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Lean Six Sigma to reduce the acute myocardial infarction mortality rate: a single center study

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Abstract

Purpose – Cardiovascular diseases are the leading cause of death worldwide. In Italy, acute myocardial infarction (AMI) is a major cause of hospitalization and healthcare costs. AMI is a myocardial necrosis event caused by an unstable ischemic syndrome. The Italian government has defined an indicator called "AMI: 30-day mortality" to assess the quality of the overall care pathway of the heart attacked patient. In order to guarantee high standards, all hospitals had to implement techniques to increase the quality of care pathway. The aim of the paper is to identify the root cause and understand the mortality rate for AMI and redesign the patient management process in order to improve it.

Design/methodology/approach – A Lean Six Sigma (LSS) approach was used in this study to analyze the patient flow in order to reduce 30-days mortality rate from AMI registered by Complex Operative Unit (COU) of Cardiology of an Italian hospital. Value stream mapping (VSM) and Ishikawa diagrams were implemented as tools of analysis.

Findings – Process improvement using LSS methodology made it possible to reduce the overall times from 115 minutes to 75 minutes, with a reduction of 35%. In addition, the corrective actions such as the activation of a post-discharge outpatient clinic and telephone contacts allowed the 30-day mortality rate to be lowered from 16% before the project to 8% after the project. In this way, the limit value set by the Italian government was reached.

Research limitations/implications – The limitation of the study is that it is single-centered and was applied to a facility with a limited number of cases.

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Practical implications – The LSS approach has brought significant benefits to the process of managing patients with AMI. Corrective actions such as the activation of an effective shared protocol or telephone interview with checklist can become the gold standard in reducing mortality. The limitation of the study is that it is single-centered and was applied to a facility with a limited number of cases.

Originality/value – LSS, applied for the first time to the management of cardiovascular diseases in Italy, is a methodology which has proved to be strategic for the improvement of healthcare process. The simple solutions implemented could serve as a guide for other hospitals to pursue the national AMI mortality target.

Keywords AMI, Mortality rate, Lean six sigma, Lean thinking, Value stream map, Healthcare

Paper type Research paper

Introduction

Healthcare providers are facing an ever-increasing pressure to improve their efficiency and the cost-effectiveness of their service due to competition between healthcare providers, increasing patient volumes putting pressure on services, customer expectations, cost pressures, an aging populations and reduced public spending (Bhat *et al.*, 2019; Herrera *et al.*, 2014).

This has led many healthcare organizations to implement various continuous improvement methods across a range of healthcare processes and service to address key issues in healthcare services (Antony *et al.*, 2018). Lean Six Sigma (LSS) has been increasingly adapted in the healthcare sector over the past 15 years (D'Andreamatteo *et al.*, 2015). Many healthcare organizations have reported success in using LSS to reduce waiting times, improve process efficiency and eliminate waste in healthcare (Bartley *et al.*, 2010; Gonzalez, 2019). Lean strategies offer a methodology to solve quality and patient flow problems, thereby improving overall hospital performance (Al Owad *et al.*, 2018; Al-Araidah *et al.*, 2010 and Trakulsunti *et al.*, 2020) have both implemented Lean tools with the aim of reducing time loss associated with drug administration in a hospital pharmacy and reducing errors.

Cardiovascular diseases are the leading cause of death worldwide (Chin *et al.*, 2011). In Italy, the country in which this case study was conducted, an increase in life expectancy has been observed in recent years, reaching 79.7 years for men and 84.4 for women (istat.it, 2021). Chronic and degenerative diseases, such as hip fractures, cardiovascular and cerebrovascular diseases, pose great challenges to care. Specifically, acute myocardial infarction (AMI), in Italy is a major cause of hospitalization and health care costs.

In an Italian hospital where this study is being carried out, we want to apply the strategies of LSS to reduce the 30-day mortality rate for AMI registered by the Complex Operative Unit of Cardiology of the San Severo hospital belonging to the Local Health Authority of Foggia (Italy) with the aim of reducing the mortality rate to 8%, the value of the national average.

The research objectives of this study are therefore as follows.

RO1. To utilize LSS methods in an Italian hospital to identify the root cause and understand the AMI failure rate.

RO2. Redesign the patient management process to reduce AMI failure rate and thus improve the mortality rate.

The following sections describe the literature review, data analysis, results, discussion and conclusion.

Lean application in healthcare

Lean has been increasingly implemented within healthcare processes to improve efficiency (Brandao de Souza, 2009; Radnor *et al.*, 2006). The concept of Lean originated in the manufacturing industry, particularly in Japan's Toyota Motor Corporation, to counter the economic and financial crisis that arose after the Second World War. Lean, therefore, was an innovative philosophy that places emphasizes strategically relevant principles and technical-operational tools, while also ensuring that fewer resources are used than in traditional production systems (Hines *et al.*, 2004; Shah and Ward 2003). The principles of Lean can be summarized as reducing waste by increasing the value produced through continuous improvement (Womack and Jones 1996). Since 2005, Lean Thinking has been adopted in the world of healthcare, particularly in hospitals, with a significant impact on quality, costs, time and staff and customers satisfaction (Papadopoulos *et al.*, 2011; Marolla *et al.*, 2021; Rosa *et al.*, 2021; Rosa *et al.*, 2019; Antony, 2018). Six Sigma methods with DMAIC methodology for problem solving have been used to facilitate problem solving and reduce variation. The combination of Lean and Six Sigma by (George, 2002) has the benefit of reducing waste and variation.

A particularly active research group in Italy, the reference country for this study, is that of Professor Improta who has studied various health processes with a LSS approach. For example (Improta *et al.*, 2018), demonstrated how Lean thinking led to a reduction in overall time in the emergency department through the implementation of the corrective actions after the Lean interventions. Further work used an LSS approach, and in particular the DMAIC (Define, Measure, Analyze, Improve and Control) cycle, to improve the process through a decrease in total length of stay (LOS) (Improta *et al.*, 2017; Latessa *et al.*, 2021).

Internationally, Ahmed *et al.* (2018a, b) studied LSS initiatives in public and private hospitals and assessed the impact on quality performance of Malaysian hospitals. Hundal *et al.* (2021) on the other hand, highlighted how LSS can help mitigate the impact of COVID-19 within healthcare environments. O'Mahony *et al.* (2021) standardized and rationalized inventory management, while Ibrahim *et al.* (2022) demonstrate that LSS can be successfully implemented in challenging public healthcare settings in Egypt. Trakulsunti *et al.* (2020) studied the application of LSS to reduce pharmacy dispensing errors in a Thai public hospital, while in India, the same techniques have been used to optimize the length and variability of patients' LOS in the clinic and increase the service capacity in ophthalmology clinics (Kam *et al.*, 2021).

