Route Educational & Social Science Journal
Volume 6(10); November 2019

Artical History

Received/ Geliş	Accepted/ Kabul	Available Online/yayınlanma
11.11.2019	20.11.2019	30.11.2019.

SIX SIGMA AND LEAN THINKING IN HEALTH CARE INDUSTRY (LITERATURE REVIEW)

نظرية الجيود السداسي واللين (التفكير الخالي من الهدر) في صناعة الرعاية الصحية(الإطار النظري)

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الملخص

تهدف هذه الدراسة الي معرفة ما إذا كانت منهجيات تحسين الجودة الصناعية يمكن تطبيقها في خدمات الرعاية الصحية ام لا؟ وكمثال على هذه المنهجيات سلطت هذه الدراسة الضوء على نظرية الحياد السداسي ونظرية اللين في خدمات الرعاية الصحية. المرجعيات الأدبية في هذه الدراسة بدأت بتعريف ماهية الجودة في الخدمات الصحية، وكيف يتم قياس أداء الخدمة في النظام الصحي، لما لفهم قيمة أدوات قياس الجودة ومؤشرات الأداء من دعم كبير في تحسين جودة النظام. ومن ثم تم تقديم شرح موجز لأدوات التنفيذ الناجح للمتطلبات المعرفية. كما تم استعراض بعض المرجعيات الأدبية بماهية الحياد السداسي ونظرية اللين (التفكير بدون هدر) وتطبيقاتها في سياق قياس الأداء. أيضا تم التحقق عن إمكانية تطبيق نظرية اللين كألية مشترك مع الحياد السداسي. تم عمل مقارنة قبل وبعد تطبيق هذه الطرق مع توضيح التحسينات التي تم اجراؤها من خلال اعتماد هذه الطرق. كما استعرضت هذه الادبيات أيضا تطبيق مؤشرات الأداء في كلا من الدول المتقدمة والنامية. أيضا تم استعراض أبرز النقاط في تحسين جودة البيانات وتأثيرها على مراقبة الجودة.

الكلمات المفتاحية: الرعاية الصحية، الحياد السداسي، نظرية اللين، مؤشرات الأداء.

Abstract

This study aims to investigate whether the industrial quality improvement methodologies could be implemented in the health care services or not? As an example of the industrial quality improvement methodologies, this review examined the applications of six-sigma and lean thinking in the healthcare services. The literature review started with defining what quality in the health services mean and how health system measures the service performance. Understanding the value of quality measurement tools and performance indicators will support in enhancing the quality of the health care system. A brief explanation of the culture requirements for the success implementations of these tools provided. The literature review then described what six sigma and lean thinking are and their application in the context of performance measurement. Then it investigates the possibility of implementing the lean thinking as a co-product with six- sigma. A comparison provided before and after the application of these methods showing the enhancements made by the adoption of these methods included. The literature also reviewed the application of the performance indicators in both developed and developing countries. Improving the data quality and its effect over the quality control highlighted.

Key words: Industry, Healthcare, Six- sigma, Lean Thinking, performance indicators.

1- Introduction:

Aim: The main purpose of this literature review is to investigate the possibility of integration of the quality measurement tools and performance indicators from the manufacturing industry into the healthcare systems. This investigation is particularly important due to the accreditation process, the new facilities, and technological advances emerging from the health informatics research.

Objectives: The objectives of this study are (1) understanding the characteristics of quality in the healthcare industry; (2) examining if the manufacturing industrial quality improvement techniques could fit in healthcare industry; (3) reviewing what six sigma and lean thinking are and their application in the context of performance measurement; (4) investigating the possibility of implementing the lean thinking as a co-product with six- sigma., and (5) finally to review the effect of the applied accredited plans on health quality indicators.

Method: Three databases were searched for this narrative review: PubMed; Cochrane library and Embase. Hand searching for all the reference lists for relative studies was also conducted, 30 papers were included all published in English language. This study was conducted to investigate the perceptions associated with implementation of quality measurement tools and performance indicators from the manufacturing industry into healthcare sector. Data items were extracted for analysis independently by the 2 authors of this paper**.**

Despite the advanced improvements in both technological and clinical methods that led to the increase in the life expectancy, the cure for many diseases and improvement in the healthcare systems performance. There is still continuous effort to improve the overall health services performance with low or no extra cost.

Although, that the cost is the core interest of quality in any service. There are difficulties in defining quality in health care services due to the multidimensional nature of quality attributes in this sector. Maxwell R.J (1992) has suggested defining it through certain components such as efficiency, effectiveness, equity, accessibility, and appropriateness. On the other hand, the main success of any quality improvement programme in health care is meeting the patient satisfaction.

In the last two decades, research studies have investigated two points of views about the application of quality improvement techniques. The first viewpoint, quality must be built into the design of new facilities and processes. The second viewpoint, quality could be improved using the existing facilities. The last point of view has been explained by Robert Chatburn (2011) in his handbook for health care research. The author states that quality could be improved using the existing facilities with some modification in the health culture. The author has claimed that the new equipment and facilities should meet the established needs, but "new does not necessarily mean better". This book has harmonized with other research papers. Heuvel, J et al (2005) have investigated the implementation of Six Sigma in a Dutch hospital with the existing facilities. The results revealed reduction on child's length of stay with approximate annual savings of $30,000. Black. K and Reverse. L (2006) have stated that the basic role of these methods (continuous quality improvement, quality assurance, lean thinking and six- sigma) is to evaluate the capability of a process to improve the quality, reduce defect and increase customer satisfaction.

This review investigates in detail the uses and the applications of these tools in the health services. The review will start with a definition of what quality in the health services means, this will be followed by an example of how a health system could measure its performance from one of the well-established health care systems, namely, the National Health Insurance (NHS) in the United Kingdom. A brief explanation of the culture requirements for the success implementations of these tools will be provided. The literature review will then describe what six sigma and lean thinking are and their application in the context of performance measurement. The review also investigates the possibility of implementing the lean thinking as a co-product with six- sigma. A comparison is provided before and after the application of these methods, showing the enhancements made by the adoption of these methods. The review includes the application of the performance indicators in both developed and developing countries. Improving the data quality and its effect over the quality control is also highlighted.

