



Risk management and cost reduction of cancer drugs using Lean Six Sigma tools

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Abstract

Purpose – This paper seeks to understand whether some Lean Six Sigma tools are useful to reduce safety and health risks to nurses and physicians who manage cancer drugs. An additional objective is to analyze economic improvements reached by the means of lean six sigma.

Design/methodology/approach – An improvement project inside the pharmacy department of an Italian hospital was observed and studied. The project was conducted through the define-measure-analyze-improve-control (DMAIC) pattern typical of Lean Six Sigma.

Findings – The FMEA risk analysis shows an improved situation concerning health and safety for nurses and physicians. Furthermore, the centralization and the use of other tools such as value stream mapping (VSM) have led to an interesting saving due to the reduction of immobilized capital inside the stockrooms of the departments. Other unexpected improvements in terms of motion and transportation reduction have occurred.

Research limitations/implications – It is difficult to generalize the developed theory from one case study to other public health care organizations. Academics and practitioners could investigate the subject in more detail by the means of other case studies or a quantitative inquiry.

Practical implications – The paper suggests an interesting and practical way to reduce risks for health and safety and costs inside pharmacy departments.

Originality/value – Lean Six Sigma and its tools have been used for the first time for reducing health and safety risks due to cancer drugs.

Keywords Accidents, Costs, Lean six sigma, Risk analysis, Italy, Health services, Drug administration
Paper type Case study

Introduction

Cancer drugs (from here on in referred to as “antiblastic” drugs) are sometimes characterized by a high level of toxicity that causes their handling to be dangerous and complicated. Furthermore, they are on average very expensive and so physicians and nurses pay particular attention to avoiding waste.

The originality of this research is to investigate how Lean Six Sigma and its tools could manage and reduce the risks related to the preparation, handling and administration of antiblastic drugs. The case study took place in a pharmacy department of an Italian public hospital. A remarkable decrease in the risks run by both nurses and physicians was made possible through the use of Lean Six Sigma.

Moreover, the processes have become faster and more efficient with a notable reduction in costs mainly due to less waste and storage of this expensive drug.

In Lean Six Sigma or Lean Sigma (Bahensky *et al.*, 2005; George, 2002) there is a particular pattern to follow named define-measure-analyze-improve-control (DMAIC) (Harry and Schroeder, 2000) that leads in a rigorous way towards improvements in general. Many tools can be used during the five DMAIC stages and this paper



particularly focuses on those that are useful for the so called risk management (Smith and Wheeler, 1992).

Introduction to Lean Six Sigma

Lean Six Sigma is a fusion of two important and powerful management systems. The first, lean thinking, is focused on the creation of value through the elimination of seven codified and well-known wastes (Womack and Jones, 1996):

- (1) Overproduction.
- (2) Inventories.
- (3) Defects.
- (4) Motion.
- (5) Transportation.
- (6) Waiting.
- (7) Processing.

Lean particularly expresses the will to reduce to the minimum the use of resources such as human resources, invested capital, space, time required to carry out a process, and other issues.

In general, the shorter the process is, the leaner the organization and consequently the fewer the wastes (Sugimori *et al.*, 1977). Thus Lean Thinking is focused on the extreme simplification of the “mainstream” with the intention of avoiding any kind of waste.

As previous authors have discussed (Proudlove *et al.*, 2008; De Souza, 2009; Grove *et al.*, 2010) in the past decade Lean has been gradually introduced in US, Canadian and European Health Care.

Six Sigma is a methodology whose target is to increase the customer’s satisfaction and reduce costs (Chowdhury, 2001; De Konig *et al.*, 2006). Each Six Sigma project is based on the DMAIC pattern and usually a team formed by a Black Belt and several Green Belts manages the five stages. The Black Belt is a typical team leader who knows all the Lean Six sigma tools well and gets an external certification for the scope. Green Belts are participants that have a less deep knowledge about Lean Six Sigma. Green Belts are also usually certified (Pyzdek, 2001). In the original scheme derived from General Electric and still substantially applied in all sectors, including Health Care, the DMAIC is structured following the below approach.

