnoses and prescribes for certain pre-designated medical conditions or a trained physician's assistant does some of the work previously done by primary care physicians, an idea that has been be vigorously resisted by primary care professional bodies everywhere it has been tried. Fifth, there is absence of patient centeredness and physician resistance driven by an array of systemic, psychological, professional, organization culture factors. These factors include use of approaches to change management that fail to provide appropriate and adequate feedback, failure to involve physicians through active participation, use of methods that focus on decreasing medical costs instead of those that emphasize increasing quality of care, failure to deploy change strategies that incorporate multi-disciplinary, systems-oriented participation and collaboration, and which do not place enough emphasis on the setting of mutual goals and objectives, demonstration to physicians the clinical benefits from new methods, and not deploying physician advisors and project champions (Carrigan and Kujawa, 2006; Ettinger and Van Kooy, 2003; Proudlove, 2008); Kim et al., 2006; Fillingham, 2007; Forthman et al., 2003, Buck, 2010).

SIX-SIGMA/LEAN THINKING IN HEALTHCARE: CRITICAL ASSESSMENT

In ground breaking research on six-sigma, Delliframe et al. (2010) undertook a rigorous evaluation of the evidence quality of publications on six-sigma and lean methods. They sought to systematically assess the extent to which "empirical evidence applying six-sigma/lean six-sigma actually produced improvement in clinical outcomes, care delivery processes or in the financial impact of projects undertaken by healthcare organizations". They assessed level of evidence using Slavin's classification system for evidence-based practice. They also assessed the strength of research design using Slavin's criteria 10 for scientific evidence (Slavin, 1995). According to these ratings, a research design can be classified from most rigorous to least rigorous as follows; 1. Randomized controlled trials; 2. Non-randomized controlled trials; 3. Quasi-experiments with nonequivalent control groups; 4. Observational studies with no control group.

Their conclusions are telling. Of 177 papers identified, only 34 presented evidence quality worthy of inclusion in their review. Evidence scores for these papers ranged from 4 to 7, with 4 indicating stronger research design, data presentation and analysis than papers scoring 7. Average evidence score for studies included in the review was 6.1, which means that even papers that met minimum evidence quality achieved low scores for evidence quality. Studies focusing on lean tools had an average evidence score of 5.7, slightly better than those focusing on six-sigma, but still below what could be deemed strong evidence quality. Those focusing on six-sigma had an average evidence score of 6.2. Studies that included both Lean and Six-Sigma Quality improvement tools had an average evidence score of 5, still well below what is required to be classified as providing good evidence. Nearly all studies included in the evaluation were conducted in hospital or multi-hospital settings. Of the 34 studies, only 3 reported on the use of six-sigma and/or lean methods to improve clinical outcomes (Garmerdinger, 2008; Griffin et al., 2007; Shukla et al., 2008) and these achieved an average evidence score of 6.3, indicating very low evidentiary quality.

This confirms our observation that studies on six-sigma/lean six-sigma in healthcare generally avoid dealing with the core clinical practices which are the heart of healthcare delivery services and which must eventually be subjected to six-sigma-lean six-sigma discipline if one is to have significant, sustainable improvements in healthcare quality and cost.

We do not as yet have a six-sigma healthcare organization that can be held up as a prototype for healthcare organizations that TPS is to manufacturing or GE Capital is to service businesses. Spear alludes to this issue when he asserts, "so far, no one can point to a single hospital and say, 'there is the Toyota of healthcare. No (healthcare) organization has fully institutionalized to Toyota's level the ability to design work as experiments, improve work through experiments, share the resulting knowledge through collaborative experimentation and develop people as experimentalists. But, there is reason for optimism. Companies in a host of other industries have already successfully followed in Toyota's footsteps, using common approaches to organizing for continuous learning, improvement and innovation that transcend their business differences. And these approaches have been successful when piloted in healthcare." (Spear, 2005). Spear's optimism may have been overstated and must await systematic study of these differences and what they mean for six-sigma/lean six-sigma in healthcare. Transferring theory and practice from one setting to another requires profound understanding of and adapting for differences, and this has not as yet been tackled in the research. There is no healthcare organization that can be said to be systematically achieving lowest cost, shortest time, near zero waste in its delivery system and has the built-in core competencies, broadly and deeply deployed to sustain them. Lean means kaizen, and the review of the literature has uncovered no healthcare organization that is even close to deploying a reasonably complete kaizen process.