This literature review is organised as follows. Section 2 discusses the quality in health care services providing important definitions and concepts. Section 3 provides a discussion of the performance indicators. Six-sigma and its alternatives discussed in Sections 4 and 5 respectively. Accreditation of health services and its relationship to the quality tools discussed in Section 6. Finally, a discussion summarising the literature reviewed in Section 7, followed by a short conclusion in Section 8.

2- Quality in health care services

2.1- Definition of quality in the health care services

Due to the diversity of the stakeholders in the health care industry, the definition will have different perspectives and directions. The main concern in the healthcare services is to manage the gaps between expectations and perceptions of stakeholders. Some define quality in health as a good performance (Campbell, S.M et al 2000) while others have tried hard to find an accurate definition for quality in the health care industry. Maxwell (1992) has suggested that quality in health care can be broken down into six components, namely, efficiency, effectiveness, equity, access, acceptability, and appropriateness. These trials of defining quality in health care not done only by the researchers and scientists, but also by governmental organisations. As in 2000, the Australian Government has developed a national health performance framework with nine principles of dimensions, namely, effective, appropriate efficient, responsive, accessible, safe, continuous, capable, and sustainable. The framework has explained the value of quality in the health care system and localized it in the

practical value. It suggested in measuring quality to focus on two principles of dimensions, which are accessibility and effectiveness. The benefit of the focus in only two of the quality principles of dimensions is considering the patient (consumers) as a core of any quality improvement project. However, the individual health plan should not be isolated from the nation plans. The elimination and the ignoring of the other seven dimensions would affect the health care plans. Issues like equity and efficiency will be the most affected. Balance should practise between the nine dimensions of evaluating the quality performance. This would ensure quality services in the most effective way.

The Picker Institute Europe have defined quality in health as *"providing the best possible care compassionately and reliably"*.

It can easily conclude that there are real difficulties in defining quality in health care services due to the diversity of perspective and the current level of quality provided. However, the main success of any quality improvement programme in health care is meeting the patient satisfaction. The world health organisation (WHO 2000) had defined quality as a process of meeting the needs and expectations of patients and health service staff. It found that, definition to be general and diverse it includes all the other definitions in it without confused by context and level of health care service provided.

2.2- Requirements for the improvement of quality in health care.

The quality improvement is a continuous process that depends on a number of factors and requirements in order to be successful. This includes the effective decision-making of an effective leadership. This way of management is targeting the organisation goals, and patient satisfaction. This is required continuous reviewed and assessed by observing the outcomes against specific measures. Continuous learning and improvement culture are crucial for quality improvement. Furthermore, improvement depends on the interaction of multiple factors including budget, measuring characteristics, implementation strategies, and the availability of resources.

Baker. A (2001) has proposed an agenda in order to improve the health care quality. This agenda has six components: (1) the safety of the patient (avoiding injuries); (2) effectiveness by providing the health care should be based on scientific knowledge and well experienced health staff; (3) the patient is the focus point in which the patient needs and expectations should be the guide for the clinical decision; (4) the time of providing the services in order to reduce the waiting list and the unjustified delays; (5) efficiency by avoiding the waste of equipment, supplies, and energy; and

(6) the equity in providing the same care services to everyone. These six components are aligned with Maxwell R.J (1992) in which it has been suggested defining quality in health care through certain components such as efficiency, effectiveness, equity, accessibility, and appropriateness. Moreover, in 2005 the Picker Institute Europe has published a document about the patient's needs and expectations during their experiences of treatment in the NHS. The results were focused on the patient expectation of a quick access to the services, with the effectiveness, and the continuity of the care. It has been suggested that the patients need to be supplied with clear information and be involved in the decision making.

This area of research has attracted the research community to further investigation about the requirements and barriers of any quality programme to make sure that it will result in a successful one. Addington, D et al (2010) have systematically reviewed the gaps between the qualities of mental health provided in the primary care and the optimal care. The authors have investigated the facilitators and the barriers to the implementation of the quality measures in primary care. The result of their study has found that the success of the implementation of quality measures depends on the interaction of multiple factors including the measuring characteristics, implementation strategies, and the resources. They have mentioned that the quality measurement of the primary mental health care has already taken place in many countries. In Canada as an example they have mentioned, there was a project launched in 2004 for the continuous enhancement of quality measurement in primary mental health services. Particular attention to the culture requirements has been concluded
Joint Commission on Accreditation of Health Care Organisation (JCAHO 2001) has emerged as one of the ongoing efforts to face the quality and safety challenges. This standardisation based on modernized health organization culture by:

(a) providing leadership
(b) Improving organisation performance; and
(c) Providing training and education techniques in information management, and patient safety.

These safety standardisation requirements are similar to the culture requirements for quality improvement provided by Sammules, D.I and Adomitis, F.L (2003) in their research paper. The authors argued that healthcare industry could use industrial quality methodologies in order to meet the customer expectations in health care organizations, improving profitability, and eliminating errors in business processes. Six Sigma is one of the popular methods and it is similar to the concept of standard deviation, as the sigma level increases, the number of defects decreases. In

spite of the facts, the authors have revealed about the important roles the top managers should play, they have not given any indication that there should be a whole transformation of the health organisations culture toward the transformation leadership. They also have not mentioned the importance of changing the health care services into learning environment. On the other hand, Hewitt, P (2005) has warned the NHS managers from the uncertainty, and the instability during the next phase of health service reforms. The health secretary has recommended and encouraged the engagement of the health managers with the frontline staff. The secretary has revealed that there is still much more to do to enhance the health care quality by reducing waiting times and increasing the patient contribution. This article is a good example of the real changes in the management thinking, which depend on the environmental change of the health care services into a learning environment, with more involvement of the patients in their health care plans, and the true application of the leadership values. All of the above represent the essential requirement for the application of any quality improvement programme or methods.

