Fast track surgery for knee replacement surgery: a lean six sigma approach

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Received 12 June 2019
Revised 13 September 2019
Accepted 31 October 2019

Abstract

Purpose – The reduction of costs has a more and more relevant role in the healthcare context, therefore, a large effort is done by health providers to this aim, for example, by reducing the length of hospital stay (LOS) of patients undergoing surgery. Fast track surgery fits perfectly this issue and was applied to patients undergoing knee replacement surgery due to Osteoarthritis, one of the most common diseases of aged population. The paper aims to discuss these issues.

Design/methodology/approach – Lean six sigma was applied to analyze the implementation of fast track surgery through the define, measure, analyze, improve, control roadmap, used as a typical problem-solving approach. It is characterized by five operational phases, which make possible the achievement of fixed goals through a rigorous process of defining, measuring, analyzing, improving and controlling business problems.

Findings – The corrective action, consisting in the application of fast track surgery, improved both effectiveness and efficiency of the process of care. The average length of hospital stay (LOS) was reduced from 8.34 to 6.68 days (–19.9 percent) and its standard deviation from 2.41 to 1.99 days (–17.1 percent). The statistical significance of this decrease was verified by means of proper tests. Moreover, some variables influencing the LOS were identified.

The authors declare they have no conflict of interests. No funding was received for this study.

The TQM Journal
Vol. 32 No. 3, 2020
pp. 461-474
Emerald Publishing Limited
1754-2731
DOI 10.1108/TQM-06-2019-0159

Research limitations/implications – The follow up and the satisfaction of patients were not analyzed and could be a future development of this study.
Practical implications – Patients will experience a faster recovery while the hospital will benefit from a rise of available beds. The effect is a general improvement of hospital management.
Originality/value – The introduction of fast track surgery for patients undergoing knee replacement surgery made significantly reduce LOS and, consequently, costs' with a money saving of more than 50,000 euro per year.

Keywords Six Sigma, Public health, Lean thinking, Clinical pathway
Paper type Research paper

Introduction

Nowadays, in health systems, great attention is devoted to sustainability, costs sustained with respect to economic resources and services' quality. In this scenario, important targets are the reduction of patient hospitalization and organizational and quality improvements, both in hospital and in surgery, at all levels, from the administrators to the clinical staff (Mueck *et al.*, 2016).

As regards surgery, during the last two decades, programs to enhance postoperative recovery and decrease morbidity have been developed across a variety of surgical procedures. These procedures are referred to as "Fast Track Surgery," and often as "Enhanced Recovery After Surgery" (Castorina *et al.*, 2017). The "Fast Track Surgery" (FTS) represents the fast path in surgery, i.e. the acceleration of the times of all the stages of hospitalization for surgery (from the preoperative phase up to the postoperative phase). More precisely, the FTS is a multidisciplinary approach, based on the idea that the perioperative phase involves many medical specializations, such as anaesthesia, nutrition and rehabilitation, which aims at reducing the operative stress, patient's discomfort and accelerating his recovery (Aditya and Prabhakar, 2014).

The practical implementation of an FTS program needs the formulation of a protocol which entails the introduction of actions to reduce the morbidity and to enhance the functional recovery, with subsequent reduction of LOS, defined as the number of days between admission and discharge from the hospital, and patient satisfaction improvement (Husted, 2012); for example through pain and haemostasis control (Kehlet and Dahl, 2003; Kehlet and Slim, 2012; Kehlet, 2013), FTS proved to be useful both to improve patients' outcome and to reduce costs. As a result, it was applied in various contexts such as gastrointestinal, colonic and orthopaedic surgeries but also in cholecystectomy and prostatectomy (Aditya and Prabhakar, 2013; Scharfenberg *et al.*, 2007; Kehlet and Soballe, 2010; Keulemans *et al.*, 1998; Gralla *et al.*, 2007).