Regarding applications related to cardiovascular patient, Martinez *et al.* (2011) described the use of LSS methodology to implement a perioperative insulin protocol in a cardiac surgery intensive care unit. Kumar and Thomas (2010) quantify the benefits of the new process flow for the treatment of chest pain patient. Instead, Agarwal *et al.* (2016) improved turnaround-time, physician downtime, on-time patient arrival, on-time physician arrival, on-time start as well as sheath-pulls inside the cardiac catheterization laboratory. Farooqui (2020) investigates a Six Sigma approach with the aim of maximizing the 50% improvement in door-to-balloon time of ST-elevation in myocardial infarction patients undergoing Percutaneous Coronary Interventions (PCI) within 90 minutes of hospital arrival. After studying the literature, some studies were also found that dealt with the improvement or development of clinical pathways through the methodology of LSS (Scala *et al.*, 2021). To date, there have been no applications on cardiovascular patients in Italy.

The importance of reducing AMI

AMI is a myocardial necrosis event caused by an unstable ischemic syndrome (Thygesen *et al.*, 2012). Acute myocardial infarction is classified both by the presence or absence of ST-segment elevation on the electrocardiogram (EKG) and into six additional types based on clinical and biochemical characteristics: heart attack due to coronary atherothrombosis (type 1), heart attack due to a supply-demand mismatch that is not the result of acute atherothrombosis (type 2), heart attack causing sudden death with no biomarker or EKG confirmation (type 3), heart attack related to PCI (type 4a), heart attack related to thrombosis of a coronary stent (type 4b) and heart attack related to coronary artery bypass graft (CABG) (type 5) (Anderson and Morrow 2017). In Italy, there has been a significant reduction in the overall volume of admission for AMI, from 123,327 admissions in 2019 to 135,621 in 2012 (pne.agenas.it, 2020). In recent decades, numerous studies have been conducted for the management of AMI which resulted in a progressive reduction in mortality and morbidity. The key to this success is the effective integration of antithrombotic therapy combined with timely reperfusion, both with primary percutaneous coronary intervention or fibrinolysis for ST-elevation myocardial infarction, and with invasive investigation and revascularization for nonST-elevation myocardial infarction, supported by risk stratification and optimized systems of care (White and Chew 2008). In this setting, timely and effective treatment is essential for patient survival (Antoniucci *et al.*, 2002). The most critical time period in AMI is its earliest phase. It is therefore necessary to intervene by assessing the appropriateness and effectiveness of the care process that begins with the patient's arrival at the hospital. However, a fundamental element is the correct management of patients even after admission for AMI through a secondary prevention program that must include dietary indications, lifestyle modifications and the definition of a correct pharmacological strategy. The occurrence of subsequent adverse events, cardiovascular or cerebrovascular, being fatal in such patients, must be avoided by a correct clinical-therapeutic management set up during hospitalization and continuing outside. This aspect is generally left to territorial care.

Within the National Outcomes Plan (PNE in Italian), the Italian government has defined an indicator called "AMI: 30-day mortality" to assess the quality of the overall care pathway of the heart attack patient, starting from the emergency service to the appearance of the first symptoms. The measurement of this indicator over time has shown its positive trend, continuously decreasing from 10.0% in 2012 to 7.90% in 2019 and always below the European average reported by the OECD in 2017 of 9.30% (pne.agenas.it, 2020); (OECD, 2020). To ensure high standards, all hospitals had to implement techniques to increase the quality of the care pathway. Several strategies have become widespread to support healthcare managers in increasing knowledge from data. Health technology assessment (Improta *et al.*, 2009; Improta *et al.*, 2012), smart technologies (Apicella *et al.*, 2021; Arpaia *et al.*, 2020; Rocco *et al.*, 2020; Angrisani *et al.*, 2020; Bernasconi *et al.*, 2020), specific care path (Improta *et al.*, 2021; Improta *et al.*, 2020), data analysis (Ponsiglione *et al.*, 2022; Improta *et al.*, 2014; Ponsiglione *et al.*, 2021a; Cesarelli *et al.*, 2012; Cortesi *et al.*, 2019) and machine learning (Improta *et al.*, 2022; Ponsiglione *et al.*, 2021b) are just a few examples.

Methods – Lean Six Sigma implementation in a case hospital

The successive treatment will follow the phases of the DMAIC cycle. This cycle refers to the data-driven optimization approach typical of Six Sigma. The name is an acronym for the five interconnected phases that constitute it (Sokovic *et al.*, 2010).

(1) Define: in this phase, the project is outlined through the identification of the problem to be solved, the objectives to be achieved and the actors involved.

(2) Measure: the key metrics for the project and the tools used to measure them are defined. One tool that will be used in this study is the VSM, which makes it possible to map the process under consideration by identifying activities, execution times and personnel employed.

(3) Analyze: in the third phase, the influences that the variables measured in the previous phase have on the problem under investigation are analyzed. Through brainstorming activities, the project team identifies the main and secondary causes that led to that particular criticality. A frequently used tool in the literature and also in this study is the Ishikawa diagram, which facilitates discussion through a systematic approach, relating cause and effect.

(4) Improve: at this point in the cycle, all the considerations made in the previous section are used to identify the optimum corrective actions to help optimize performance.

(5) Control: the last phase of the cycle is used for the long-term monitoring of the implemented corrective solutions to ensure the actual benefits introduced. In this study, a new VSM will first be constructed to detail the new process and any savings achieved, and then the previously defined key performance indicators will be measured.

Therefore, this section will present the context, the data collected and analyzed, and the corrective solutions that the multidisciplinary team identified following the characterization of the as-is flow and the identification of the causes producing inefficiencies. The last phase of the DMAIC will be presented in the Results section.

Data collection and analysis

This study applies the LSS methodology to reduce the 30-day mortality of hospitalized patients with AMI. To do this, a multidisciplinary team, composed of the authors and all the actors involved in the management of patients with AMI, commenced a project utilizing Lean methodology to analyze the process and identify corrective actions. The case study is that of the "Teresa Masselli Mascia" hospital located in San Severo and belonging to the Local Health Authority of Foggia (Italy). Foggia is the 2nd largest province in Italy with a population of 601,419 inhabitants (istat.it, 2021).

Defining and measuring the problem

The first phase was the definition of the problem and gathers the relevant stakeholders. In this work, the in-hospital flow of 25 patients who arrived at the hospital emergency department for an AMI was studied. Patients who have already been diagnosed with an ongoing AMI do not have to go to the emergency department, but have direct access to Hemodynamics. Before analyzing the process, a series of preliminary meetings were necessary to understand the diagnostic, clinical and care pathways of this specific category of patients. To this end, a multidisciplinary team was indispensable in order to understand all the different aspects of the process and treatment of AMI. The process was then defined through a process mapping session and "Gemba" walk of the patient flow. The times of the different phases were then measured and data collected. The patient enters the emergency department and, after the first triage phase, waits for a first medical examination and the necessary evaluation tests, such as the EKG, are requested. At this point, the patient undergoes the EKG and a medical evaluation and then awaits for a cardiology consultation. After completing the consultation and taking the necessary time to communicate with the patient, the patient is transferred to Hemodynamics. In Hemodynamics, the patient undergoes a second evaluation, an anterior and posterior 12-lead EKG and further blood tests. The results are evaluated, an echocardiography is performed and preparation for the surgery begins. At this point, the patient is transferred to the operating room and after 1-minute wait, the coronography, PTCA and/or insertion of a stent depending on the case begins. Hemodynamics is also the access point for patients for whom the diagnosis of AMI has already been established prior to hospital admission. Process flow was further mapped using VSM to see and understand the flow of materials and information and understand the Current State process. VSM has been utilized in similar studies in hospitals to improve flow and patient care (Chen and Meng, 2010). The current state VSM is shown in Figure 1.