Examples from developed and developing countries followed. Chassin, M.R (1998) have briefly explained the required environment in the USA health system for the application of Six Sigma. The author has claimed that there are some requirements that should exist before applying Six Sigma in health services. These include changes in the health environment by adopting new education model, understanding the causes of errors, increasing the consumer awareness and participation in order to reach consumer satisfaction and finally encouraging the investments in the health sector in the field of quality improvement. The author has specified certain requirements for the success of the Six Sigma that require a long time to be materialised.

Elapanda, S et al (2019) have summarized the pre implementation environment requirements for applying Lean Six-Sigma (LSS) in testing laboratory quality management system in India. The authors highlighted the basis for the success of the implementation of LSS are based on the pre-implementation phase. Identification of the appropriate Lean Six sigma tools, the selection of the DMAIC (Define, Measure, Analyse, Improve and Control) methodology which is suitable for integration. In addition to training and education programmes for the employees about the importance of LSS as a quality control method. Finally development of the LSS framework before the integration phase.

In order to summarise the findings of the above studies, there is no difference between the culture requirements for quality improvement in developing and developed countries. The culture should be flexible to

adopt an education model, which helps in understanding the causes of errors, and increasing the consumer awareness and participation. This culture should encourage the investments and provide training and education techniques in information management.

3- Performance indicators

The higher education statistic agency in the United Kingdom has defined the Performance indicators as quantifiable measurements that agreed to beforehand, which reflect the critical success factors of any organisation.

3.1-Performance indicators are measurable items for quality

Campbell, S.M et al (2000) have identified the importance of the performance indicators while defining quality in health services. The performance indicators are the measurable items in which we can evaluate the structure, processes, and outcomes with specific criteria and standards. The authors explained that the service should be tested for acceptability, feasibility, reliability, sensitivity to change, and validity. This test would improve the effectiveness in the quality improvement strategies, as the indicators would be more effective when they based on scientific basis. The authors have claimed that simply measuring the quality would not automatically improve the services. However, the usage of certain performance indicators would enhance the improvement of the health services.

In Australia, as mentioned earlier, the national health performance committee has provided framework with nine performance indicators. These indicators are effectiveness, efficiency, appropriate care, responsiveness, accessibility, safety, continuously, capability, and sustainability. Finding the balance among these indicators is essential in identifying the ways to deliver the services. For example, the effectiveness and efficiency are important goals to ensure that the health service provided in an appropriate cost and at the same time in a high-quality standard. The significance of this report is that it shows how important the quality performance of the health organisations to the governments, especially in the last few decades, when the quality and safety issues became demanding in the health sector (National Health Performance Committee and AIHW 2003).

De Vos. M et al, (2009) have systematically reviewed the implementation strategies of the quality indicators in hospital care, and their effectiveness in improving the quality of care. This review has included 21 studies. The

majority of them focused on the care process only. However, six studies focused on the evaluation of the implementation of the quality indicators, with the implementation of other strategies and their effect on the patient outcomes. The results of this literature suggested that the most significant improvements that could be achieve with the quality improvement result if it is combine with other implementation strategies such as the education implementation strategy.

The area of performance indicators and improvement in quality is of great interest to the policy makers in heath sectors and human services managers who seek understanding of their organisational outcomes. Klassen, A et al (2009) have systematically reviewed the performance measurement, and improvement frameworks in the health, education, and social services. This study confirms that performance indicators could be used in the services system including the health sector. The authors have given definitions to (a) the *quality improvement processes* as the processes with continuous activities including programme evaluation, performance monitoring, and accreditation; and (b) the *performance indicator*: as measurable item that can be used to evaluate the status and the performance of the organization. The authors in this paper have given an example of children with complex chronic diseases, and/or children with special needs. Their cases might have needed caring services that go beyond the traditional health services. Therefore, other services also should provide additional support from other sectors like the community, and the school support.

The results of this study about the quality improvement process aligned with the results of Baker, A (2001). There is no different between the requirements of the quality indicator performance in health services and any other social services, or between developed and developing countries, as concluded earlier.

3.2- Using performance indicators to improve health care quality

Several studies have tried to investigate whether these indicators could improve the quality in health or not. Freeman, T (2002) has systematically reviewed the empirical and theoretical ways to improve the health care quality in (NHS) through the application of performance indicators. The author has found that there are various ranges of performance indicators according to the efficiency, effectiveness, and outputs/outcomes. It found that there are two principle uses of the indicator system. First, are the summative mechanisms, and second are the formative mechanisms. The author has argued that the uses of the formative mechanism for the internal

quality improvement provide trust and communication between clinicians and management. On the other hand, the uses of the summative mechanism put more pressure on the clinicians and management. This is because the trust is in the system rather than the individuals, which leads to corrosion and corruption even to the performance indicator itself.

The main point of importance in this study is that the performance indicators in health sector may be inaccurate and misleading. It should be taken as the first step for further investigation and discussion. The managers should focus on creating a culture of open discussion and learning instead of blaming the health staff.

On the other hand, the Australian Institute of Health and Welfare (AIHW) has supported the idea of using the performance indicators and has developed a set of safety and quality indicators through the National Indicators project, which has recommended a set of 55 national indicators of safety and quality in health care, provided to patients across the Australian health care system. The scope of this indicator set is the safety and quality of clinical care provided to patients across the Australian health care system. The methods used to develop an indicator set in close consultation with the project's National Indicators Advisory Group (NIAG). The focus is on safety and four quality domains, namely, appropriateness, effectiveness, continuity, and responsiveness. This could serve two main purposes. It can provide transparency also can inform decision-making about overall priorities and system-level strategies for safety and quality improvement. Moreover, it can inform quality improvement activities of service providers. AIHW (2009).