The World Health Organizations defines the Osteoarthritis (OA) as a long-term chronic disease characterized by the deterioration of cartilage in joints, which results in bones rubbing together and creating stiffness, pain and impaired movement. It is the most common disease of aged population and one of the causes of disability preventing people from walking, climbing stairs, bathing, getting dressed, preparing meals and living life to its fullest. The number of patients undergoing prosthetic replacement surgery has increased in the last 15 years in Italy, as testified by the Superior Institute of Health; the rate was 181.738 in 2015 (56.3 percent for hips and 38.6 percent for knees) and is still rising[1]. Indeed, recent literature studies testified that total knee arthroplasty improves primary outcomes of OA and has a low rate of significant medical complications (Charlesworth *et al.*, 2019). Cost-utility analysis of total hip and knee replacement has been performed by Jenkins *et al.* providing cost-effectiveness data for total joint replacement and showing that this kind of surgery is extremely effective both clinically and in terms of cost-effectiveness (Jenkins *et al.*, 2013). As such, currently, the direction of the Department of Public Health of the University Hospital "Federico II" has decided to adopt a FTS protocol for patients undergoing prosthetic knee replacement surgery. It has been carried out in the same frame of a more general project aimed at reducing the LOS of people undergoing hip and knee replacement surgery

(Improta *et al.*, 2015, 2017; Improta, Balato, Ricciardi, Russo, Santalucia, Triassi and Cesarelli, 2019). Due to the preceding encouraging results, the same FTS protocol was applied to knee replacement surgery.

Many methods have been suggested for the treatment and managing of chronic diseases (Santini *et al.*, 2017; Biondi *et al.*, 2013; Ricciardi *et al.*, 2019), and innovative procedures have been introduced to reduce waste in healthcare processes (Improta, Romano, Di Cicco, Ferraro, Borrelli, Verdoliva, 2018, Improta, Ricciardi, Borrelli, 2019) and support decision makers in the evaluation of technologies and in the choice of appropriate therapies (Improta, Russo, Triassi, Converso, Murino, Santillo, 2018; Improta *et al.*, 2012).

Therefore, while in the previous works of the project the aim was to evaluate the introduction of pre-hospitalization in the process of knee and hip replacement surgery (Improta *et al.*, 2015; Improta *et al.*, 2017) and the implementation of FTS in hip replacement surgery (Improta, Balato, Ricciardi, Russo, Santalucia, Triassi and Cesarelli, 2019), the purpose of this paper is to analyze the application of the FTS protocol on patients undergoing knee replacement surgery through the Lean Six Sigma (LSS) methodology.

Literature review: FTS

FTS consists in a clinical pathway, also known as care pathways, critical pathways, integrated care pathways (Zander, 2002; Pearson *et al.*, 2001; Hindle and Yazbeck, 2005). Although there are several applications, there is still a lack of shared and accepted description and protocol (Harkleroad *et al.*, 2000); besides, their actual impact on outcomes is not completely clear (Van Herck *et al.*, 2004; Panella *et al.*, 2003).

De Luc found about more than 15 names that are used in literature to cite these pathways and about 84 possible definitions were also identified (De Luc, 2000).

Nevertheless, according to Vanhaecht *et al.* (2006, 2007) crucial features of care pathways comprise:

- a statement of aims and main elements of care based on evidence, best practice, and patient expectations;
- the simplification of the communication, organization of roles, and dividing the activities of the multidisciplinary care team, patients and their relatives; and
- the documentation, monitoring and evaluation of variances, outcomes and appropriate assets.

Despite the differences in the application of these pathways, nowadays, they are employed in many fields of medicine: recently, Proietti *et al.* (2018) used it in cardiology, Frakking *et al.* (2018) for children. Concerning orthopedics, Kang *et al.* (2018) elaborated a rehabilitation strategy after hip replacement surgery while Featherall *et al.* (2018) studied a way to reduce LOS and improve the outcome of patients undergoing hip replacement surgery.

