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LEAN, SIX SIGMA IN HEALTHCARE: A LITERATURE REVIEW

Anamaria HUZU, Claudiu Vasile KIFOR, Roxana Florenta SAVESCU, Gianina LUP

Abstract: *In recent years, the interest of practitioners and researchers in the use of the Lean Six Sigma tools to improve processes in the medical sector has increased significantly.*

This paper aims to provide information on the research topics, on the context of the research and the research methodologies approached by the recent scientific literature on the impact of Lean Six Sigma methods on improved operational efficiency, a higher profitability and quality of the processes in the medical sector. Research results are useful both to practitioners in the field who can identify ideas or solutions to the issues they are facing, as well as to scholars in search for future research opportunities.

The paper also includes a critical analysis which highlights the advantages and disadvantages of applying the various methods and makes recommendations on their application.

Key words: *Lean, Six Sigma, health.*

1. INTRODUCTION

Healthcare systems in Europe and worldwide are constantly seeking solutions to balance the relation between the ever-increasing cost of healthcare and the ability of healthcare systems to meet the needs of society, ie the development of basic, accessible, high-quality and cost-effective healthcare services for all, with a focus on prevention and promotion of a healthy lifestyle. The Romanian healthcare system is part of this process, even though its critical situation has been on the public agenda for several years; the issues that top the agenda are: under-financing, the migration of professionals and the undesirable events associated with healthcare.

Workflow processes in medicine are not well designed and are characterized by unnecessary duplication of services, by long waiting time and delay for providers and patients. Costs surge and waste is identified as an important factor in rising health spending. As a result, healthcare is not consistently able to respond to patient needs. (Van de Heuvel J., Does R.J.M.M, & Koning H., 2006) [1].

Operational inefficiency is omnipresent in current healthcare systems. Some of these operational inefficiencies arise because of

impediments and redundancies in the supply of direct medical services. Others seem to be associated with the logistical, administrative and operational aspects of the healthcare system. Both areas are susceptible to systematic innovation and process improvement activities. Improving the quality of healthcare services results in improved patient satisfaction. (Corbin C.L., Kelley S.W. & Schwartz R.W., 2001) [2].

Providing better quality while incomes are decreasing is the major healthcare challenge (Van de Heuvel J., Does R.J.M.M & Koning H., 2006) [3].

Lean Six Sigma processes have been successfully applied in the "medical industry" to improve efficiency. As cost reduction pressure increases, the quality of diagnostic tool maintenance must also be improved and rethought in Romania to ensure that the value of healthcare can be continually improved for patients and other stakeholders. Radiology and medical imaging service providers are facing significant challenges in this area, but Lean Six Sigma approaches and tools can contribute as a solution to their resolution.

An approach based on Lean Six Sigma can be a possible solution to such a problem, as it brings benefits in terms of improved operational efficiency, higher return and higher

quality of the process, with the aim of increasing the value of services supplied to patients and thus increasing their satisfaction.

2. OBJECTIVES

2.1 Researchers' Objectives

- a. provide information on research topics, the context of research, and research methodologies reflected by recent scientific literature on the impact of Lean Six Sigma methods on improved operational efficiency, higher profitability and higher quality of processes in the medical sector;
- b. provide a comparison among different research methods in the medical sector;
- c. identify possibilities for further research;

2.2 Practitioners' Objectives

- a. identify ideas or solutions to various issues faced by medical practitioners;
- b. identify cutting-edge approaches to the main cost-cutting methods in the health sector, ensuring a higher level of profitability and superior quality of the medical sector processes.

3. RESEARCH METHODOLOGY

The authors studied 131 scientific papers from the Web of Science Core Collection database, published between 2003 and 2018. The articles were selected based on the search filter: "Lean Six Sigma health".

The systematic review was conducted in accordance with current best practice as follows:

- a. The papers identified in the database and assessed for eligibility: N = 131, of which: Article (N = 92), Review (N = 18), Proceedings paper (N = 16), Book chapter (N = 5), Editorial material (N = 4).
- b. Studies included in qualitative analysis:
 - Article (N = 21) of which: 10 open access and 11 not open access;
 - Review (N = 9) of which: 7 open access and 2 not open access;
 - Proceedings paper (N = 10), of which: 0 open access and 10 non open access.

3.1 Eligibility criteria

Table 1.

Inclusion and exclusion criteria applied to studies.