4- Six Sigma

Harry, M. J and Schroeder, R (2000) have explored the roots of the Six Sigma. They explained how it has begun as a quality improvement plan in Motorola in the late 1980s. Reducing defects, improving the profit line, and increasing the customers' satisfaction were the aim of using this methodology. It all had begun in 1970's when Art Sundry was criticizing Motorola's bad quality. At that time, there was a belief that quality would cost extra money. However, it has proven its success in reducing the costs including the costs for repair. Then, Bill Smith in 1986 has developed the Six Sigma methodology. This methodology depends on statistical methods, and the initiating of the infrastructure of Champions, Master Black Belts, Black Belts, and Green Belts with its implementation**.** This tool has allowed the manufacturing industry to measure, analyse, improve, control the product, and achieve the stability in the process. The authors have also explained the definition of Sigma and Defects per Million

Opportunities (DPMO) as follows. *Sigma*: is a quality metric that counts the number of defects per million opportunities, while the *Defects per Million Opportunities (DPMO)* is the total number of defects per unit divided by the total number of opportunities for defects per unit, multiplied by 1,000,000. The main point of interest the authors argue in this book is that the cost of the quality for most industrial companies ranges between 25%-40% of the sales revenue, which is the total amount of money received by the company for selling goods or providing services during a certain period. However, by using Six Sigma, the cost of quality has declined to less than one percent. Moreover, the authors have discovered that the Six Sigma positive result might take up to five years to be fully achieved, as there is a need to change the learning culture, and for also the transformation in the leadership philosophy.

Tjahjono, B et al. (2010) also have revealed that the Six Sigma is a set of statistical tools expressing a management philosophy. This depends on scientific methods and analysis. The two main goals of Six Sigma are improving the efficiency and increasing the profit. The authors also have clarified how to use the statistical tools, and how the simulation can help in the proactive analysis of the systems. The authors have argued that although the application of Six Sigma had proved its success in the manufacturing industries, the detailed implementation in the services industries was not widely reported in the academic literature, which means that this area of research needs more investigation. Three years before that study, Antony, J et al (2007) and Saadat, M., & Antony, J. (2007). has revealed that although the number of applications of Six Sigma in manufacturing industry has gone down. On the other hand, the applications of Six Sigma in health care have gone up. Since that more studies, investigations and results about the usability of Six Sigma in health care have been conducted.

4.1- Six Sigma applications in developing and developed countries: a comparison

as an example of Six Sigma application in developing countries Gamal, A. A (2011) has performed an empirical survey, using 500 self-administered questionnaires. This survey is about the implementation barriers of the Six Sigma that may vary in relation to dimensions of organisational factors especially in the developing country. The author found that most effective barriers to the Six Sigma implementation classified into two categories: (1) the soft impediments, which include knowledge and support; and (2) hard impediments which include professionals and finance. The author has argued that the managers should focus before the application of Six Sigma in the knowledge barrier by

sharing and discussing the implementation with the staff members. Moreover, the organisations should give more attention to issues related to this barrier and should not waste their resources preparing for addressing all the barriers of the Six Sigma implementation. The author has revealed that this paper is one of the first studies in developing countries, which examines some of the Six Sigma barriers, and their effectiveness in relation to dimensions of organisational factors.

On the other hand, and as an example of Six- Sigma application in developed countries, Psomas, E. (2016) has examined the barriers of implementing Six-Sigma in a manufacturing organization in Greece. The study results revealed that lack of interest in Six- Sigma with the misunderstand of its implementation patterns are factors that could affect the success of Six- Sigma implementation. In addition to the organization culture and the prioritization of applying such quality management method. In the health sector, Jiju, A. K et al. (2007) and Antony, J et al. (2007) have examined in their papers the ability of Six Sigma to improve the financial and operational performance of the NHS in the UK. They have revealed that the purpose of these papers is to increase the awareness and the importance of Six Sigma in the health care. The authors have given a quick summary about how the Six Sigma beachhead in health care services, and its slow progress since 2000.Two years later, a large number of hospitals in the USA have adopted the Six Sigma methodology. The authors have discussed briefly how the use of Six Sigma and the DMAIC methodology could reduce the cost of the services without affecting the quality of the care. The authors have then briefly explained the five stages of the DMAIC as follow:

D: Defining the problem
M: Measuring the defects
A: Analyse the causes of defects
I: Improve the performance
C: Control the process

The authors have strongly recommended the implementation of the Six Sigma in the health services industry, especially in its financial sectors as much as it is widely used in the manufacturing industry. Particularly with the challenges that face the NHS in order to respond to the changing needs, the Six Sigma as a framework offers the structure for improvement. The important point in this research is that the authors have explained how the Six Sigma takes the Total Quality Management (TQM) efforts to the next level and how it has a great potential in health care.

4.2- Six Sigma in small hospitals

Could Six- Sigma be applied in small/medium organization and achieve good result? In the industrial sector Six- Sigma proves its ability to provide good quality products on low cost even in small organization such as bicycle chain manufacturing unit (Kaushik, P. et al 2012). In the health sector, Davig, W et al. (2003) have done a survey paper that took place in Kentucky, USA. The objectives of this study were to determine the level of effort and the degree of effect of the total quality management model over their managers in small manufacturing organisations. The result has proven that the penetration of the TQM concepts among the managers in the small manufacturing organisations had a positive effect .The authors have asserted that Six Sigma is just one of the quality measurement methodology adopted by different service industries to improve the performance, and increase the customer satisfaction. However, the results vary according to both the size of the organization, and the type of service it provides. Six Sigma and the other methodologies usually follow the method of Define, Measure, Analyse, Improve and Control (DMAIC) to identify the root of the problems and meet the customers' requirements.

The benefit of using these tools can be integrate with the existing initiatives, business strategy, and key performance measures. However, these results could not be 100% useable in the services industry as the whole survey has taken place in small manufacturing organisations. But, Six Sigma forum magazine (2005) has published an article about the small Dutch hospitals. These local hospitals have succeeded in applying Six Sigma with their existing initiatives. The article has claimed that even in small hospitals, Six Sigma can make a great difference because of its easy software. This paper increases the possibilities of applying these tools in even small/local hospitals.

4.3- Implementing Six Sigma in health care: success stories

In order to implement Six Sigma in the health services industry, Sammules, D.I and Adomitis, F.L (2003) have argued that the top managers should give more attention when applying this tool by:

(1) Defining the purpose and the scope of the project;
(2) Analysing the root of the problem by the actual data; and
(3) Evaluating the performance of the process before and after the implementation.