Define. In this first stage the sponsor of the projects, usually the general manager of the hospital as well as the head of the departments involved, discusses with the Black Belt the main objectives to reach, how to measure them, the team involved, the possible budget and the time to reach targets.

The objectives are often linked to the “voice of the customer” (VOC) which is the process of capturing a customer’s needs and requirements. In health care, customers are normally divided into “external” and “internal” customers (Keil, 2010).

The Black Belt usually deploys the objectives into measurable characteristics called critical to quality (CTQs). These latter are characteristics that affects the reachable targets; for instance if the target is to reduce the health and safety risk for nurses, then a CTQ could be the number of accidents in a certain period or the number of near misses.

Measure. The team measures the current situation of the processes and in particular of the CTQs. In addition, in this stage every aspect that could be useful for the analysis is measured and collected.

Analyze. The data and information gathered are analyzed in detail to understand what the root causes of the CTQs are.

Improve. The team launches action plans for reducing or removing the root causes. Usually in this stage the sponsor can be asked once more for approval of the investments.

Control. The team measures the new state of the processes and of the CTQs. The Black Belt certifies the results and savings achieved and the team can be rewarded. Six Sigma is problem focused and it assumes that process variation is waste because it generates defects and cost of poor quality (COPQ). Lean Six Sigma combines the “speed” introduced by Lean, the management of improvement projects, the Six Sigma DMAIC pattern and the Six Sigma capability of reducing variation. Lean Six Sigma seems to be a well-established model for business excellence as confirmed by several authors (Arnheiter and Maleyeff, 2005; Kumar *et al.*, 2005; Wedgwood, 2006). Lean Six Sigma, in a nutshell, is the linking of different tools by the DMAIC pattern that aims to reduce waste and COPQ (Arnheiter and Maleyeff, 2005).

Research methodology

The project lasted about one year and involved a team consisting of one consultant, six nurses, two physicians and the author as an external researcher. A public Italian hospital located in Tuscany carried out the project in the pharmacy department that has about 20 employees and provides drugs in general, including antitubercular drugs, to all the other departments. The author conducted participant observation to collect data and information for the research without interfering with the project (Savage, 2000). In order to better analyze and discuss the findings of the observation the findings were discussed with the two physicians. Participant observation is a typical qualitative method that leads to the development of theory in an inductive way (Bryman, 1988). Limitations of this method are due to the fact that is difficult to generalize the developed theory to other public health care organizations.

The results of the research are presented using the five stages of the DMAIC pattern. For each stage the author analyzes the particular findings and discusses what the Italian hospital did and what it achieved.

Results and discussion

Define

Understanding the VOC is one of the most important issues in the define stage (George, 2002). The hospital divided the customers into two main categories:

- (1) External customers: in this category are patients, taxpayers (e.g. insurance companies and local authority) and external medical practitioners.
- (2) Internal customers: in this category are head of departments, physicians, nurses and unions.

Each year the general manager, based on the priorities assigned by senior management, tries to understand what the customers' needs are; this is achieved

through the use of surveys. The senior management decided that the highest priorities for the year in order to better satisfy the above mentioned internal customers were:

- more health and safety for physicians and nurses who manage antitubercular drugs; and
- a cost reduction concerning the management of antitubercular drugs.

The head of the pharmacy department was appointed as a sponsor of the projects.

In any case, the main target to achieve was compliance with the Italian law on safety. In particular, risks to the safety and health of the physicians and nurses were taken into account according to Italian laws and regulations. It was well known that employees, especially nurses, had been injured. Furthermore, savings were expected from the reorganization of preparation and administration. The drug is expensive, therefore any improvement concerning its waste could lead to savings but in this stage nobody knows the actual amount of waste. The head of the pharmacy department appointed the team members. He decided to involve an external Lean Six Sigma consultant certified as a Black Belt because the hospital did not have a Black Belt. The team members, even though they were not Green Belts, had a good knowledge about quality tools and improvement projects. The Black Belt provided initial training to the team about Lean Six Sigma tools and the DMAIC pattern.