Analyzing the process

The VSM was analyzed to further establish where there were examples of waste. From a critical evaluation of the VSM, it is clear that in general, the waiting times for the flow are all contained and in line with targets except for those in the emergency department. Several of the seven wastes of Lean (Ohno, 1988) were observed within the VSM after analysis by the project

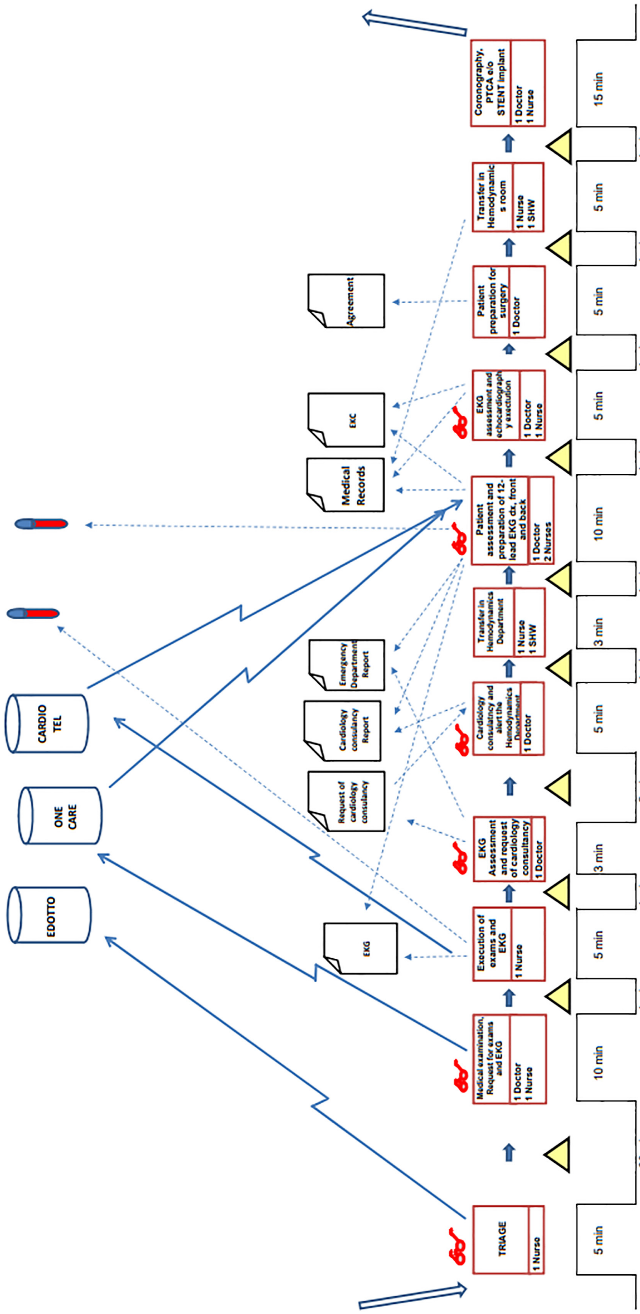

Figure 1.
VSM (before project)

team. The main wastes observed were waiting, transport (in the sense of the patient moving from area A to B) and over-processing. A brainstorming exercise and a visual review of the VSM and data were carried out to identify and analyze wastes. Overcrowding (Di Somma *et al.*, 2015; Di Laura *et al.*, 2021) could cause delays in the provision of services.

In order to understand the process and complete the VSM, nonvalue-added and value-added process times were measured. In fact, after the triage phase, which lasts an average of 5 minutes, the patient waits 30 minutes before the first visit and setting up and requesting of an EKG trace in the presence of a doctor and a nurse. After 1-minute wait, the patient undergoes a first EKG and blood tests (5 min) delivered by a nurse and, after a further minute of waiting, the EKG is assessed by a doctor and a cardiology consultation is requested (3 min). After a further 5 minutes of waiting, the consultation is performed by a cardiologist in the presence of a nurse, who alerts to Hemodynamics. After 1 minute, the patient is transferred by a social health worker (SHW) (professional figure providing basic nursing care) to the Hemodynamics, where, after 1-minute wait, diagnostic tests, such as 12-lead EKG and blood tests, are performed in the presence of a doctor and two nurses for 10 minutes. After a minute of waiting, a doctor assisted by a nurse evaluates the EKG and performs the echocardiography (5 min). At this point, after 1 minute, a doctor prepares the patient for surgery (5 min), he or she is transferred by a SHW and a nurse to the operating room (5 min), and after a minute, the team consisting of a doctor and a nurse performs the necessary surgical procedure, which lasts on average of 15 min. The above-mentioned activities are summarized in Table 1.

The time analysis showed that the total process cycle time was 115 minutes, of which 72% or 60 minutes were for non-value-added activities and 28% or 43 minutes for non-value added activities and therefore needed to be reduced. At this point, the multidisciplinary team discussed the corrective actions to be taken to reduce the 30-day mortality rate and to limit the waiting times. The tool used to characterize the main elements generating delays and their root causes was the Ishikawa diagram. It can be applied for the analysis and evaluation of a quality problem (Luca *et al.*, 2017).

A brainstorming session with a cause and effect diagram was used to establish the reasons for high mortality. The main problems producing high mortality are related to four main causes: organization (i.e. operational protocol, patient flow, number of human and technological resources employed, etc.), hospital follow-up management, management of territorial follow-up (i.e. the patient care management after the hospital discharge) and training. These main causes are associated with several secondary causes derived mainly from the lack of a shared protocol. Figure 2 shows the Ishikawa diagram.

The issues identified in the cause and effect (Ishikawa diagram) were evaluated and classified in terms of their potential contribution to 30-day AMI mortality and the team's potential to influence and solve the issues. Starting from the decomposition of the problem into main and secondary root causes, corrective actions were identified. Brainstorming was carried out and corrective actions were developed.

Improve phase

After the analysis of the VSM and root causes, key actions were identified and implemented.

Table 2 shows the key actions implemented.

For each identified and implemented corrective action, internal actions and key performance indicators (KPIs) useful for continuous improvement were defined. Table 3 shows the KPIs and threshold target values.