Literature review: the methodology

Arnheiter and Maleyeff performed the combination of lean thinking and six sigma more than a decade ago (Arnheiter and Maleyeff, 2005). They showed that a joint implementation of both programs would have overcome the limitations of both methodologies employed in isolation; the result is a maximization of value activities, as pursued by lean thinking, and a minimization of costs, as pursued by six sigma.

Many researchers have studied the benefits and the challenges of LSS in different areas, from the manufacturing one to services (Singh and Rathi, 2019). In a first period the applications were only industry-based, and they are continuing also today (Buell and Turnipseed, 2004; Tolga Taner *et al.*, 2007; Alkunsol *et al.*, 2019; Mishra and Rane, 2019); then,

LSS was moved to healthcare studies with a positive impact (de Koning *et al.*, 2006; DelliFraine *et al.*, 2010; Montella *et al.*, 2017). Trzeciak *et al.* (2018) analyzed patients with prolonged mechanical ventilation in a multidisciplinary intensive care unit in order to reduce LOS, while Molla *et al.* (2018) focused on the timing of patients' discharge.

Henrique and Godinho Filho (2018) reviewed the empirical research as regard lean thinking, six sigma and LSS in healthcare: the majority of papers deals with the emergency department while the orthopaedic one is not cited in the most frequent analyzed areas of an hospital.

Define, measure, analyze, improve and control (DMAIC) roadmap refers to a data-driven lifecycle, systematic and fact-based approach of six sigma projects for the continuous improvement of a process (Sokovic *et al.*, 2010). It is used all over the world also in healthcare: George *et al.* (2018) reduced the number of medication errors in a Major Trauma care center in India while Shirey *et al.* (2018) applied it to a large healthcare organization in the southwest USA for facilities management.

Finally, the wastes identified by lean thinking in the manufacturing sector were conversed also in healthcare, giving them an appropriate meaning (Chiarini, 2013; Filingham, 2008):

- transport is intended as movement of patients and equipment;
- inventory is identified as unneeded stocks and supplies;
- motion is similar to transport but meaning movement of staff and information;
- waiting, as expected, means delays in diagnosis and treatment;
- over production is considered an unnecessary test;
- over burden is related to stresses, overworked staff; and
- defects can be more dangerous in healthcare since they are medication errors and infections.

Material and methods

The project was developed at the Complex Operative Unit of Orthopedics and Traumatology of the University Hospital "Federico II." The unit has an availability of 24 beds, 18 of which are dedicated to regular accesses and 6 of them to day surgery activities and 3 operating rooms.

Data of all the patients involved in the present study were collected from printed medical records and digital information system database of the University Hospital "Federico II," including anamnestic (age and gender) and clinical variables (dates of admission, surgery and discharge, comorbidities, American Society of Anesthesiologists scores (ASA)). Statistical analyses, including Jarque–Bera and *t*-tests, were carried out by means of Matlab 2017a and test calculators (GraphPad, Social Science Statistics, Excel).

Define

A multidisciplinary team dealt with this study at the Complex Operative Unit of Orthopedics and Traumatology of the University Hospital "Federico II." The first step was the creation of a project charter (Table I) to create a shared knowledge of project's details: critical to quality (CTQ), question, target, in and out of scope, timeline.

The team was composed by four engineers, one economist and an orthopaedic: an engineer was identified as the project leader and another engineer was identified as the project champions; the others were included in the team members.

In the same phase, together with the project charter, an Input Process Output analysis was elaborated to clarify which were the main process characteristics (Breyfogle, 2003):

Project title	
Fast track surgery for knee replacement surgery: a lean six sigma approach	
Problem statement	**Objective statement**
Inappropriate prolongation of the length of hospital stay for patients undergoing replacement surgery prosthetic knee	Introduce a clinical pathway that can solve the presented problem
Critical to quality	**Target**
The CTQ is therefore the duration of the length of hospital stay.	Realize corrective measures in order to reduce the CTQ.
Project leader:	Names will be added if the paper is accepted.
Project champion:	
Team members:	
Timeline	
Define→November 2016	
Measure→December 2016	
Analyze→December 2016	
Improve→January 2017	
Control→January 2017-December 2017	
In scope	**Out of scope**
1. Prosthetization of knee	1. Whatsoever other type of intervention
2. Department of Orthopedics of "Federico II"	2. All other structures

Table I.
Project charter

(1) Input: surgical and medical services.