Cases of six-sigma in healthcare reported in the literature tend to be narrowly focused on problems such as reducing medication errors or compressing wait times. In the organizations that have achieved dramatic improvements in these limited areas, we have no reported evidence that six-sigma initiatives have been broadened beyond the limited scope projects that served as the testing ground for six-sigma introduction and learning. We have seen very few studies that systematically revisit the organizations initially reported on to assess the degree to which six-sigma and lean projects are becoming or have become institutionalized. Spear reports on a rear case (p. 91). Yet, institutionalization of practices and methods is the key hurdle that every organization must face before it can be said to be truly deploying six-sigma methods and lean thinking to create sustainable competitive advantage (xxxxxx, 2010; 2009a; 2009b; 2008; 2005; Spear, 2005).

The literature on six-sigma/lean in healthcare is largely silent on the issue of building a six-sigma/lean culture. The evidence is that the culture of healthcare organizations is far from lean. The very way in which healthcare is practiced and delivered fosters waste. Core healthcare professions and professionals generally view waste reduction as potentially detrimental to quality. Physicians, pharmacists, nurses and others are not trained to think in terms of cost reduction and time compression, and they think both are inimical to quality. Healthcare culture is today where manufacturing culture was fifty years ago, which assumed that increasing quality can only come through increasing cost. TPS changed that view and without any prototypical TPS in healthcare, no culture of lean exists making six-sigma and lean unsustainable.

Six-Sigma/Lean thinking has almost completely avoided core healthcare organizations, the professional medical practices. Consequently, organizations that pursue six-sigma/lean six-sigma are either admitting that the core medical practices are already operating at the six-sigma level, which they clearly are not, or are saying that their performance is not critical to achieving six-sigma or that six-sigma/lean six-sigma concepts do not apply to the core medical practices, or that bringing the core medical practices under the discipline of six-sigma represents an insurmountable challenge. This latter position is closer to the truth. Core medical practices are developed, refined and transmitted by various professional bodies which regulate the activities of their members. They are the final arbiters of what constitute sound practice. Before one can successfully apply six-sigma/lean methods to core medical disciplines, one must change the way these professional bodies view, teach and deliver medical services, a tough challenge. The medical practices come with their culture, and to the extent that six-sigma/lean methods require radical change in culture, implementing six-sigma/lean in healthcare organizations comes up against two very difficult challenges of culture change. Not only must one change the culture of an existing organization where one is implementing six-sigma/lean methods, but one must also influence the culture promulgated professional bodies.

Some research reported on actually six-sigma metrics for the processes studied. No healthcare organization reported on in the literature is remotely close to achieving benchmark six-sigma performance of 3.4DPMO in any area of healthcare delivery. Even for the organizations reported on that have purportedly implemented or are implementing six-sigma, defect/error rates are at best at three (3) sigma levels, which is the sigma limit of statistical process control charts developed some seventy (70) years ago, and which was routinely achieved by manufacturing company users some forty years ago. It is a stretch to refer to any healthcare organization today as a six-sigma organization, when the literature review shows that the best performance produced by these organizations is about 3.0 Sigma.

Every case reported on involves one or at most two projects observed or documented over a short period. We have no evidence that these projects have been followed over a reasonably period of time, say ten years, to allow one to conclude that these projects have taken root and that the initial improvements are sustainable, at least in the areas reported. We have no evidence that the organizations that implemented these projects have significantly broadened the improvement effort to other areas or have used the initial results to make six-sigma and lean methods implementation a fundamental change in strategy and its execution. And we have no evidence that even in the limited areas reported these organizations are inexorably pushing performance towards the six-sigma benchmark of 3.4 DPMO. The literature on six-sigma/lean in healthcare covers a very limited sample of organizations, maybe twenty (20) cases that have been referred to over and over again as the evidence that six-sigma is taking root. Even in these organizations, we see no evidence of the next crucial steps to push six-sigma/lean to the next level to become a broadly deployed, organization-wide improvement strategy.

We have not seen emerge even the beginnings of a systematic theory of six-sigma/lean thinking in healthcare. It was the systematic pulling together of disparate ideas, concepts and reports based on anecdotal evidence into a theory of manufacturing (Drucker, xxxxx) that led to unprecedented systematic hypothesis testing, theory refinement and the explosion of prescriptive practice for the sustainable improvement of manufacturing operations. Such theory building was critical to the propagation of prescriptive practice in Total Quality Management (TQM), and which also stimulated the widespread adoption of the TQM paradigm by a large number of firms (Deming, 1986, 1982; Juran, 1986). Diffusion of the TQM paradigm provided a practice-based field of research for generating and testing hypotheses and refinement of theory on which these hypotheses were based. Consequently, when the Baldrige Quality Awards was launched in 1982, it could draw on a well-articulated and tested theory of quality management to identify the critical elements of a quality management system and the core practice that can be deployed to drive sustainable improvement in quality. The emergence of a theory was instrumental when TQM was being broadened from its manufacturing base to services in the 1970s, and when production management concepts and methods were being transferred to services in the 1980s (Chase, 1978; Chase, 1981; Chase and Tansik, 1983; Dean and Bowen, 1994; Samuels and Adomitis, 2003). Unless a theory of six-sigma/lean in healthcare emerges, research will continue to be largely descriptive and haphazard at best, driven by reports based on anecdotal evidence, with very little or no hypothesis testing, and lacking the sound theoretical foundation upon which prescriptions for the systematic management of quality, time and efficiency improvement can be based. It is through the testing and refining of hypotheses that are grounded in theory that both the latter and prescriptive managerial action can be improved.