Before the project, the number of patients who died from AMI 30 days after the medical procedure was 16%, or 4 deaths out of 25 cases treated as shown in Figure 3.

The benefits obtained from the implementation of corrective actions were observed in the control phase, a year after implementation. The next section reports the long-term result.

Phase		Value add (min)	Non-value added (min)	Non-value added but necessary (min)
Triage	Acceptance	5		
	Vital signs measurement			
	Triage code			
	Medical examination waiting		30	
Medical examination	Medical examination	9		
	Exams request			1
	Execution waiting		1	
Examination	Exams execution	5		
	1st evaluation waiting		1	
1st evaluation	EKG evaluation	2		
	Consultancy request			1
	Consultancy waiting		5	
Consultancy	Cardiology Consultancy	4		
	Hemodynamics Department alert			1
	Transfer waiting		1	
	Transfer in Hemodynamics Department			4
	Taking charge waiting		1	
Taking charge of the patient	Patient evaluation	10		
	EKG and other exams execution			
	2nd evaluation waiting		1	
2nd evaluation	EKG evaluation	2		
	Echocardiography	3		
	Preparation of surgery waiting		1	
Surgery	Preparation of surgery	5		
	Transfer waiting		1	
	Transfer in Hemodynamics operating room			5
	Waiting before surgery		1	
	Performing surgery	15		
Total		*60*	*43*	*12*

Table 1.
Add and non-add activities (before project)

Results and the control phase

The identification of the shared protocol in the Complex Operative Unit (COU) of Cardiology and in the emergency department made it possible to reduce the time for nonvalue-added activities. Specifically, after the project, the timeline was repeated, leading to the construction of a new VSM, shown here in Figure 4.

Within the new VSM, much waste was reduced. Transport, waiting and processing waste were significantly reduced in many areas. The activation of the pathway and the transmission of information via ICT technologies made it possible to transfer the patient directly to Hemodynamics without waiting for a cardiology consultation. The waiting time between admission and medical evaluation was also reduced to just 5 minutes from the initial 30 minutes, an improvement of 83%. The total cycle time of the process was 75 minutes, with an overall reduction on the entire flow of 34.78%. The value-added and nonvalue-added activities after the design and implementation of the future VSM are summarized in Table 4.

Figure 5 shows a process balance chart with the deviation times before and after value-added versus nonvalue-added activities.

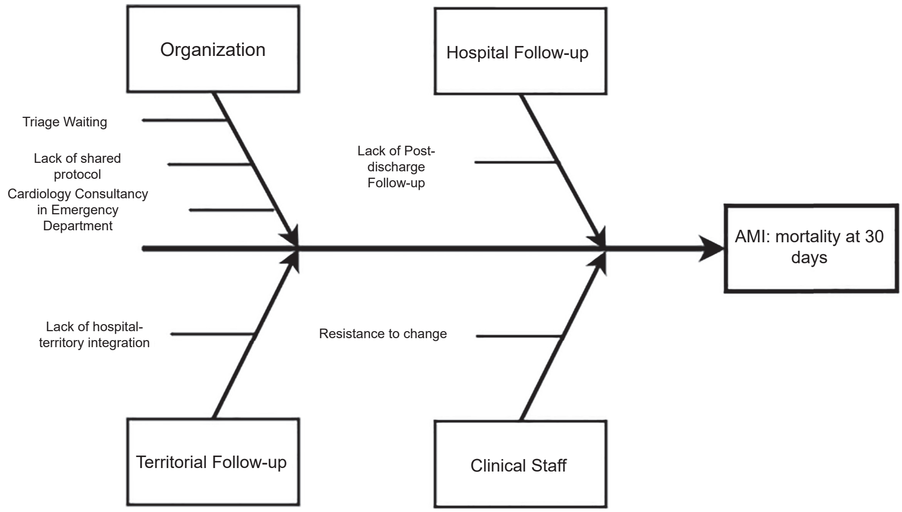

Figure 2.
Ishikawa diagram

Phase	Description
Hospital flow	Shared protocol Emergency Department – Cardiology Department Activation of Diagnostic Therapeutic Assistance Path (DPTA) AMI
Hospital follow-up	Activation of post-discharge outpatient clinic Telephone interview with checklist Tele-consultation activation

Table 2.
Corrective actions

Action	Indicator	Target value
Shared protocol for Emergency Department and Cardiology Department	Staff training	100%
Activation of post-discharge outpatient clinic	Execution of visits within 30 days	>90%
Telephone interview with checklist	Patients contacted within 15 days of discharge	100%

Table 3.
Indicators for each corrective action

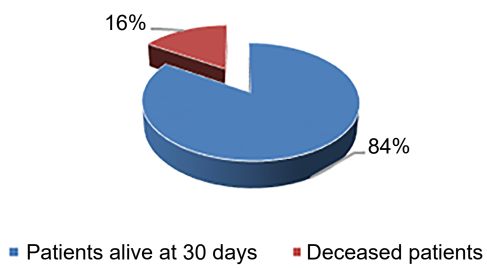

Figure 3.
Mortality rate for AMI at 30 days (before the project)