These require changes in the culture of the health care sector. The question now is whether the Six Sigma can really affect the performance

and the level of patient satisfaction in the health care system or not? Torres, E.J et al (2004) have suggested the evaluation and measurement of patient satisfaction levels before and after the implementation of Six Sigma. Through gathering and analysing of the data related to the overall performance and the degree of patient satisfaction. This would allow the managers to evaluate the real impact of Six Sigma. The elimination of the causes of patient dissatisfaction would enhance the performance, and improve the overall outcome in the future. Following these steps can be effective not only in achieving customer satisfaction, but also reducing costs and improving profitability.

Lanham, B et al. (2003) have investigated the result of applying Six Sigma in health services. The Six Sigma implementation has included the laboratory specimen, the medical administration, and the operation areas. This experience has begun in 1999, when The American Society for Quality with the Froedtert hospital had formed a partnership. Their purpose was the successful implementation of Six Sigma. The aims were reducing the medical error, enhancing patient safety, and reducing services cost. The authors have recommended the usage of the Six Sigma in the health care sector. The importance of the paper is that it gives a real practical example of the successes of Six Sigma in health services and how it could reduce the medical errors (with the usage of the available resources), without any extra cost. This result has denied the belief that quality costs extra money. Therefore, the health industry could gain the benefit of applying quality improvement methodology just the same like the manufacturing industries. The only drawback in this experience was the difference between the time of the experience and the time of writing this paper, as the experience took place in 1999, while the authors wrote this paper in 2003. The consequence of other studies or even the continuous recording of the results would support the authors' findings even more.

Almost ten years after this study, Lifvergren, S et al. (2008) have argued that during the last two decades, Six Sigma successfully applied in many industries, and recently it applied in the health care. In the health care sector, Six Sigma applications succeeded in cutting down the patient visiting time in hospitals, improving the quality of care, and increasing the efficiency of the administrative processes. The authors have stated that the basic role of the Six Sigma is to evaluate the capability of a process to improve the quality, reduce defect, and increase customer satisfaction. The authors have explained in detail the Warfarin, which is a medical drug usually used for the prevention and the treatment of thromboembolism. This drug has a deadly side effect, which is bleeding that might occur if high dose has been given. This research paper is concerned with the

implementation of Six Sigma, and its ability in reducing the risks associated with this treatment. The authors have used the DMAIC to analyse the problem. The result of this study has claimed that the Six Sigma has achieved a real success in enabling the percentage of the International Normalised Ratio (INR) to reach 70-75. (INR) determines the clotting tendency of blood in the measuring of Warfarin dosage. This considered as a baseline for further investigation about the success of applying Six Sigma in the health care under certain circumstances, which is related to the environmental difference between the health industry and the manufacturing industry.

4.4- Barriers to the implementation of Six Sigma

Chiarini, A. (2013) has briefly explained the health care industry specific nature. The author claimed that the health care industry has a unique nature. It is a service industry available on demand, and varies according to the situation (as every patient is different) this cannot be compared to the manufacturing or the other non-service industries. Those are usually having a fixed process, product, and design. The authors have also explained the challenges that might face the health care system and summarise them as follow: (i) lack of communication, (ii) different goals and strategies in-between the same hospital departments and (iii) insufficient investments in the the quality aspect of care.

These specific factors and challenges should take into account when implementing any quality improvement tools or programme. The reliable question this paper provides is whether the health culture would accept the application of the manufacturing quality improvement tools. The findings support the initiative that every patient is different, and that the health services are not providing a product line with exactly similar features and dimensions. Taking the same point of view, Stahl, R et al. (2003) have argued that due to the lack of proper design of the health care industry compared to the manufacturing one, there will be a limitation in the improvements of the health care industry.

5- Alternative tools to Six Sigma

The question now whether there are other alternative tools that can be used in the health care services instead of Six Sigma or not. Black, K and Reverse, L (2006) have analysed in detail the use of the Six Sigma methodology to improve quality performance in the health care. The authors have explained the difference between it and the Total Quality Management (TQM) where TQM is referring to the continuous effort of employees to produce quality products while Six Sigma is a set of management techniques proposed to improve result by greatly reducing

error and defect. The authors have claimed at that time that the future of Six Sigma in health services is vague, and that is due to some limitations of the Six Sigma application. Another study which supports the use of TQM instead, done by Locock, L (2003) who has explained the redesign in the health care system that can be done by using the Total Quality Management (TQM) or the Continuous Quality Improvement (CQI). The author has explored the meaning of redesign, its theoretical origins and the evidence of its application. The purpose of the redesign is to improve the overall quality of care, and the patient satisfaction level. This could be valid through the achievement of a quick and effective quality improvement programme without any unnecessary delays or errors. The main challenge to any redesign plan is the resistance of change. The main important finding of this research is that it shows the importance of leadership. The inclusion of some re-engineering techniques may help to overcome the challenge of incomplete quality improvement. In the following sections, there will be an investigation of an alternative tool, also adapted from the manufacturing industry; this tool is *Lean-thinking technology*.

5.1-Lean thinking

The NHS is one of the world leaders in the implementation of the Six Sigma, and the Lean thinking methodologies during the redesign period of the NHS. The NHS website contains a lot of valuable information, training resources, development tools, and case studies. This website explains the beginning of the lean thinking methodology as a quality improvement tool that has developed by Toyota for getting the right things to the right place, at the right time, in the right quantities, eliminating the waste, and being flexible, and open to change.

Jones, D and Mitchell, A (2006) have mentioned that the aim of using lean thinking in the NHS as one of the manufacturing quality methods in the heath sector was to offer better patient care with low cost, without new investments. In the same paper, the authors have given a real example, this time from Australia. The Flinders Medical Centre in Adelaide, South Australia that can be classified as a medium-sized public sector, also as teaching hospital, has applied the Lean principles for just over two and a half years. The results are significantly better as indicated by the following: (1) 15% to 20% rise in the performance (workload) using the same budget; (2) using the same infrastructure; and (3) above all, the improvement occurs with an extra attention to both staff and technology safety.