(2) Process – care process:

- pre-hospitalization;
- surgery;
- postoperative activities; and
- discharge.

(3) Output: recovery of the functional state of the knee – diagnostic and therapeutic information – health.

The process of patients undergoing knee replacement surgery was already improved through a reduction of LOS from more than 14 days to a mean of 8.3 days (Improta *et al.*, 2017). Now, the new objective is determined as the "reduction of hospital days less than 7 days."

Measure

During the define phase, the multidisciplinary team identified the main different characteristics of the work, such as the problem to be solved, the CTQ and the methods to adopt, whereas during the measure phase, measurements were carried out in order to evaluate the performances of the current process.

In this phase, the data set was obtained from the sample constituted by the 133 patients undergoing prosthetic knee replacement surgery (January 2015– December 2016). After the implementation of the new protocol (January 2017–December 2017), information were collected from a sample of 58 patients in order to establish the effects of the improvement actions on the

LOS. Among them, one patient of the first group and eight patients of the second one were excluded from the analysis due to non-clinical complications (such as missing data). Therefore, the first group involved 132 patients while the second one 50 patients.

For each patient, the following information was collected:

- gender and age;
- presence of allergies, cardiovascular diseases and diabetes;
- ASA score;
- date of admission;
- date of surgery; and
- date of discharge.

Statistical analyses (whose results will be presented in the following paragraphs) were carried out to estimate the mean LOS, the deviation standard (considering even the variables that we identified as relevant) and to achieve a better characterization of the chosen CTQ.

A Jarque–Bera test ($\alpha = 0.05$) was first performed through Matlab to assess the normality of the distribution.

A run chart and run tests, with a significance level α of 0.05, were employed afterwards. It allowed us to assess the influence of possible factors affecting the process, such as specific periods of inefficiency in the performance of the process. The run test had a p-value of 0.466. Run charts are in the section "Control."

Analyze

On the basis of the achievements of both define and measure phases, the process was analyzed to recognize every factor causing variations and delays. First of all, a simple basic stream map (Figure 1) was useful to obtain a workflow of the process and evaluate which were the non-value adding activities.

Through this diagram, it was possible to describe synthetically the "as-is" process.

The last step of the analysis phase was a brainstorming session including both staff and multidisciplinary team, useful to discuss causes of delays and inefficiencies; in particular, orthopedists, nurses, physical therapists, anesthesiologists and consultant physicians of the department participated to this discussion.

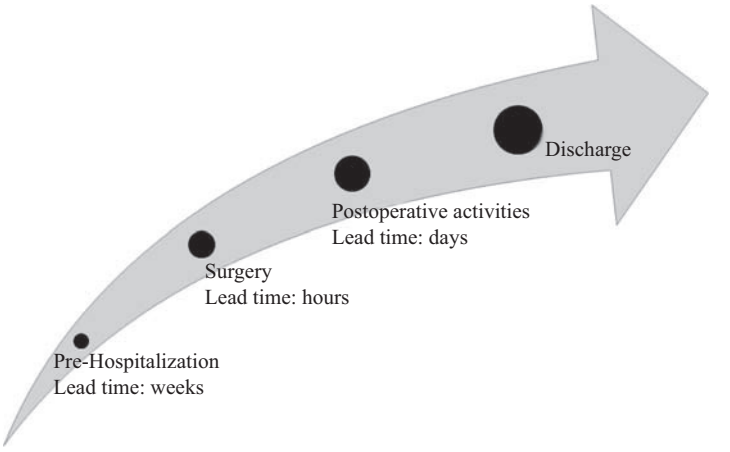

Figure 1.
Basic stream map

Three major causes were identified:

(1) patient;

(2) healthcare staff; and

(3) system and process.