Inclusion Criteria	Exclusion Criteria
1. Published in a peer-reviewed journal	
2. Involves hospital-based or outpatient-based radiology department	Letter Editorial
3. Lean, Six Sigma, or Lean Six Sigma QI methodology is implemented	Book chapter Nonempirical study Departments studied did not include health sector
4. Adequately describes an empirical study that contains a control or comparison group	

All studies published in peer-reviewed journals, regardless of the study project, language or year, were eligible for inclusion if performed exclusively in the context of healthcare; if developed to evaluate the implementation of Lean, Six Sigma or Lean Six Sigma methods to improve quality and / or care processes; and if measured the results before and after implementation. Full details on the inclusion and exclusion criteria are outlined in Table 1.

3.2 Selection of studies

Eligibility was decided independently by the four authors. The title and abstracts were examined first, followed by full text screening for eligible studies. If an abstract from a returned citation was not available from the database during the initial screening phase, the full-text reference was accessed and reviewed to assess eligibility. The date of the last search was 15 May 2018.

3.3 Synthesis of the results

The meta-analysis was not performed because of the lack of statistical data analysis in most of the studies included and heterogeneity in the study development and results. Instead, a descriptive synthesis was provided.

4 RESULTS

4.1 Improving Quality (QI) in Healthcare

The improvement of the process can be summarized as a series of steps taken to identify, study and improve an existing process to reach new targets or new aims. It is important to keep in mind that processes need to be repetitive in order to be able to improve the process. Examples of repetitive processes in radiology include radiology investigations, magnetic resonance imaging and patient sedation of interventions. (Tamm E.P., Szklaruk J., Puthooran L., Stone D., Stevens B.L. & Modaro C., 2012) [4].

With the rapid expansion of knowledge and technology and a healthcare system operating below acceptable levels to ensure the safety and needs of patients, general healthcare professionals need to understand the basics of quality improvement methodologies and terminology (Varkey P., Reller M.K. & Resar R.K., 2007) [5].

As demand exceeds supply, quality improvement initiatives and tools (QIs) may be beneficial to improve the safety, efficiency, effectiveness, equivalence and timely delivery of health services. The quality of healthcare is given by the degree to which health services for individuals and populations increase the likelihood of desired outcomes and are in line with current professional knowledge. (Varkey P. & Kollengode A., 2011)[6].

From the point of view of researchers Varkey P. and Kollengode A. (2011) in the field of healthcare, it is no longer appropriate for actors to focus on quality assurance, namely the assessment of products or services according to expectations or standards, but it is also important to focus on improving the QI quality, which provides tools and methods for improving the process / product compared to the analysis of shortcomings.

Regardless of the problem, once the project is identified, it is essential to gather the most efficient team that will help solve the problem. The effectiveness of the teams is usually interdisciplinary and multiprofessional and should consist of representatives with a) the authority to institute the change, b) the technical expertise, and c) the daily knowledge

of the subject. This combination of representatives is the one that will be able to make a process or product change effective and efficient. Once a strategy is identified to improve the product or process, several tools and methodologies for QI, including Plan-Do-Study-Act (PDSA), Lean, Six Sigma and Lean-Six Sigma, can be used. (Varkey P. & Kollengode A., 2011) [7].

4.2 Lean

The Lean approach evaluates a process from the perspective of finding and removing non-value added work (NVA) and promoting improved execution of those steps in the process that bring added value. The Lean approach requires a thorough understanding of a process, including not just how the process is intended to function, but also the many variations that have occurred during the process. (Lighter D.E., 2014) [8].

In addition, Lean offers a set of standard solutions for common organizational issues. Visual management, reduction of complexity, the 5S method, cell production (production by using production cells), drawn systems, line balancing, one piece flow and SMED (Single Minute Exchange of Dies - Reduction of Manufacturing Change Time) are some of the most familiar. In the literature, the advantages of Lean and the principles behind these solutions are described in depth. (Standard and Davis, 1999; George, 2003) [9],[10].

For a successful implementation of Lean methodology and to create a system, not only based on system solutions but also on potential, and providing conditions to facilitate excellence, employees should (Dombrowski U., Schmidtchen K. & Mielke T., 2011) [11]:

- have knowledge about Lean, have the ability to recognize the waste and take action to improve the work system;
- participate in continuous training courses, use creative thinking techniques, 5S and analyze the cause and effects (Ishikawa diagram);
- have the self-improvement wish, be motivated, and payed decently;
- define unambiguously the purpose of tasks, the rights and responsibilities;

- have time that can be dedicated to improvement actions.