Mazzocato, P et al. (2010) have systematically reviewed 33 articles. The authors have found a wide range of lean applications in many health

organisations. Lean thinking has successfully improved the effectiveness, efficiency of the performance, and also has raised the collaboration, awareness, and reduced the wastes. Nevertheless, there is still limitation in technical application. The authors have recommended the involvement of the senior management and involvement of the patients.

5.2- Lean thinking applications in developing and developed countries: a comparison

McCulloch, P et al. (2010) have explained the success of the implementation of the lean thinking in improving the quality, and safety in the emergency general surgery ward. This practical study has taken place in one of the university hospitals in the United Kingdom. There was a rise in the inquiry about the patients' safety in this hospital. This was due to the presence of errors during the service. The implementation of the lean methodology has involved the redesign of the system. This redesign has targeted five of the seven care processes relevant to the patient safety. The study period was eight months; four of them before the implementation of the lean methodology, and four after its implementation. There was a great rise in the improvement rate from 28% to 149 %, and the proportion rate of patients requiring transfer to other wards has fallen down from 27% to 20%. The authors have argued that because of the interconnected nature of the hospitals, this improvement could transfer to the all the departments, just after the removal of the change resistance barriers. This study provides a real practical evidence of how the lean method could improve the reliability and efficiency of the health services. That is the main core of our literature review.

However, there are some challenges that may inhibit the Lean thinking implementation. Kotogal, M et al. (2009) have explained a different kind of challenges that might face the hospitals in the developing countries, when applying Lean thinking. This study took place in one of Rwanda's hospitals in rural Africa, where there are lack of electricity, supplies, and staff. The authors have examined the application of simple quality improvement tools, which are the plan-do-study-act cycles, and process maps. The authors have explained that the proposal of this study was to teach the health staff the quality improvement techniques, and to implement the stepwise. There was a significant success in two weeks period time, as all indicators have achieved a 95% of the goals. The data has been analysed using time series analysis and has compared against time using run chart rules for statistical significance of improvement. The result of the study explained (1) how the improvement could be achieve with the existent resources**;** (2) how does the visibility of the data promote changes; (3) the value of the leadership, how could the real leader encourages and motivates

the health staff in improving the health quality; and (4) interestingly although it took place in a very short period of time (only 2 weeks), by using of the simple plan-do-study-act cycle, 95% of the goals have been achieved. This may be due to the complicated situations this hospital had faced. However, the only critical point is that the authors have not declared why these tools have been selected and not any other diagnostic tools.

5.3- Implementation of Lean thinking in health care: success stories

Three success studies presented in this section. Joosten. T et al. (2009) have discussed the Lean thinking and its application in the health care system. The authors have mentioned that the real needs of using the Lean methodology in the health care. This was due to the level of quality, which stimulated the health leaders to redesign the services delivery. However, the implementation of the Lean thinking methodology faced the challenges of resistance and there is still lack of high-quality evidence that could support the lean method application. The main point of interest is that the application of Lean thinking had proven its success, its application in health care has been limited to the original lean tools, and focused mainly on operational aspects not the sociotechnical improvements .It would be more useful if the authors have explained briefly how this could be doing in practice.

Papadopoulos, T (2011) has done a qualitative case study of Lean thinking implementation in health care. The author has explained the link between continuous improvement (CI), and dynamic actor associations through the case study. This study took place in a unit of one of the NHS hospitals. The main argument in this paper lies on the continuous improvement, and the culture changes. The author has discussed briefly the beginning of Lean thinking and the five core principles of Lean. These principles in the manufacturing industries are (1) the customer value; (2) the identification of the value stream for each product; (3) the elimination of all the waste; (4) the continuous flow of the product; and (5) establishment of management system that could reduce waste to zero. On the other hand, the Lean core principles in health care have focused on the continual improvement of clinical processes by identification and elimination of the waste. This will have a direct impact on the quality, safety, and efficiency of the services.

Five years earlier, the institute of innovation and improvement of the NHS (2006) has worked on a case study. This study took place in Hereford hospital in the pathology department. The proposal of this study was to examine the success of the Lean thinking methodology in the (1)

improvement of the turnaround times; (2) The best use of the staff in the most effective manner; (3) quality improvement; (4) waste reduction; and (5) finally the best use of the resources. In 2005/2006, the Audit Commission stated that there is significant improvement in the turnaround times in pathology (40 % in 7 days). This improvement would have direct impact on the improvement of both the efficiency and patient satisfaction. This significant and quick improvement considered as a success of the implementation of Lean thinking methodology in health care.

Grove et al. (2010) have also explained the result of a 13-month study experience of the implementation of the Lean thinking in the NHS. The framework the authors had followed was as follow first, value-stream mapping and stakeholder mapping were used to map out the essential tasks of health visiting service and determine the links between all relevant stakeholders; second, waste processes were identified. After analysis, the results have shown that 65% of these processes were waste, and that waste could be removed during the redesign process. The authors have found that the implementation of Lean thinking could reduce the wastes. The authors have claimed that the main point of strength in their study was the ability of the value stream mapping in freeing up some resources which can be redirected to provide better care to patients.

5.4- Integration of Lean and Six Sigma

In the last few years, some research papers, such as Degado, C et al. (2010), have studied the possibility of the combination between both Lean and Six Sigma, which leads to a methodology named Lean Six Sigma (LSS). Black, K and Reverse, L (2006) have analysed the use of the Six Sigma methodology to improve quality in health care, and the difference between it and the Total Quality Management (TQM). It has argued that the future of Six Sigma in health services is uncertain, and this is due to the limitations of Six Sigma. The authors have suggested two other alternatives, namely, Design for Six Sigma (DFSS) and Lean methodology. They have given an example of the US health care organisation that has begun a new quality improvement that is the DFSS. This specified on the deep analysis of the problems. The DFSS required a complete redesign of the organisation, which would allow the opportunity of saving much more time and energy. On the other hand, Lean methodology came from the Toyota Production System, with the proposal of eliminating the waste, and reducing the cost. The authors have mentioned that Lean methodology should considered as a co-product of Six Sigma. This is because there is strong motivation from different organisations in the implementation of both methodologies under the name of Lean Six Sigma.