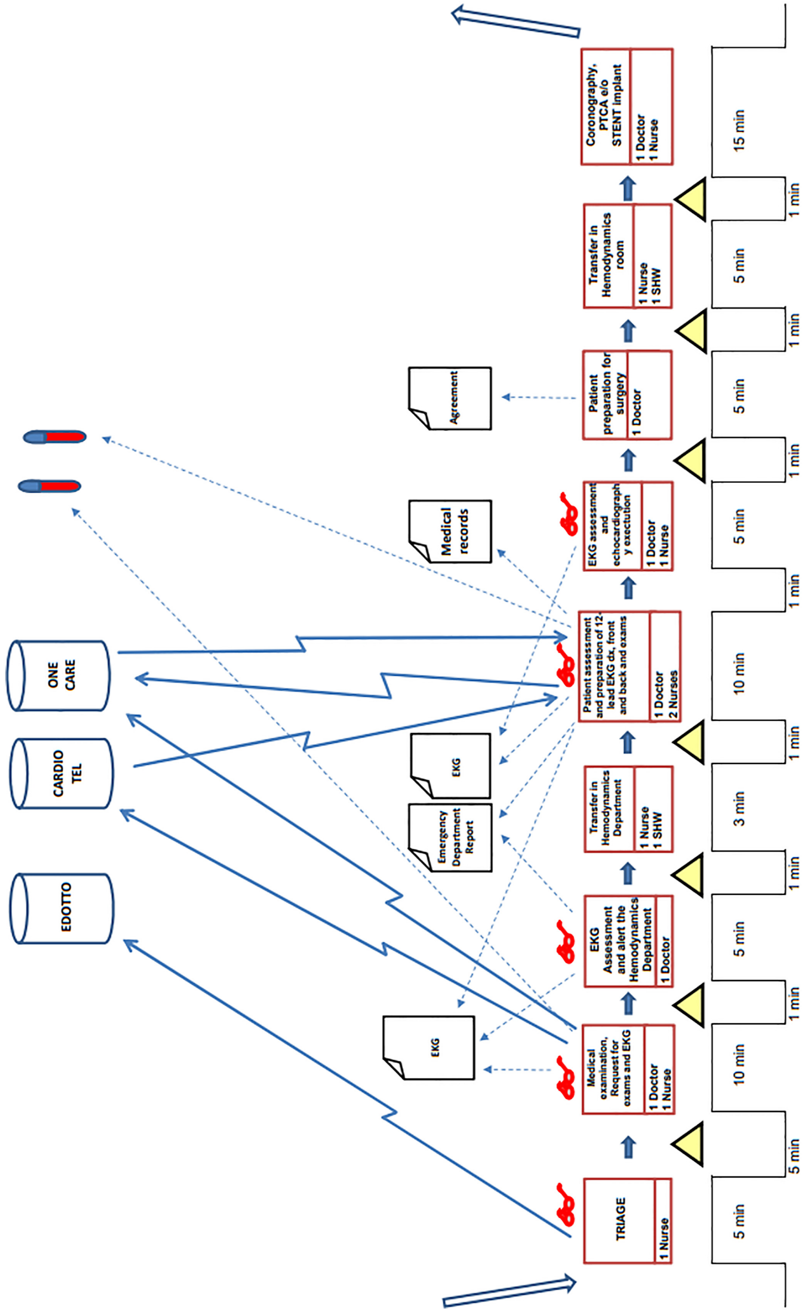

Figure 4.
Future VSM

Phase		Value added (min)	Nonvalue-added (min)	Nonvalue-added but necessary (min)
Triage	Acceptance	5		
	Vital signs measurement			
	Triage code			
	Medical examination waiting		5	
Medical examination	Medical examination	9		
	Exams request			1
	Execution waiting		1	
1st evaluation	EKG evaluation	4		
	Hemodynamics Department alert			1
	Transfer waiting		1	
	Transfer in Hemodynamics Department			3
	Taking charge waiting		1	
Taking charge of the patient	Patient evaluation	10		
	EKG and other exams execution			
	2nd evaluation waiting		1	
2nd evaluation	EKG evaluation	2		
	Echocardiography	3		
	Preparation of surgery waiting		1	
Surgery	Preparation of surgery	5		
	Transfer waiting		1	
	Transfer in Hemodynamics operating room			5
	Waiting before surgery		1	
	Performing surgery	15		
Total		*53*	*13*	*10*

Table 4. Add and non-add activities (after project)

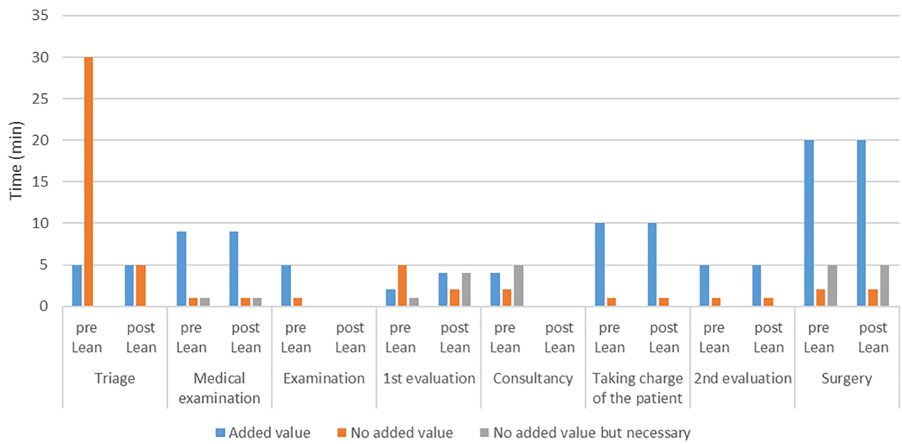

Figure 5. Balance chart

As shown in Figure 5, there was a reduction in overall time in the specific areas such as triage, examination, surgery, etc. due to the implementation of corrective actions after the LSS interventions.

The most significant benefit in reducing 30-day mortality was achieved through the activation of the post-discharge outpatient clinic. Specifically, a special health status and therapy adherence questionnaire was created, which is carried out by telephone by a nurse 7 days after the patient discharge. If the patient reports particular symptoms, a hospital clinic visit is scheduled and the appointment is priority for the patient to access the outpatient clinic. Figure 6 shows the result obtained in terms of target indicator.

On a similar number of cases (25 before the project vs. 24 after the project), the number of deaths fell from 4 to 2 cases, bringing the indicator to 8.3%, in line with the national average. With regards to the process indicators defined by the new structure, we report that.

(1) Staff training: reached 70%,

(2) Visits within 30 days: reached 80%,

(3) Telephone contact within 15 days: reached 95%.

A final part of the LSS control phase is to examine the cardiovascular key performance data as part of the facility's management reviews.

Discussion

In this work we analyzed the 30-day mortality of patients admitted for AMI at the "Teresa Masselli Mascia" hospital of San Severo, within Local Health Authority of Foggia (Italy). To do this, the process of patients who enter the hospital with a diagnosis or a suspicion of AMI was analyzed using LSS tools through the creation of a multidisciplinary team, the identification of the main phases, the times associated with them and the actors involved. From this analysis, it was possible to complete a VSM and characterize the times associated with the activities in value-added and nonvalue-added terms. On the nonvalue-added activities, the multidisciplinary team focused its attention to identify the main and secondary causes of these wastes and the associated problems. The Ishikawa diagram supported the completion of this analysis. With the help of the diagram, the team found solutions to the problem more easily. Specifically, the lack of a shared protocol between the emergency department and the COU of cardiology did not allow the immediate identification of the patient with AMI and the acceleration of the transfer to Hemodynamics. Another focus of the intervention was to activate a post-discharge outpatient clinic and a telephone contact within 15 days to check the health status and adherence to therapy of patient. Prior to the project, patients who died of AMI accounted for 16% of all AMI-related deaths, whereas after the project and LSS re-engineering this percentage dropped to 8%, in line with the Italian national average.

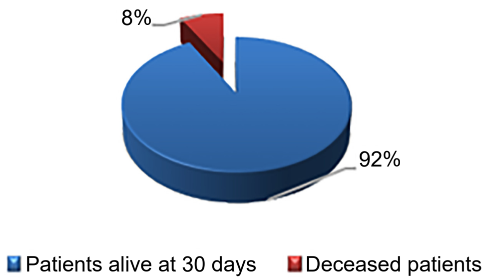

Figure 6. Mortality rate for AMI at 30 days (after the project)

In addition to the solutions, key performance indicators have been defined to allow the monitoring of corrective actions.