Starting from the primary causes, some secondary causes were found: regarding patients, great pain, bleeding and comorbidities could be causes of a longer LOS; as regards healthcare staff, delay in health recovery increased, of course, the stay in the hospital; concerning system and process, waits for specialist's consultancy and functional examinations made the LOS rise consistently while wrong surgical planning and complex bureaucratic procedures were causes of wasted time.

These wastes correspond to those reported by Chiarini (2013) and Filingham (2013): waiting and over production for patients, over burden and defects for healthcare staff. Causes and validation methods were tied up in Table II.

Solutions to the emerged problems were reached and discussed afterwards in the improve phase.

Improve

In this phase there was the real implementation of the corrective actions. A definite fast track protocol was implemented at the Orthopedics Department of the University Hospital "Federico II" in 2017. The FTS setup does not exclude anyone, no matter which age, comorbidities, ASA score, living situation they have. The protocol consisted in a multimodal approach to obtain pain and hemostasis (bleeding/thromboembolism) control.

A homogeneous program in the operating set up involved the usage of local (3 grams /50 ml saline solution) tranexamic acid and local wound infiltration together with anesthetic agents.

Postoperatively, physiotherapy began within the first 24 h and takes place once or twice a day till discharge. Physiotherapy concentrates on range of motion of the operated joint, strengthening of the muscles, and gain of a normal gait pattern with crutches. Multimodal intravenous and oral opioid-sparing analgesia was administered to each patient, opioid was included only if requested. Non-steroidal anti-inflammatory drugs and paracetamol were commonly concomitant drug combinations used for multimodal analgesia.

For thromboprophylaxis, low-molecular-weight heparin was provided once a day until 30 days after the operation. Medical and functional criteria were considered in order to decide the discharge of patients. The patient had to independently dress, go to the toilet and walk 30 meters with crutches, to climb stairs (if able to walk with crutches). Furthermore, the achievement of stable health conditions and adequate pain relief was a must. Finally, the wound had to be dry or almost dry, and the patient should not be experiencing any dizziness or nausea.

After the corrective action, the LOS was monitored by the team. The mean LOS was equal to 6.68 days, which represents a reduction of −19.9 percent compared to the 8.34 days calculated for the first data set. Simultaneously, a smaller reduction (−17.1 percent) was obtained for the LOS standard deviation, which decreased from 2.41 to 1.99 days.

Causes	Validation methods
Lack of standard discharge procedure	Gathering data in the phase of hospital discharge
Postoperative complications	Major number of hospitalization days (number of cases)
Delay in recovery	Interviewing the health staff

Table II.
Causes and validation methods

Control

The aim of this phase is the validation of the FTS and the planning of revision's actions to ensure a long run result. A Jarque–Bera test was first performed to assess data distribution for each group; p-value=0.846 made us accept the hypothesis of normality. All patients were then grouped according to some important medical parameters that the clinicians identified as relevant, such as gender, age, allergies, cardiovascular diseases, ASA score and diabetes, to better highlight in which cases the new surgical path provides health improvements.

For those groups who were not dichotomous (age) analysis of variance was carried out. t-test (significance level α of 0.05) was realized to compare LOS between patients operated before and after the implementation of the corrective action. This comparative analysis was carried out by grouping patients according to the gathered clinical information that were considered in the study (see Table II). In addition, a demographic study was implemented as regards the independent variables in order to investigate the frequencies of each subset of patients. Thus, a χ^2 test was applied with an α=0.05 to all the subgroups (Table III).

Concerning the actions planned to ensure results sustainability in the long run, the team, also on the basis of their previous study, decided for the following:

- periodical assessment summits to estimate the status of the process implementation;
- inner checking to validate the implemented solutions; and
- exploiting visual management tools to verify the future situation.