It was decided that the project should last no more than one year. The Black Belt, along with the team and the head of department identified the CTQs (Klefsjo *et al.*, 2001; Antony and Banuelas, 2002):

the risk to nurses and physicians, and the amount of drug inventory.

Measure

At this stage the team focused on the collection of historical, numerical and non-numerical data that could be useful to describe and better understand the stages of the different processes (Vincent, 2004).

First of all the CTQs were measured. It emerged that the number of occurred injuries in the past year were 8 for a total of 45 nurses and physicians who managed antituberculars. Several near misses occurred in the same period but unfortunately these events were not registered and counted. The typical path of an antitubercular drug is shown in Figure 1. The table also shows the number of injuries for each activity. It can be noted how the majority of the injuries are concentrated in the preparation stage inside the department.

As shown in Figure 2, in this stage, the team also used value stream mapping (VSM) (Prathibha *et al.*, 2007; Poksinska, 2010) in order to better visualize how many

Activity flow						
Request of the drug from the department	Unload from the pharmacy warehouse	Transport from the pharmacy to the requesting department	Storage inside the department	Preparation inside the department	Transport to administration points	Administration to patient
→						
Number of injuries	0	1	0	5	1	1

Figure 1.
“As-is” flow of the antitubercular drug

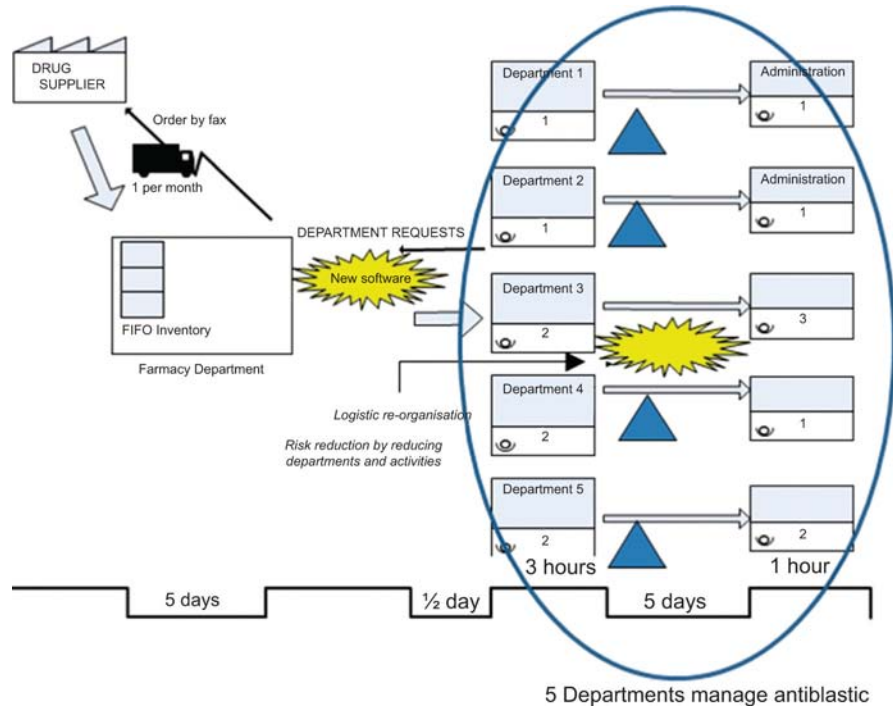


Figure 2.
VSM “as-is” of the
antihypertensive drug flow
inside the hospital

departments were involved and the drug flow. VSM is a typical Lean Six Sigma tool and it is important because it shows at first glance the wastes inside the flow. The first issued VSM represents the process “as-is” and the team can begin to measure and analyze the wastes.