Even a cursory examination of healthcare organizations will reveal that they have markedly distinctive characteristics that set them apart from other service organizations. Yet, research on six-sigma/lean thinking in healthcare has not produced a cogent model of the distinctive characteristics of healthcare and related organizations' and related these to the opportunities and challenges of implementing six-sigma/lean in these organizations. The transfer of manufacturing thinking to services was similarly hindered by the absence of such a model prior to Chase's fundamental insight on the customer contact model, and the plethora of systematic research, hypothesis testing and theory building that was spun from it (Chase, 1978; Chase, 1981; Chase and Tansik, 1983). The breakthrough made by Chase was the observation that the fundamental differences and similarities between manufacturing and services arose from the fact of the degree of contact between the customer and the service delivery system. Where there is low customer contact, the service process behaves essentially like a manufacturing system, and this facilitated the direct transfer of manufacturing thinking, methods and processes to these low contact services. However, high contact systems deviate significantly from the modus operandi of manufacturing and required the development of new systems, methods and processes to manage the key challenges and constraints of these high contact service delivery systems.

Research on six-sigma/lean methods in healthcare appears to be predicated on the assumption that healthcare services are substantially like all other services and, therefore, whatever methods, thinking, and processes that have been developed for these other services are wholly applicable to healthcare. Healthcare is service, but we conjecture that it is very different service, unique in many respects (xxxx, 2002a; 2002b; xxxx, 2005c).

Finally, Landek and others have identified some potential drawbacks, benefits and challenges of the six-sigma in services (Banuelas and Antony, 2002; Does et al., 2002; Landek, 2006; Kwak and Anbari, 2006; Antony, 2007). Six-sigma must be seen as a simple tool towards improving a healthcare delivery process rather than a revolutionary methodology to solve every problem. Further, six-sigma is a costly procedure and hospitals cannot invest as much money as Motorola and others. Landek avers that simpler tools such as lean methods and root cause analysis can deliver savings comparable to those obtained with six-sigma. Another flaw of six-sigma is that its application needs the best technologists to focus on six-sigma projects on a full-time basis. Finally, the author states that the goal of reaching 3.4 DPMO in clinical laboratories is not realistic. For Sehwail and De Young (2003), the three main obstacles to implementing the six-sigma breakthrough methodology in healthcare are; (1) difficulty in identifying adequate metrics to quantify performance, (2) overcoming reticence to cultural change, which six-sigma and lean thinking require, and (3) applying this philosophy to a non-production-focused environment.

CONCLUSION

Six-sigma and lean thinking are modern management paradigms that specifically focus on the task of driving waste out of a productive process. Waste in healthcare is significant and prevalent. So, prima facie, six-sigma and lean thinking dovetail excellently with the performance imperatives of healthcare delivery. However, a comprehensive review of literature has revealed that success in the crusade to apply six-sigma/lean thinking to improvement in healthcare is modest at best. Further, the results reported in the literature reveal neither broad, nor deep, nor sustained improvement in waste reduction in healthcare as a result of deploying six-sigma/lean thinking.

There is little doubt that healthcare organizations have distinctive characteristics when compared to both manufacturing and other services. Yet, most of the current research on six-sigma/lean in healthcare either does not take these differences into account or minimize their impact. Because of this, improvement initiatives undertaken and results observed in one organization cannot be used either to formulate prospective actions for others or to formulate predictive models, or to derive core principles for managing improvement in healthcare processes. It is our view that that explains why research on six-sigma/lean in healthcare tends to be undertaken using one of a kind improvement projects instead of being based on large enough samples of firms or improvement initiatives.

Consequently, the pressing research imperative must be the identification of the fundamental characteristics of healthcare organizations, that is, the few critical factors that differentiate between one healthcare organization and another, as was done in Chase's CUSTOMER CONTACT MODEL. There needs to be a classification of these organizations into categories, the mapping out of the core differences between these organization in terms or culture and values, structure, processes, and technology. Another imperative is the systematic, research-driven identification of the critical challenges, constraints, opportunities and contingencies that must be explicitly taken into account when adapting six-sigma/lean thinking to or deploying them into these organizations. This is the essence of contingency theory and we conjecture its central tenets may represent the most fruitful way forward for executing research on applying six-sigma/lean in healthcare.

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