It is essential to make a diagnosis of organizational culture and to identify workers' preferences, which can contribute to the introduction of changes in work systems (Zasada B., 2011) [12], but also takes into account soft factors. Moreover, such methods as 5S, TPM (Total Productive Maintenance) or visualization can support the creation of the continuous improvement culture. On the other hand, it has been suggested that a culture encouraging autonomous, independent work and learning to experiment could accelerate the process of Lean concept implementation (Crute V., Ward Y., Brown S. & Graves A., 2003) [13].

Eliminating waste in the value flow, with the exception of a few points, creates processes with less human effort, space, capital and time to produce products and provide services at lower costs and with far fewer defects (Wyrwicka M.K. & Mrugalska B., 2017) [14].

However, the Lean methodology appears to be the next revolution for better, improved and value-based healthcare; as a result, the Lean approach has been increasingly adopted and adapted in the healthcare sector over the last 20 years. Because the Lean approach is best understood as a means of increasing productivity, the hospital has been the most explored framework, with the emergency and surgery units as pioneering departments. As a result of the research conducted by D'Andreamatteo A., Ianni L., Lega F. & Sargiacomo M. (2015) who analyzed 243 articles to identify the empirical and theoretical articles published in September 2004 on Lean in healthcare, the United States seems to be the lead country for the number of applications. The theoretical works focused mainly on obstacles, challenges and success factors. Sustainability, the measurement framework and critical appreciation remain underestimated. Assessments of the "system approach" are still not numerous enough. (D'Andreamatteo A., Ianni L., Lega F. & Sargiacomo M., 2015) [15].

4.3 SIX SIGMA

Six Sigma is an organized and systematic method of improving strategic processes and developing new products and services based on statistical methods and scientific methods of drastic reduction of client-defined fault rates. (Linderman K., Schroeder R.G., Zaheer S. & Choo A.S., 2003) [16].

Six Sigma is the perfect quality assurance program for the healthcare industry, as it involves prioritizing, analyzing in detail and efficient processing of all processes.

Since 2002, Six Sigma has been deployed in the Red Cross Hospital in Beverwijk, the Netherlands, which is a 384-bed general hospital and a 25-bed national burn center. With an annual budget of €72 million in 2004, the hospital admitted 12,669 patients, treated 11,064 people in the day-care center, and performed 78,832 initial consultations at first contact of patients with the hospital. Six Sigma was introduced to the Red Cross Hospital with the aim of enhancing continuous improvement (Van den Heuvel, J., Does R.J.M.M. & Bisgaard S., 2005) [17]. "At the end of 2004, we launched 44 projects and 21 projects were completed. Total savings amount to 1.2 million euros, and these sums are cumulative savings each year. Early in 2004, the Red Cross Hospital anticipated serious financial problems. The management encouraged Six Sigma to initiate an additional number of smaller "fast-paced" projects instead of staff lay-offs. This additional program has led to additional savings of up to € 1 million. The 2004 annual report thus showed a tremendous net result of over 2 million euros" (Van den Heuvel J., Does R.J.M.M., Bogers A.J.J.C. & Berg, M.A., 2006) [18].

In addition, the introduction of Six Sigma at Red Cross Hospital in Beverwijk, the Netherlands has stimulated an awareness culture to find opportunities to improve the delivery of healthcare and also to take responsibility for eliminating the deficiencies. In the past, decisions were often based on hypotheses and feelings as well as on inaccurate and incomplete information. By using Six Sigma, today, work colleagues take responsibility and provide management based on facts and data (Van de Heuvel J., Does R.J.M.M. & Koning H., 2006) [19].

4.4 Integration of Six Sigma and Lean: Lean Six Sigma

The use of the Lean-Six Sigma methodology involves a combined approach of both methodologies, six sigma being used to identify the problems that cause variance and Lean being used to implement interventions. (Varkey P. & Kollengode A., 2011) [20].

Lean and Six Sigma have complementary advantages. For integration, Lean can use the management structures Six Sigma offers: Six Sigma project-by-project approach provides an effective integration framework to apply Lean principles. Moreover, Lean does not have a diagnostic method, but only limited analysis methods. It is rather unilaterally oriented to the problems of the process, which are solved by a set of standard solutions. Lean does not analyze the economic performance indicators of a process to determine where the main improvement points are, but focuses on process flow inefficiency, even if the main improvement opportunities have not been yet identified. The Six Sigma DMAIC method provides a thorough analysis and diagnostic roadmap, powered by powerful tools and techniques. However, Six Sigma is a general problem-solving environment. Given the ubiquity of process inefficiencies, Six Sigma projects - especially those that aim to improve process efficiency and speed - can benefit from the standard solutions Lean offers. The key to a successful integration of Lean and Six Sigma is to consider the management of the Six Sigma project and the DMAIC roadmap as a general framework for problem solving and process improvement. Thus, within this framework, Lean's standard solutions and mentality find their place (Van de Heuvel, J., Does, R.J.M.M & Koning, H. 2006) [21].