The blue triangles indicate inventories of drugs between the five departments and the point of administration, and this was a relevant waste in terms of cash flow as now discussed. In addition to the seven Lean wastes, VSM enables the measurement of wastes such as motion, transportation and processing. Even if this was not the main target of the project, the VSM in Figure 2 underlines for example that inside the five departments the preparation of antihypertensive drugs took three hours and this is considered a long time. Furthermore, nurses had to walk a long distance from the pharmacy to the departments to deliver the drugs. In addition, the management of the created inventories in the department stockrooms set the lead-time at five days. In fact, the drugs inside the departments were stored using the first-in-first-out method (FIFO) and each drug that entered the stock was unloaded on average after five days. The yellow clouds indicate the main improvements required. VSM can also be useful to design the future state of the process after carrying out the improvements.

In order to measure the current value of the risks to the operators, a failure modes and effects analysis (FMEA) was conducted (Sharon and Allard, 2009). For each activity in Figure 1 an FMEA was carried out. An example of the FMEAs is shown in Table I. The example activity shown is the activity with the most number of injuries: “preparation inside the department”. Contamination is the risk of the activity and its

causes can be: the drug being dropped on the floor inhalation and the handler’s skin being pricked. For every cause a “risk priority number” (RPN) has to be calculated. The RPN is the multiplication of three factors: the “occurrence” (O), the “severity” (S) and the “detection” (D). Each of these factors can be scored from 1 to 10. For O, the higher the value the higher is the probability that the cause happens. For S, the higher the value the higher is the damage to the nurse or doctor, for instance 10 means fatal. For D, the higher the value the less the nurse or doctor can detect the cause before it happens, therefore 10 means that is impossible to become aware of it in advance. The RPN shows that some causes, for instance inhalation, had a relatively high O value (4 out of 10) with a high S for nurses and physicians (8 out of 10) and a very low D (9 out of 10).

The Pareto analysis in Figure 3 showed that five departments prepared and administered antineoplastics: medical oncology, haematology, oncologic surgery,

Process	Risk	Causes	O	S	D	RPN
Preparation inside the department	Contamination	Fall to ground	2	7	9	126
		Inhalation	4	8	9	288
		Prick	2	5	8	80

Notes: O = Likelihood of occurrence (1 – low to 10 – high); S = Severity once happened (1 – low to 10 – high); D = Detection or capacity of detecting the cause before it happens (10 – low to 1 – high); and RPN = multiplication of $O \times S \times D$

Table I. Example of FMEA for the preparation of the drug

Departments	Yearly consumption (units)	Cumulative %
1 – Medical oncology	1960	55.67
2 – Paediatrics	1002	28.46
3 – Oncologic surgery	356	10.11
4 – Oncologic immunotherapy	121	3.43
5 – Haematology	82	2.33
Total	3521	100

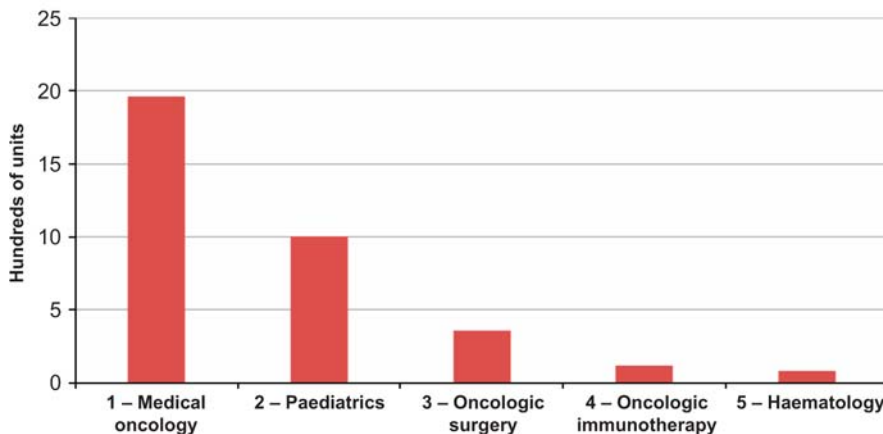


Figure 3. Pareto analysis for the consumption of antineoplastic drugs

oncologic immunotherapy and paediatrics. However, more than 80 percent of the administration was carried out in only two departments.