The identified corrective solutions, which are easy to implement, guarantee the two cornerstones of AMI treatment, that is, timeliness and therapy adherence control. The excellent results obtained not only helped the hospital reduce the mortality rate and make the treatment process more efficient, with obvious clinical implications, but the same solutions can be used as guidelines and then easily adopted in other hospitals similar in terms of population.

In addition to the implemented actions, further solutions have been identified including the use of telemedicine and the plan to create a specific DTAP for patients with AMI. This study emulated the literature in which studies dealing with the improvement or development of clinical pathways through the methodology of LSS were found (Scala *et al.*, 2021).

Conclusion

In this study, LSS methods were applied for the first time for the strategic management of cardiovascular diseases in Italy. This work demonstrated the importance of LSS methods and problem solving methodology in all areas of the healthcare system and, in particular, in the area of patient safety and improve prognosis. This study reduced many areas of variation and waste that could delay patient treatment with potentially fatal outcome by improving processes. This study is important one for the Italian healthcare system and for future applications of cardiovascular project. Academics, practitioners and managers in healthcare section can use the study and benchmark it to leverage lesson for the application of LSS in critical healthcare processes. The expansion of the study and learnings to more cardiovascular units in Italian hospitals is a further research opportunity.

The work is not without its limitations. First, it is a single-centered study, conducted in a single hospital with a limited number of cases. Furthermore, clinical parameters were not included.

Future developments include the monitoring of the benefits obtained over time and the introduction of modern technologies to facilitate communication between doctors and with the patient (e.g. through the use of Telemedicine and special devices), which offer the possibility of collecting clinical data which, suitably processed, allows key indicators of clinical deterioration to be identified.

Acknowledgments

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Declaration section

Ethics approval: In compliance with the Declaration of Helsinki and with the Italian Legislative Decree 211/2003, Implementation of the 2001/20/CE directive, since no patients/children were involved in the study, the signed informed consent form and the ethical approval are not mandatory for these types of studies. Furthermore, in compliance with the regulations of the Italian National Institute of Health, our study is not reported among those needing assessment by the Ethical Committee of the Italian National Institute of Health.

Consent for publication: All authors have read and agreed to the published version of the manuscript.

Availability of data and materials: The datasets generated and/or analyzed during the current study are not publicly available for privacy reasons but could be made available from the corresponding author on reasonable request.

Authors' contributions

Conceptualization: A.R., O.M. and G.M.; methodology: D.N., A.C. and T.A.T.; validation: D.N., A.C. and T.A.T.: formal analysis, D.N., G.M. and T.A.T.; investigation: D.N., G.M. and T.A.T.; resources: A.R., O.M. and G.M.; data curation: D.N. and T.A.T.; writing—original

draft preparation, D.N. and T.A.T.; writing—review and editing, A.R., O.M. and G.M.; visualization: D.N., A.C. and T.A.T.; supervision, A.R. and O.M.; project administration: A.R. and O.M. All authors have read and agreed to the published version of the manuscript.

Competing interests: The authors declare that they have no competing interests.

References

Agarwal, S., Gallo, J.J., Parashar, A., Agarwal, K.K., Ellis, S.G., Khot, U.N., Spooner, R., Tuzcu, E.M. and Kapadia, S.R. (2016), "Impact of Lean six sigma process improvement methodology on cardiac catheterization laboratory efficiency", *Cardiovascular Revascularization Medicine*, Vol. 17 No. 2, pp. 95-101.

Ahmed, S., Abd Manaf, N.H. and Islam, R. (2018a), "Measuring Lean Six Sigma and quality performance for healthcare organization", *International Journal of Quality and Service Sciences*, Vol. 10 No. 3, pp. 267-278, doi: 10.1108/IJQSS-09-2017-0076.

Ahmed, S., Abd Manaf, N.H. and Islam, R. (2018b), "Effect of lean six sigma on quality performance in Malaysian hospitals", *International Journal of Health Care Quality Assurance*, Vol. 31 No. 8, pp. 973-987, doi: 10.1108/IJHCQA-07-2017-0138.

Al Owad, A., Samaranayake, P., Karim, A. and Ahsan, K. (2018), "An integrated Lean methodology for improving patient flow in an emergency department–case study of a Saudi Arabian hospital", *Production Planning and Control*, Vol. 29 No. 13, pp. 1058-1081.

Al-Araidah, O., Momani, A., Khasawneh, M. and Momani, M. (2010), "Lead-time reduction utilizing Lean tools applied to healthcare: the inpatient pharmacy at a local hospital", *Journal for Healthcare Quality*, Jan-Feb, Vol. 32 No. 1, pp. 59-66, doi: 10.1111/j.1945-1474.2009.00065.x.PMID:20151593.

Anderson, J.L. and Morrow, D.A. (2017), "Acute myocardial infarction", *New England Journal of Medicine*, Vol. 376 No. 21, pp. 2053-2064.

Angrisani, L., Arpaia, P., Donnarumma, F., Esposito, A., Frosolone, M., Improta, G., Moccaldi, N., Natalizio, A. and Parvis, M. (2020), "Instrumentation for motor imagery-based brain computer interfaces relying on dry electrodes: a functional analysis", *2020 IEEE International Instrumentation and Measurement Technology Conference (I2MTC)*, IEEE.

Antoniucci, D., Valenti, R., Migliorini, A., Moschi, G., Trapani, M., Buonamici, P., Cerisano, G., Bolognese, L. and Santoro, G.M. (2002), "Relation of time to treatment and mortality in patients with acute myocardial infarction undergoing primary coronary angioplasty", *The American Journal of Cardiology*, Vol. 89 No. 11, pp. 1248-1252, doi: 10.1016/s0002-9149(02)02320-2.

Antony, J. (2018), "A conceptual Lean Six Sigma framework for quality excellence in higher education institutions", *International Journal of Quality and Reliability Management*.

Antony, J., Palsuk, P., Gupta, S., Mishra, D. and Barach, P. (2018), "Six Sigma in healthcare: a systematic review of the literature", *International Journal of Quality and Reliability Management*, Emerald Publishing, Vol. 35 No. 5, pp. 1075-1092.

Apicella, A., Arpaia, P., Frosolone, M., Improta, G., Moccaldi, N. and Pollastro, A. (2021), "EEG-Based measurement system for student engagement detection in learning 4.0", *Scientific Reports*, Vol. 12, doi: 10.1038/s41598-022-09578-y.

Arpaia, P., Canfora, V., Crauso, F., de Benedetto, E., Improta, G. and Serino, F. (2020), "Smart IoT system for remote patient monitoring", *24th IMEKO TC4 International Symposium and 22nd International Workshop on ADC and DAC Modelling and Testing*, available at: https://www.scopus .com/inward/record.uri?eid=2-s2.0-85096812606&partnerID=40&md5=71ba3e569ae5e98f769cc137e278eb97

Bartley, J.M., Olmsted, R.N. and Haas, J. (2010), "Current views of health care design and construction: practical implications for safer, cleaner environments", *American Journal of Infection Control*, Vol. 38 No. 5, pp. S1-S12, Supplement.