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Lean and Six Sigma are commonly combined in health care because they address two related but separate issues. Lean's focus on cost reduction and cost-effectiveness is a perfect complement to tracking precision and accuracy of Six Sigma. Many healthcare organizations have begun the Lean Six Sigma "journey," and some have already achieved significant results. (Lighter D.E., 2014) [23]. Defects in healthcare are called complications. They do harm to patients and cost huge amounts of money. Thus, Six Sigma and Lean improve quality and reduce costs. They do this by following different strategies and, in this respect, are very complementary. The combination is even stronger since Six Sigma offers a full quality improvement program, and Lean tools can be easily integrated into it (Van de Heuvel J., Does R.J.M.M, Koning H., 2006). (Van de Heuvel J., Does R.J.M.M, Koning H., 2006) [24].

Healthcare customers are patients. In contrast to the manufacturing industries, "medical industry" customers are more involved in the whole process, rather than enjoying the benefits of the final product. Therefore, successful implementation of

management tools to improve the efficiency of a work process would probably improve our patient experience and lead to greater "customer satisfaction". (Agarwal S., Agarwal K.K., Parashar A. & Kapadia S., 2016) [25].

Several large European hospitals have embraced the Lean Six Sigma application to improve workflow processes related to healthcare, with benefits in improving the quality of patient care as well as lowering costs; several examples are shown below:

- a. The implementation of Lean Six Sigma in a large Red Cross hospital in the Netherlands has influenced the reduction of waiting times in an overcrowded emergency room. Additionally, the Lean Six Sigma team also acknowledged some operating theater workflow issues that contributed to employees' inefficiencies, delays and complaints. Applying this management tool has helped improve the admission process and workflow that have considerably improved operational efficiency. In addition to improving workflow, this application has been appreciated by employees as a very useful tool, thus greatly improving the morale at work. (Van de Heuvel J., Does R.J.M.M, Koning H., 2006) [26].
- b. Following the initiation and implementation of Lean Six Sigma process improvement within the Cleveland Clinic's Catheterization Laboratory, the group of researchers lead by Agarwal S. (2016) noticed three years after the onset of the project a significant improvement in the patient's time of return, periods of physician inactivity (non-use of physician), timely arrival of the patient, timely arrival of the physician, timely commencement of the procedure, as well as improvement in sheath pulls within the catheterization lab (Agarwal S., Agarwal K.K., Parashar A. & Kapadia S., 2016) [27].
- c. Lighter D. E. (2014) describes the Lean Six Sigma success story obtained by the Akron Children's Hospital, which created the 2008 Center for Excellence for Operations Mark A. Watson and has since prepared hundreds of staff, saved 13.4 million dollars, and reduced NVA work time by

more than 41,000 hours. These efforts have led to a reduction in waiting times for patients, in addition to cost savings. The

- d. hospital reports a number of successes of the project:
 - Reconfiguration of the sterile processing department avoided the need for an expansion of \$ 3.5 million, while improving the work environment and reducing the return time of surgical instruments;
 - A 90% decrease in waiting times for MRIs in the radiology department has increased the volume of MRIs that have increased revenue and made the service more accessible to the community.
 - Improvement in the accuracy of weight determination for patients with burns in the pediatric department to reduce medication and fluid management errors (Lighter D. E., 2014) [28].

4.5 Systematic analysis of the application of Lean and Six Sigma quality improvement methodologies in radiology

Expenditure on healthcare programs continues to increase, despite frequent adjustments. For many reasons, radiology practices are a prime target of specialists' attempts to control costs. First of all, radiology practices depend on a wide variety of very expensive complex machines and systems, and the rapid evolution of new technologies often makes these devices obsolete and require replacement. Secondly, despite the high overall cost of radiological imaging, diagnostic imaging services have been used at a significantly higher frequency over the last decade (Amis, E.S.Jr., Butler, P.F., Applegate, K.E., Birnbaum, S.B., Brateman, L.F., Hevezi, J.M., Mettler, F.A., Morin, R.L., Pentecost, M.J., Smith, G.G., Strauss, K.J. & Zeman, R.K., 2007) □29□.