Some of the departments were not provided with the necessary equipment and training. Furthermore, as previously discussed, inside the five departments with the passing of time inventories of antineoplastics increased in value. In fact, some departments ordered from the pharmacy on average 38 percent more drugs than was necessary and instead of taking the leftover drugs back to the pharmacy they were just stacked up. Taking a picture at a certain time it was calculated that there was more than €800,000 of drug value inside the stockrooms of the five departments. Indeed, an antineoplastic can reach a value of €3,000. Table II shows the distribution of the inventories inside the departments, their amount and the value in Euros.

The calculations have been made by multiplying the number of drug units inside the stockroom by the value of the unit.

Even if the Haematology and Oncologic immunotherapy departments had a relative low yearly consumption (see Figure 3), they had 168,000 of drug value inside the stockrooms.

These figures generated the idea that a centralization of the structures was possible.

Analyze

The analyze stage was carried out by means of tools such as brainstorming and cause-effect diagrams (Figure 4). The objective of this stage is to find the root causes of risks so that they can be eliminated to improve the process. In this stage the team used in particular a simple cause-effect diagram. The diagram was invented in the 1960s by Ishikawa (Ishikawa, 1963) and it is still applied today in the problem-solving process (Pyzdek, 2001).

The Ishikawa or “fishbone” diagram divides the potential causes that affect the effect into four categories called the “4Ms”: machines, methods, men (staff) and materials. During the brainstorm process the team discusses the potential causes and classifies them into one of the four categories. The substance of the causes is then tested and some causes can be rejected. For instance, at the beginning of the process the team focused on the possibility that some accidents were caused by the fragility of antineoplastic phials. However, after improved analysis of the phials and their handling this hypothesis was discarded.

By the means of the 5WHYs tool the team asks itself several times (roughly five times) whether the cause is at its root or can be linked to another one (Latino, 2004). For example “unsuitable equipment” is a cause of accident to nurses during the manipulation stage. The team asked itself a first time why this could happen; the

Table II.
Distribution of the inventories inside the departments before the improvements

Departments	Inventory level	Value in Euros
1. Medical oncology	120	357,330
2. Paediatrics	79	197,500
3. Oncologic surgery	80	113,200
4. Oncologic immunotherapy	91	63,800
5. Haematology	73	104,200
Total	3,521	836,030