Finally, Figure 2 displays two complete and easy run charts to monitor the change of the CTQ for both periods (before and after improvements).

Variable	Categories	Before protocol	After protocol	Difference (%)	p-value
All patients		8.34 ± 2.41	6.68 ± 1.99	−19.9	<0.0001
Gender	Male	7.15 ± 1.41	7.43 ± 2.51	+3.9	0.6176
	Female	8.78 ± 2.40	6.56 ± 1.92	−25.3	<0.0001
Age	<60	8.35 ± 2.48	6.00 ± 2.45	−28.1	0.0192
	60<Age<75	7.98 ± 2.01	6.93 ± 1.84	−13.2	0.0234
	>75	9.07 ± 2.41	6.42 ± 2.19	−29.2	0.0067
Allergies	Yes	8.15 ± 2.25	6.75 ± 1.49	−17.2	0.0127
	No	8.63 ± 2.18	6.90 ± 2.31	−20.0	0.0004
Cardiovascular disease	Yes	8.35 ± 2.48	7.65 ± 1.90	−8.4	0.2077
	No	8.28 ± 2.13	6.03 ± 1.83	−27.2	<0.0001
Diabetes	Yes	9.35 ± 2.69	7.50 ± 2.17	−19.8	0.1127
	No	8.15 ± 2.31	6.81 ± 1.97	−16.4	0.0011
ASA score	I–II	8.42 ± 2.08	6.87 ± 1.74	−18.4	<0.0001
	III–IV	8.23 ± 2.76	6.70 ± 2.79	−18.6	0.1212

Table III.
Difference in the length of stay related to variables

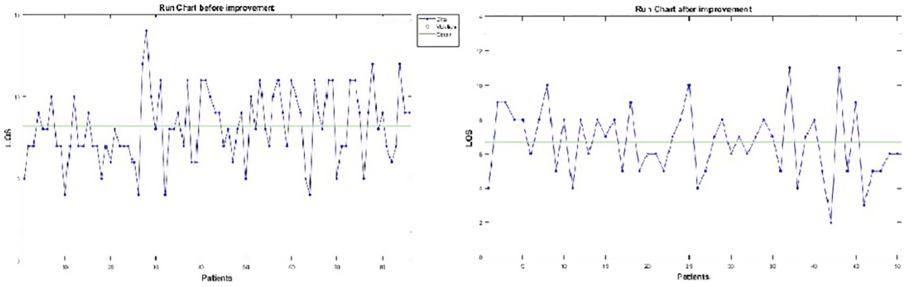

Figure 2.
Run chart before and after the improvement

Results

LOS values before and after the introduction of the FTS protocol are reported in Table III. An average LOS of 8.34 days, with a standard deviation of 2.34 days, was found in the first period for patients who underwent knee surgery from January 2015 to December 2016. This result refers to the "as-is" process.

Table II along with Figure 2 shows that the implemented actions of improvement brought to a significant decrease of LOS, which was reduced by 19.9 percent from a mean value of 8.34 to 6.68 days. A simultaneous reduction of 17.1 percent was registered for its standard deviation, which changed from 2.41 to 1.99 days. There was the most significant reduction for patients without cardiovascular diseases (−27.2 percent). Similar results were observed for patients with a low ASA score, without diabetes and both with and without allergies (about −20 percent). The lowest differences were obtained by patients aged between 60 and 75 years and by those who were affected by a cardiovascular disease. Despite a small difference, the subgroup of male patients was the only one that had an increased LOS.

Probably due to the high value of standard deviation, despite a high percentage reduction in LOS, *t*-test for the following subgroups and categories was not significant:

- Gender: male.
- Cardiovascular disease: yes.
- Diabetes: yes.
- ASA score: III–IV.

Finally, a comparative statistical analysis was performed for clinical and demographic variables using the χ^2 test with a significance level α of 0.05 to find significant differences among groups (Table IV): excluding age and diabetes, the groups can be considered equals.