Delgado, C et al (2010) have explained in details the combination of both Lean and Six Sigma. The authors have argued that the Lean methodology would address the process of flow and waste, while the Six Sigma would focus on the variation and design. They can viewed as complementary disciplines. The aim of this combination is the reattachment of the business and operation excellence. However, there are still difficulties in the implementation of LSS in health services. These difficulties related to the resistance of the employees in collaboration. This may be due to (1) lack of communication; (2) Improper understand of the mathematical and statistical nature of some tools; and (3) lack of motivation as the improvement of the outcome usually takes long time. The authors have argued that the managers in financial services need to use LSS to improve the efficiency and effectiveness of the organisations through reducing cost and improving the quality. Despite the fact that this is a relatively recent research paper, it has not provided sufficient evidence of the success or the failure of the Lean Six Sigma methodology.

5.5- Success of Lean Six Sigma (LSS)

Murphree, P., & Daigle, L. (2011) have focused their study on the ways of sustaining the use of Lean Six Sigma (LSS) projects in health care. They have summarised the DMAIC uses with the Six Sigma. DMAIC as mentioned before is the (define, measure, analyse, improve, and control). The authors have developed a checklist targeting specific items that should addressed before the quality improvement project enters to the control phase. As the quality improvement projects usually stop after the achievement of the expected outcomes, the authors have recommended the move of these projects to the control phase. The authors in this article have addressed the current hospitals' policies in using multiple quality improvement techniques to help in the improvement of the performance in general. In this study, the authors have mentioned some specific clinical aspects in particular the Catheter Associated Urinary Tract Infections (CAUTI), decubitus ulcers, and community-acquired pneumonia. The importance of this article in our literature is that it admits the successful use of the LSS in the health services. The authors have mentioned that one of the advantages of the checklist they suggested is that it validated the systematic method in addressing the problem, and guaranteed the sustained improvement in the performance. The authors have claimed that by using the checklist it would be less likely to decline back to the baseline of performance.

6-Accreditation in health care organisations

It is important to understand the importance of accreditation in the health services**.** Beaulieu, N. D., & Epstein, A. M. (2002). have discussed the importance of the accreditation in health care organizations. The authors have discussed the following quality assurance statuses, namely, National Committee for Quality Assurance (NCQA) and National Committee on Quality Assurance accreditation status (HEDIS). NCQA is a private not-for-profit organization dedicated to improve the health care quality. HEDIS is a tool used by more than 90 percent of America's health plans to measure performance. The authors have linked the (HEDIS) scores with the patient-reported quality and satisfaction scores to compare accredited health plans to non-accredited plans. The importance of this study is in its result. The result of this study has shown that the accreditation does not ensure high quality care. As the result has found that the accredited plans may have higher HEDIS scores, but it would have similar or lower performance on patient satisfaction level. It has suggested again that rising the involvement and awareness level of the patients in their treatment journeys may improve their satisfaction level. The objectives of this study were (1) to understand the characteristics of health plans that have submitted; (2) to review also the effect of the accredited plans on quality indicators, and (3) finally to review the effect of accreditation on enrolment. A comparison between the accredited health plans, and the non-accredited plans has provided.

In the following section, there will be a clarification of how the use of Six Sigma and Lean thinking with other quality standards system such as ISO9000/QS9000 could be a useful and valid idea. The reason for supporting this conjunction is that it will allow a reasonable comparison before, and after the application of Six Sigma and Lean thinking.

6.1- Integration of Six Sigma with the quality standards systems

Mahesh, S et al. (2005) as mentioned earlier have stated that Six Sigma is a toolset, and not a management system. Its immediate goal is to reduce the defect level, which leads to several consequences including (1) cost reduction, (2) customer satisfaction, and (3) improvement of the product. On the other hand, the wrong application may lead to unexpected consequences. The authors have argued that for the best result Six Sigma could use in conjunction with other quality standards system such as Baldrige Criteria for Performance Excellence, and ISO9000/QS9000. This conjunction between Six Sigma and the other quality systems that usually used in the health services sector could facilitate the measurement of the

success rate of Six Sigma through evaluating the health organisations, which are applying Six Sigma before, and after its implementation through one of the quality standard systems such as the ISO9000.

6.2-Integrating Lean thinking with ISO 9001

Chiarini, A (2011) has discussed the guidelines of the integration between ISO 9001 and the Lean thinking. The author has argued that this paper is one of the first attempts to understand the impacts of Lean thinking on ISO 9001. In this general review, the data and the information collected over nine years, from 107 different manufacturing companies in different European countries. All of these companies have received the ISO 9001 certificate and have successfully applied the mature stage of lean implementation. The author has argued that the net result of these research has found that the Lean thinking implementation affects the quality procedures, and work instructions. He has mentioned in details the Lean thinking tools used in the selected 107 companies, which are:

1- Value Stream Mapping (VSM) that helps identifying the value adding and non-value adding activities.

2- Lean metrics: in which the waste reduction measured by efficiency and effectiveness indicators.

3- 5S: which is the five steps to clean up the workplace that would significantly decrease the accidents. They are: (1) sort, (2) set in order, (3) shine, (4) standardize, and (5) sustain.

4- Takt time: The customer needs the product in this period. “Takt time” is the maximum amount of time in which a product needs to be produced in order to satisfy customer demand

The limitation in this paper is due that; the research depends on the sampling process, which is a subset of the population. In addition, there was lack of detailed guidelines for integrating ISO 9001 and Lean thinking. This is due to the long period of gathering the data (nine years).

This paper still supports and clarifies how the integration of Six sigma and Lean thinking with other quality standards system such as ISO 9000/QS 9000 could be more useful in health care services. In addition, it supports the combination between one of the quality improvement methodologies adapted from the manufacturing industries, and one of the quality standards that usually used in the health sector. This would allow a reasonable comparison before, and after the application of Six Sigma and Lean thinking.