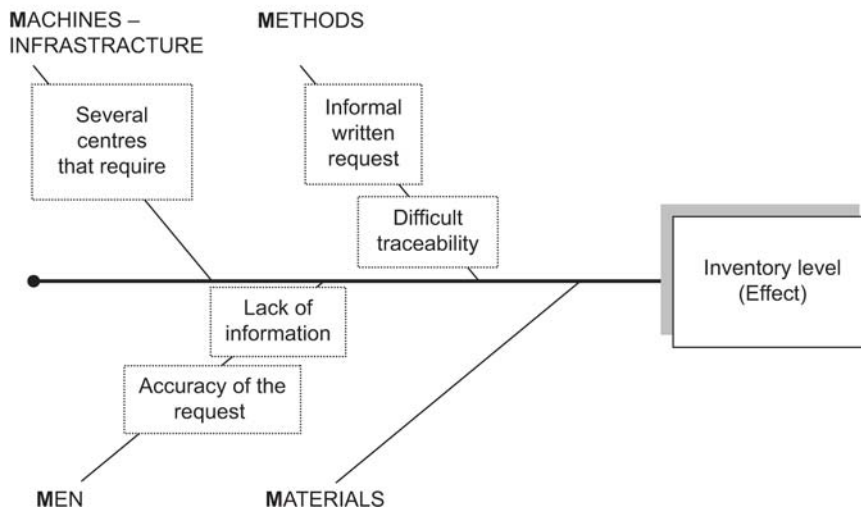
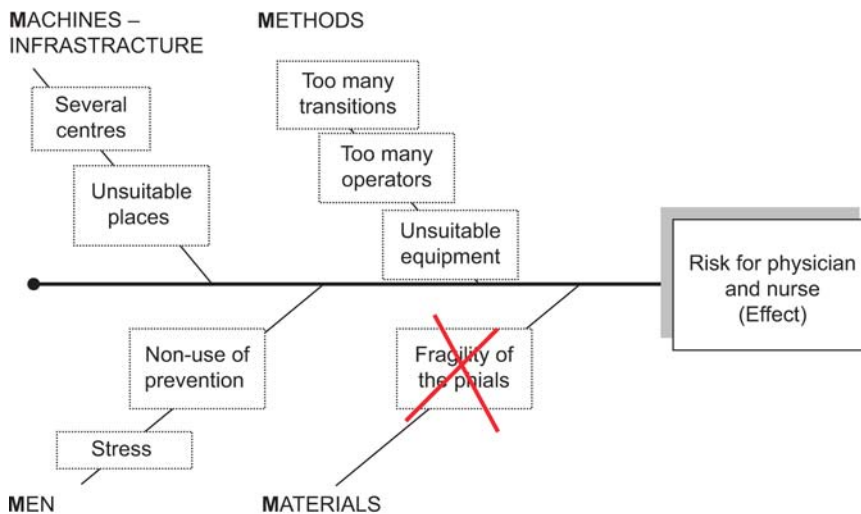


Figure 4.
Cause-effect diagrams used during the analyze stage

answer was because nurses used the wrong gloves. Why did nurses use the wrong gloves? Answer: because of a mistake in the order process to the supplier. Finally the team understood that the purchases were done without following precise requirements for the gloves. This is the real root cause.

In this way several gaps emerged during the analysis of the causes of the risks:

- Several centres of preparation and administration and too many transitions among the departments.

- Non-use of prevention by the staff, especially inside the requesting departments.
- Unsuitable places and equipment inside the requesting departments.

The last important factor was determined by the fact that too many operators handled these dangerous drugs and that increased the number of endangered people. The high values of the RPN show that many operations imply a high risk for both nurses and physicians and even patients. It was therefore necessary to eliminate all unnecessary actions and reduce the risk for those actions that are necessary.

Concerning the inventories inside the five departments, the causes analyzed were surely due to the five departments and to the amount of the drug the physicians required. In fact an informal written request from the departments to the pharmacy could enable any doctor to obtain any amount of antitubercular drugs. That implied two effects:

- (1) Waste of drug in terms of inventories.
- (2) Difficult traceability of events; this meant that it was very difficult to reconstruct the preparation of the drug and its “path” to being administered.

Furthermore, inside the team a nurse pointed out factors such as workload, shifts, stress and lack of information. This latter, as shown in the next subsection, has been partly solved through the introduction of work instructions. However, it is probable that psychological factors can affect the results in terms of accidents and injuries. The team decided to investigate these factors after carrying out this first project.

At this point the involved team launched improvement plans to remove the causes and fill the gaps.

Improve

The most important improvement action launched by the team has been the development of a centralized unit dedicated to the management of the antitubercular drugs. As previously described, this led to a reduction in the number of transports and consequently a reduction in the probability of accidents. The centralized unit has been organized to guarantee the operating requirements of all the departments. At the activation of the service, the five production centers were closed. Linked to the new centralized unit other improvements have been launched:

- First, extensive staff training focusing on safety.
- Continual staff training and information in order to raise awareness on the risks.
- The introduction of a health surveillance service as well as of an assessment of exposition.
- The issue of specific work instructions for the handling of drugs.
- The creation of two administration areas for outpatients and day hospital patients: a paediatric one and one for adults. In the case of hospitalized patients in any department who cannot be moved to the centralized administration area, but who need antitubercular therapy, staff members from the centralized area can go to the department where the patients are hospitalized and administer the therapy.