Bernasconi, A., De Franco, C., Improta, G., Verrazzo, R., Balato, G., Rizzo, M., Lenzi, M. and Smeraglia, F. (2020), "Foot and ankle measurements on cone beam weightbearing computed tomography", *Journal of Biological Regulators and Homeostatic Agents*, Vol. 34 3 Suppl. 2, pp. 23-32.

Bhat, S., Antony, J., Gijo, E.V. and Cudney, E.A. (2019), "Lean Six Sigma for the healthcare sector: a multiple case study analysis from the Indian context", *International Journal of Quality and Reliability Management*, Vol. 37 No. 1, pp. 90-111, Emerald Publishing.

Brandao de Souza, L. (2009), "Trends and approaches in Lean healthcare", *Leadership in Health Services*, Vol. 22 No. 2, pp. 121-139.

Cesarelli, M., Romano, M., Bifulco, P., Improta, G. and D'Addio, G. (2012), "An application of symbolic dynamics for FHRV assessment", *Studies in Health Technology and Informatics*, Vol. 180, pp. 123-127.

Chen, L. and Meng, B. (2010), "The application of value stream mapping based Lean production system", *International Journal of Business and Management*, Vol. 5 No. 6, p. 203.

Chin, C.T., Chen, A.Y., Wang, T.Y., Alexander, K.P., Mathews, R., Rumsfeld, J.S., Cannon, C.P., Fonarow, G.C., Peterson, E.D. and Roe, M.T. (2011), "Risk adjustment for in-hospital mortality of contemporary patients with acute myocardial infarction: the Acute Coronary Treatment and Intervention Outcomes Network (ACTION) Registry®–Get with the Guidelines (GWTG)™ acute myocardial infarction mortality model and risk score", *American Heart Journal*, Vol. 161 No. 1, pp. 113-122.

Cortesi, P.A., Castaman, G., Trifirò, G., Creazzola, S.S., Improta, G., Mazzaglia, G., Molinari, A.C. and Mantovani, L.G. (2019), "Cost-effectiveness and budget impact of emicizumab prophylaxis in haemophilia A patients with inhibitors", *Thrombosis and Haemostasis*, Vol. 120 No. 2, pp. 216-228.

D'Andreamatteo, A., Ianni, L., Lega, F. and Sargiacomo, M. (2015), "Lean in healthcare: a comprehensive review", *Health Policy*, Vol. 119 No. 9, pp. 1197-1209.

Di Laura, D., D'Angiolella, L., Mantovani, L., Squassabia, G., Clemente, F., Santalucia, I., Improta, G. and Triassi, M. (2021), "Efficiency measures of emergency departments: an Italian systematic literature review", *BMJ Open Quality*, Vol. 10 No. 3, e001058.

Di Somma, S., Paladino, L., Vaughan, L., Lalle, I., Magrini, L. and Magnanti, M. (2015), "Overcrowding in emergency department: an international issue", *Internal Emergency Medicine*, Vol. 10, pp. 171-175, doi: 10.1007/s11739-014-1154-8.

Farooqui, S. (2020), "Reducing delays in heart attack patients with six sigma", *i-Manager's Journal on Management*, Vol. 14 No. 4, p. 41.

George, M.L. (2002), *Lean Six Sigma: Combining Six Sigma Quality with Lean Production Speed*, McGraw-Hill, New York.

Gonzalez, M.E. (2019), "Improving customer satisfaction of a healthcare facility: reading the customers' needs", *Benchmarking: An International Journal*, Emerald Publishing, Vol. 26 No. 3, pp. 854-870.

Herrera, C.A., Rada, G., Kuhn-Barrientos, L. and Barrios, X. (2014), "Does ownership matter? An overview of systematic reviews of the performance of private for-profit, private not-for-profit and public healthcare providers", *PloS One*, Vol. 9 No. 12, e93456.

Hines, P., Holweg, M. and Rich, N. (2004), "Learning to evolve: a review of contemporary Lean thinking", *International Journal of Operations and Production Management*, Vol. 24 No. 10, pp. 994-1011.

Hundal, G.S., Thiyagarajan, S., Alduraibi, M., Laux, C.M., Furterer, S.L., Cudney, E.A. and Antony, J. (2021), "Lean Six Sigma as an organizational resilience mechanism in health care during the era of COVID-19", *International Journal of Lean Six Sigma*, Vol. 12 No. 4, pp. 762-783, doi: 10.1108/IJLSS-11-2020-0204.

Ibrahim, I., Sultan, M., Yassine, O.G., Zaki, A., Elamir, H. and Guirguis, W. (2022), "Using Lean Six Sigma to improve timeliness of clinical laboratory test results in a university hospital in Egypt", *International Journal of Lean Six Sigma*, Vol. 13 No. 5, pp. 1159-1183, doi: 10.1108/IJLSS-08-2021-0138.

Improta, G., Balato, G., Romano, M., Ponsiglione, A.M., Raiola, E., Russo, M.A., Cuccaro, P., Santillo, L.C. and Cesarelli, M. (2017), "Improving performances of the knee replacement surgery process by applying DMAIC principles", *Journal of Evaluation in Clinical Practice*, Vol. 23 No. 6, pp. 1401-1407.

Improta, G., Borrelli, A. and Triassi, M. (2022), "Machine learning and lean six sigma to assess how COVID-19 has changed the patient management of the Complex operative unit of neurology and stroke unit: a single center study", *International Journal of Environmental Research and Public Health*, Vol. 19 No. 9, p. 5215.

Improta, G., Luciano, M.A., Vecchione, D., Cesarelli, G., Rossano, L., Santalucia, I. and Triassi, M. (2020), "Management of the diabetic patient in the diagnostic care pathway", *European Medical and Biological Engineering Conference*, Springer, Cham, pp. 784-792.

Improta, G., Pasquale, N., Carmela, S.L. and Triassi, M. (2014), "Health worker monitoring: Kalman-based software design for fault isolation in human breathing", *EMSS 2014 Proceedings*.

Improta, G., Romano, M., Di Cicco, M.V., Ferraro, A., Borrelli, A., Verdoliva, C., Triassi, M. and Cesarelli, M. (2018), "Lean thinking to improve emergency department throughput at AORN Cardarelli hospital", *BMC Health Services Research*, Vol. 18, p. 914, doi: 10.1186/s12913-018-3654-0.

Improta, G., Scala, A., Trunfio, T.A., Guizzi, G. (2021), "Application of supply chain management at drugs flow in an Italian hospital district", *Journal of Physics: Conference Series*, IOP Publishing, Vol. 1828 No. 1.

Improta, G., Simone, T. and Bracale, M. (2009), "HTA (health technology assessment): a means to reach governance goals and to guide health politics on the topic of clinical risk management", *World Congress on Medical Physics and Biomedical Engineering, September 7-12, 2009, Munich, Germany*, Springer, Berlin, Heidelberg.