While spending on healthcare has reached a historical level, the rates of clinically preventable medical errors remain significant systemic. (Amaratunga T. & Dobranowski J., 2016) □30□, have shown that Industry Quality Improvement Methodologies (QIs) are potentially useful in health and radiology as they use an empirical approach to reduce variability and improve workflow.

The conclusion by Amaratunga T. & Dobranowski J. (2016) is that Lean and Six Sigma QI methodologies have the potential to reduce errors and costs and improve quality in radiology. However, there is a pressing need to conduct high-quality studies to demonstrate the true potential of these Quality Improvement (QI) methodologies in the field of healthcare and radiology.

5 CONCLUSIONS

Lean and Six Sigma are innovative quality improvement methods (QI) that have been successfully used in industry to reduce variability and improve workflow.

The Lean and Six Sigma methodologies have been applied across a wide range of areas and processes in the health sector, including radiology, where a number of metrics and quality results have been improved.

Even though Lean's results seem promising, so far, the findings do not allow a final conclusion to be drawn on their impact or positive challenges when introduced into the healthcare sector. Researchers are called upon to further explore Lean's potential and weaknesses, especially in terms of the scale of investment required and the engagement of the entire organization that is an increasingly strategic choice, while healthcare professionals, managers and decision-makers could and should learn from the researcher how to play an essential role for a more effective implementation of Lean in different healthcare contexts. (D'Andreamatteo A. et al., 2015) [31].

This increase in patient satisfaction is beneficial to the medical organization by achieving high levels of retention and patient loyalty. In addition, improving operational efficiency should help reduce healthcare costs by eliminating redundancies and streamlining workflow.

Therefore, successful implementation of management tools to improve the efficiency of the work process would probably improve Romanian patients' experience and lead to greater "customer satisfaction".

The quality of the evidence regarding the efficacy of Lean and Six Sigma within

radiology is very poor, and when classified according to the framework proposed by the GRADE working group, the risk for bias (P values not provided in 87% of included studies) and imprecision (CIs not provided in 96% of included studies) of the included studies as a whole was considered high (Amaratunga T. & Dobranowski J., 2016) [32].

In the coming decades, those providing radiologic imaging services will increasingly have to cope with the challenges of economic, demographic and political forces that affect healthcare to improve their efficiency, to increase the value of their services and to achieve greater customer satisfaction. It is essential that radiologists master and apply consistently basic skills in process improvement that have enabled professionals in many other areas to thrive in a competitive environment (Tamm E.P., Szklaruk J., Puthooran L., Stone D., Stevens B.L. & Modaro C., 2012) [33].

In conclusion, the results of this systematic review indicate that benefits can be obtained by applying Lean and Six Sigma methodologies in radiology. However, if the initial costs and effort to implement these rigorous quality improvement (QI) methodologies outweigh these benefits, and if they are superior to other more traditional QI methods in the health sector, such as quality assurance, usage review, audit programs and so on, these are the real questions researchers must answer. The methodological deficiencies in the current literature make it impossible for us to answer these questions with confidence. Clearly, therefore, well-designed studies are required.

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Lean, six sigma în sănătate: o revizuire de literatură

Rezumat: În ultimii ani, interesul practicanților și cercetătorilor în utilizarea instrumentelor Lean Six Sigma pentru îmbunătățirea proceselor din sectorul medical a crescut semnificativ.

Lucrarea urmărește să furnizeze informații cu privire la subiectele de cercetare, contextul cercetărilor și metodologiilor de cercetare abordate de recenta literatură științifică privind impactul metodelor Lean Six Sigma asupra eficienței operaționale îmbunătățite, a unei profitabilități și calități mai ridicate a proceselor din sectorul medical.

Rezultatele cercetării sunt utile atât pentru practicanții din domeniu care pot identifica idei sau soluții la problemele cu care se confruntă, cât și pentru cercetători în căutarea unor oportunități viitoare de cercetare.

Lucrarea include, de asemenea, o analiză critică care evidențiază avantajele și dezavantajele aplicării diferitelor metode și face recomandări cu privire la aplicarea acestora.

Anamaria HUZU, Universitatea Lucian Blaga din Sibiu, anamariahuzu@yahoo.com

Claudiu Vasile KIFOR, Universitatea Lucian Blaga din Sibiu, claudiu.kifor@ulbsibiu.ro

Roxana Florenta SAVESCU, Universitatea Lucian Blaga din Sibiu, roxana.savescu@ulbsibiu.ro

Gianina LUP, Universitatea Lucian Blaga din Sibiu, gianina.lup@ulbsibiu.ro