- New software for the requests from the departments has been implemented to avoid requests that exceed needs.
- Bar codes have been introduced in order to label the packages containing the drug that is being processed. This method eliminates all possible errors when a drug is administered and therefore makes it possible to offer the patient a reliable service.

After six months the improvements were all implemented, consequently the team could measure the achieved success and in particular the CTQs.

Control

Control is the last stage of the DMAIC pattern in which the improvements are checked and measured.

The first important CTQ to measure is the risk for nurses and physicians. A good way to evaluate progress is to recalculate the RPN inside every FMEA. Risk levels have greatly decreased especially concerning preparation activity as the example shows in Table III.

A more thorough analysis of the RPN highlights that the decrease is mostly due to a reduction in the value of the “occurrence”. It can also be noted that the value of “severity” does not change; this means that if an accident occurs, then the consequences could be as serious as before. Another very important factor is represented by the fact that thanks to the centralization two activities have been eliminated thus reducing the risk of accidents, these are:

- (1) The transport of drugs to the departments.
- (2) The storage of drugs in the departments.

The elimination of these two activities has also led to a reduction in transportation time, motions and lead-time.

The second target, the reduction of inventory costs, was achieved through:

- (1) A decrease in waste.
- (2) Reduction of immobilized capital (Neumann and Hoisington, 2008): stockrooms inside the five departments have been completely eliminated and the only one left in the centralized service has not been enlarged; this has led to a decrease in the amount of stocked material.

A new measure of the CTQ of the inventory has demonstrated a drastic reduction in the inventories and their value. The total amount after improvements was around €200,000. The amount was concentrated around 95 percent within the pharmacy and the remaining in the two new administration points.

Process	Risk	Causes	O	S	D	RPN
Preparation	Contamination	Fall to ground	1	7	9	63
		Inhalation	1	8	8	64
		Prick	1	5	8	40

Table III.
Improved FMEA for the preparation of the drug

Conclusions

The project was conducted successfully through the use of the DMAIC pattern and tools of Lean Six Sigma, such as Pareto analysis, cause-effect analysis, FMEA and VSM. Two CTQS were identified at the beginning to evaluate the project success: the risk for nurses and physicians and the total cost of the drug inventories.

FMEA, which is a typical Six Sigma tool, was fundamental to calculate and analyze the safety and health risks to nurses and physicians. VSM that belongs to the Lean world was used in order to better understand the inventory level as well as transportations, motions and lead-time. The improvements carried out have been underpinned mainly by a centralized service and two very controlled administration points. Other improvements such as training, work instructions, implementation of barcodes and new software for drug requests have also contributed to the project.

The creation of a new centralized service into which all the activities concerning antiblastic management merged, led to safety risk reduction in accordance with national laws. In addition, centralization enabled the reduction of financial costs in the pharmacy department due to the removal of immobilized capital inside the stockrooms of five departments.

Furthermore, improvements in terms of motions, transportations and lead-time reduction were achieved, even if they were not expected or planned. Roughly speaking the team have calculated a six-day reduction in lead-time and 60 percent less time for transportations and motions inside the departments.

Further research is needed because this research is based on a single case study; therefore academics and practitioners could investigate the subject in more detail by the means of other case studies or a quantitative inquiry. For instance, it is important to understand whether FMEA is the best tool inside Lean Six Sigma to manage safety and health risks to nurses and physicians. Indeed some authors examined the limitations of FMEA and introduced other tools especially for managing patient safety risk (Marx and Slonim, 2003).

In addition, as emerged during the analyze stage, psychological factors such as workload, shifts and stress can also affect the number of injuries to nurses and physicians. For example, some authors have investigated errors resulting from the psychological limitations of humans (Helmreich, 2000).

The lack of health and safety for nurses and physicians that manage antiblastic drugs and other processes could be put in correlation with psychological factors.

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