Improta, G., Triassi, M., Guizzi, G., Santillo, L.C., Revetria, R., Catania, A. and Cassettari, L. (2012), "An innovative contribution to health technology assessment", *Modern Advances in Intelligent Systems and Tools*, Springer, Berlin Heidelberg, Vol. 431, pp. 127-131.

istat.it (2021), "[webpage on the Internet] [Annual Italian statistics 2020] Rome: istituto nazionale di statistica", available at: http://dati.istat.it (accessed 22 November 2021).

Kam, A.W., Collins, S., Park, T., Mihail, M., Stanaway, F.F., Lewis, N.L., Polya, D., Fraser-Bell, S., Roberts, T.V. and Smith, J.E. (2021), "Using Lean Six Sigma techniques to improve efficiency in outpatient ophthalmology clinics", *BMC Health Services Research*, Vol. 21 No. 1, pp. 1-9.

Kumar, S. and Thomas, K.M. (2010), "Utilizing DMAIC six sigma and evidence-based medicine to streamline diagnosis in chest pain", *Quality Management in Healthcare*, Vol. 19 No. 2, pp. 107-116.

Latessa, I., Fiorillo, A., Picone, I., Balato, G., Trunfio, T.A., Scala, A. and Triassi, M. (2021), "Implementing fast track surgery in hip and knee arthroplasty using the Lean Six Sigma methodology", *The TQM Journal*, Vol. 33 No. 7, pp. 131-147.

Luca, L., Pasare, M. and Stancioiu, A. (2017), "Study to determine a new model of the Ishikawa diagram for quality improvement", *Fiability and Durability*, Vol. 1, pp. 249-254.

Marolla, G., Rosa, A. and Giuliani, F. (2021), "Addressing critical failure factors and barriers in implementing Lean Six Sigma in Italian public hospitals", *International Journal of Lean Six Sigma*, Vol. 13 No. 3, pp. 733-764.

Martinez, E.A., Chavez-Valdez, R., Holt, N.F., Grogan, K.L., Khalifeh, K.W., Slater, T., Winner, L.E., Moyer, J. and Lehmann, C.U. (2011), "Successful implementation of a perioperative glycemic control protocol in cardiac surgery: barrier analysis and intervention using Lean six sigma", *Anesthesiology Research and Practice*, Vol. 2011 No. 565069.

OECD (2020), "Health statistics Ed.".

Ohno, T. (1988), *Toyota Production System: Beyond Large-Scale Production*, Taylor & Francis, Cambridge.

O'Mahony, L., McCarthy, K., O'Donoghue, J., Teeling, S.P., Ward, M. and McNamara, M. (2021), "Using lean six sigma to redesign the supply chain to the operating room department of a private hospital to reduce associated costs and release nursing time to care", *International Journal of Environmental Research and Public Health*, Vol. 18 No. 21, 11011.

Papadopoulos, T., Radnor, Z. and Merali, Y. (2011), "The role of actor associations in understanding the implementation of Lean thinking in healthcare", *International Journal of Operations and Production Management*, Vol. 31 No. 2, pp. 167-191.

pne.agenas.it (2020), [webpage on Internet]. [Report 2020], available at: https://pne.agenas.it/main/doc/Report_PNE_2020.pdf (accessed 22 November 2021).

Ponsiglione, A.M., Romano, M. and Amato, F. (2021a), "A finite-state machine approach to study patients dropout from medical examinations", *IEEE 6th International Forum on Research and Technology for Society and Industry (RTSI)*, pp. 289-294, doi: 10.1109/RTSI50628.2021.9597264.

Ponsiglione, A.M., Cesarelli, G., Amato, F. and Romano, M. (2021b), "Optimization of an artificial neural network to study accelerations of foetal heart rhythm", *IEEE 6th International Forum on Research and Technology for Society and Industry (RTSI)*, IEEE, pp. 159-164.

Ponsiglione, A.M., Amato, F., Cozzolino, S., Russo, G., Romano, M. and Improta, G. (2022), "A hybrid analytic hierarchy process and likert scale approach for the quality assessment of medical education programs", *Mathematics*, Vol. 10 No. 9, p. 1426.

Radnor, Z.J., Walley, P., Stephens, A. and Bucci, G. (2006), *Evaluation of the Lean Approach to Business Management and its Use in the Public Sector*, Government Social Research, Edinburgh.

Rosa, A., Marolla, G., Lega, F. and Manfredi, F. (2021), "Lean adoption in hospitals: the role of contextual factors and introduction strategy", *BMC Health Services Research*, Vol. 21.

Rosa, A., Marolla, G. and Zammori, F. (2019), "Applicazione dello strumento Lean A3 al percorso di presa in carico di pazienti anziani con frattura del femore: il caso studio di un ospedale pugliese", *MECOSAN*, Vol. 106, pp. 37-63, doi: 10.3280/MESA2018-106003.

Rocco, N., Papallo, I., Nava, M.B., Catanuto, G., Accurso, A., Onofrio, I., Oliviero, O., Improta, G., Speranza, D., Domingos, M., Russo, T., De Santis, R., Martorelli, M. and Gloria, A. (2020), "Additive manufacturing and technical strategies for improving outcomes in breast reconstructive surgery", *ACTA IMEKO*, Vol. 9 No. 4, pp. 74-79.

Scala, A., Ponsiglione, A.M., Loperto, I., Della Vecchia, A., Borrelli, A., Russo, G., Triassi, M. and Improta, G. (2021), "Lean six sigma approach for reducing length of hospital stay for patients with femur fracture in a university hospital", *International Journal of Environmental Research and Public Health*, Vol. 18 No. 6, p. 2843.

Shah, R. and Ward, P.T. (2003), "Lean manufacturing: context, practice bundles, and performance", *Journal of Operations Management*, Vol. 21 No. 2, pp. 129-149.

Sokovic, M., Pavletic, D. and Pipan, K.K. (2010), "Quality improvement methodologies–PDCA cycle, RADAR matrix, DMAIC and DFSS", *Journal of Achievements in Materials and Manufacturing Engineering*, Vol. 43 No. 1, pp. 476-483.

Thygesen, K., Alpert, J.S., Jaffe, A.S., Simoons, M.L., Bernard, R.C. and Harvey, D.W. (2012), "Third universal definition of myocardial infarction", *Journal of the American College of Cardiology*, Vol. 60, pp. 1581-1598.

Trakulsunti, Y., Antony, J., Dempsey, M. and Brennan, A. (2020), "Reducing medication errors using Lean six sigma methodology in a Thai hospital: an action research study", *International Journal of Quality and Reliability Management*, Vol. 38 No. 1, pp. 339-362.

White, H.D. and Chew, D.P. (2008), "Acute myocardial infarction", *The Lancet*, Vol. 372 No. 9638, pp. 570-584.

Womack, J.P. and Jones, D.T. (1996), "Lean thinking", *The Financial Times*, Book Review, September 30.

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