Discussion and conclusion

The proposed application of the LSS methodology, which aimed at improving the management of patients undergoing surgery for prosthetic knee, confirms the achievements highlighted in previous works (Improta *et al.*, 2015, 2017; Improta, Balato, Ricciardi, Russo, Santalucia, Triassi and Cesarelli, 2019). It is worth underlining that the previous works faced the improvement of the pre-hospitalization phase (Improta *et al.*, 2015, 2017); whereas, according to Improta *et al.* (Improta, Balato, Ricciardi, Russo, Santalucia,

Variable	Categories	Before protocol	After protocol	*p*-value
Gender	Male	42	12	0.3027
	Female	90	38	
Age	<60	70	7	0.0002
	60<Age<75	46	31	
	>75	16	12	
Allergies	Yes	50	20	0.7929
	No	82	30	
Cardiovascular disease	Yes	63	25	0.7840
	No	69	25	
Diabetes	Yes	38	6	0.0182
	No	94	44	
ASA score	I–II	89	40	0.0955
	III–IV	43	10	

Table IV. Comparative statistical analysis before and after the implementation of the new protocol

Triassi and Cesarelli, 2019), the work here described dealt with the postoperative phase: in particular, a FTS protocol was introduced as a corrective action.

The obtained results showed that age and clinical factors of different nature, such as the presence of cardiovascular diseases or diabetes can contribute to the prolongation of the LOS; as such, health providers should consider acting on these comorbidities to keep LOS as low as possible. Moreover, the average LOS of patients with OA and its standard deviation are reduced of about 19.9 percent and 17.1 percent, respectively; this last result is in accordance with the aims of the six sigma methodology.

In contradiction with other studies (Collins *et al.*, 1999; Ridgeway *et al.*, 2005), this one does not confirm the idea of an association between high LOS and ASA of III–IV, but it gave a positive check about the association of a higher LOS in presence of diabetes and cardiovascular diseases. In presence of them, the difference of LOS is respectively −9.2 percent and an impressive −21.2 percent.

A limitation of the study could be the absence of a follow up; thus, as a future development, it could be interesting to study and quantify with LSS methodology the improvement brought to morbidity, mortality and functional convalescence on patients undergoing prosthetic knee replacement surgery. Besides, patients satisfaction will be monitored in future works.

However, summarizing, this paper showed again the validity of LSS methodology with a DMAIC problem-solving strategy in healthcare; it is essential to introduce qualitative methodologies in this context, especially in Italy, well-known for its healthcare and economic problem in the past years. Moreover, this application can be useful for health facilities and public policy since they could be inspired to transfer the kind of protocols discussed in this work also in other areas of medicine.

Practical implications

As well as the previous researches carried out through the LSS at the Complex Operative Unit of Orthopedics and Traumatology of the University Hospital "Federico II" (Improta *et al.*, 2015; Improta *et al.*, 2017; Improta, Balato, Ricciardi, Russo, Santalucia, Triassi and Cesarelli, 2019), this work confirmed again that the LSS approach can effectively reduce costs and be useful in the development and optimization of new protocols or clinical pathways. Considering the average cost of one day of hospital stay at the national level, which is around €674 , the reduction of LOS obtained by means of this work would result in annual cost savings of more than €60.000 (Ministero dell'Economia e delle Finanze, 2012). Considering also the implementation of the preceding FTS in patients undergoing hip replacement surgery cost saving rises till €100.000.

Moreover, the significant reduction in LOS with the consequent increasing in admissions lets us think about further substantial and positive improvements of hospital management.

Glossary

CTQ	Critical to Quality
FTS	Fast Track Surgery
LOS	Length of Hospital Stay
LSS	Lean Six Sigma
OA	Osteoarthritis

Note

1. Quarto Report 2017 – ISS – Istituto Superiore di Sanità- http://old.iss.it/binary/riap2/cont/PSE_Volume_RIAP_2017.pdf

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