7-Discussion

Berman Brown, R., & Bell, L. (2005) have mentioned in their paper that the philosophy of any quality improvement programme should focus on the consumer. The patient at the end is the judge of the performance, and previously some research papers have discussed the patient participation as a domain and as an essential basic point in any of the future quality programmes.

Summing up, the main idea in the literature review is that: *the aim of all the quality improvement programmes is reflecting the consumers' needs and expectations*. Young, T et al. (2004) have asked the main question of this literature review. Whether the industrial quality improvement methodologies could be implemented in the health care service or not? They have focused their research on three of these methodologies (1) the Lean thinking, (2) The Six Sigma, and (3) the theory of constraints and their effect on the modernisation of the NHS. The effect of the implementation of these methodologies on the improvement of the health quality, reduction of the waiting time, and enhancement of the working environment has investigated. The great success of the industrial services over the last four decades in improving the quality and efficiency of their services has motivated the leaders in health care service. It has claimed that the potential of using industrial methodologies in health care, and has focused on exploring how the concept of these methodologies could be related to the health care.

In order to summarise the results, it found that the three methodologies have the same common features. There will always be a complex interaction and coordination between the employees, and their leaders. However, understanding the statistics, algorithms, and the participation of all workers are essential in the success of these methodologies. It also mentioned that the succuss should not expected immediately but it would occur gradually, and it needs strong leadership. It has expected that the patient might be included as a participator during the implementation of these methods. In this study, the main idea of this review summarized, which is the adoption of the industrial quality improvement methodologies in health care services, their concepts and the cultural requirements for success.

8-Conclusion

As summarized in table 1, the quality is an ongoing process, which requires the support of a learning culture. The different quality management methodologies such as continuous quality improvement, Lean thinking and Six Sigma which have been adapted from the manufacturing environment, have proven its success and that its suitability to the health services. This literature review has discussed the application of the performance indicators that could be useful in the improvement of the health services. The interest of patients, stakeholders, and health workers has considered. The reason for the success and the recommendation of these tools is that it based on scientific principles. Decisions based on facts and data. Software tools used to make the techniques available and accessible to health workers with little or no training. Detailed discussions of the success implementation of both Six Sigma and Lean thinking provided with practical success stories. Finally, the review provided an investigation about the successful use of Six Sigma and Lean thinking in conjunction with other quality standards system such as ISO 9000/QS 9000. This could be more useful in health care services. In addition, it supports the combination between one of the quality improvement methodologies adapted from the manufacturing industries, and one of the quality standards, which usually used in the health sector. This would allow a reasonable comparison before and after the application of Six Sigma and Lean thinking. Based on the results of the aforementioned studies, the quality management tools have proven its ability to fit in and excessively improve the health care services.

Table 1, studies included in the literature.

Study	Quality measurement method	Country	Industry/setting
1- Chassin, M. R. (1998).	Six Sigma	USA	Viewpoint/ health industry
2- Beaulieu, N. D., & Epstein, A. M. (2002).	Accreditation	USA	Health industry
3- Davig, W. et al (2003)	Total Quality Management (TQM)	Kentucky USA	small manufacturing business
4- Lanham, B., &	Six Sigma	_____	Health industry

Maxson-Cooper, P. (2003)			
5- Locock, L (2003)	Total Quality Management (TQM) or the Continuous Quality Improvement (CQI).	UK	Health industry
6- Sammules, D.I and Adomitis, F.L(2003)	Six Sigma	_____	Viewpoint. Health industry
7- Stahl, R et al. (2003)	Six Sigma	USA	Health industry
8- Young, T et al. (2004)	Lean six sigma and the theory of constraints	UK	Health industry
9- Berman Brown, R., & Bell, L. (2005).	New quality instruments	Essex, England	Health industry
10- Heuvel, J et al (2005)	Six Sigma	Netherlands	Red cross hospital/Health industry
11- Mahesh, S et al. (2005)	Six Sigma	USA	Health industry
12- Black, K., & Revere, L. (2006)	Six Sigma grew out of the concept of Total Quality Management (TQM)	USA	Viewpoint study in Health industry
13- Jones, D and Mitchell, A (2006)	Lean thinking	Flinders Medical Centre in Adelaide, South Australia	Health industry
14- Antony, J et al. (2007).	Six sigma	UK	Viewpoint /health industry
15- Jiju, A., K (2007)	Six Sigma	UK	Viewpoint/ health industry
16- Saadat, M., &	Six sigma	USA	Viewpoint study

Antony, J. (2007)			
17- Lifvergren, S.et al (2008)	Six sigma	Sweden	Health industry
18- Joosten. T et al. (2009)	Lean thinking	Netherlands	Viewpoint/ Health industry
19- Kotogal, M et al. (2009)	Lean thinking	Rwanda	Health industry
20- Delgado, C. et al (2010)	lean Six Sigma	_____	Financial services organizations
21- Grove, A. L et al (2010)	Lean thinking	UK	Health industry
22- McCulloch, P et al. (2010)	Lean thinking	UK	Emergency department/Health industry
23- Chiarini, A. (2011)	Integrating Lean thinking with ISO9001	Europe	107 manufacturing companies
24- Gamal Aboelmaged, M. (2011)	Six Sigma	United Arab Emirates (UAE)	Quantitative study in manufacturing and service organizations
25- Murphree, P., & Daigle, L. (2011)	Lean Six Sigma	_____	Health Industry
26- Papadopoulos, T (2011)	Lean thinking	UK	Health industry
27- Kaushik, P et al (2012).	Six Sigma methodology	_____	small and medium-sized manufacturing enterprise (bicycles chains) / case study
28- Chiarini, A. (2013)	Six Sigma model	Italy	Italian public healthcare sector

29- Psomas, E. (2016) in a	Six-Sigma	Greece	manufacturing organization
30- Elapanda, S., Rao, U. A., & Choudary, K. A. (2019).	Lean Six Sigma	India	Health industry/ laboratories setting

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