An Integrated Approach to Enhance Quality and Reliability of Healthcare Processes

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The dynamism and competitiveness of actual markets have imposed on companies effective methodologies in order to improve the quality and reliability of systems and processes. In the healthcare field, the possibility to adopt improvement techniques can lead to obtain a positive impact on society (patients, employees, environment) and a higher performance level of healthcare organizations. Failure Mode and Effects Analysis (FMEA) represents one of the most effective answers to reach customer satisfaction through the risk assessment and continuous improvement. The goal of this paper is an integrated implementation of improvement techniques (Healthcare FMEA), problem solving methods (DMAIC) and performance indicator metrics in a radiology department of a healthcare local unit in order to share and diffuse results and practices.

Keywords:

Healthcare, FMEA, Continuous Improvement

1. INTRODUCTION

An increasing competitiveness and the introduction of more constraining prescriptions have pushed companies to invest in innovative methodologies to enhance quality and reliability. In particular, in the healthcare field the possibility to adopt improvement techniques can lead to obtain a positive impact on stakeholders (patients, families and employees) and shareholders (healthcare organizations).

The performance results of healthcare services justify the application of integrated reliability techniques. Thomas et al. [1, 2] stated that medical errors injure 1 in 25 hospital patients and cause death for roughly 44,000 to 98,000 Americans annually [3-5].

In United States, the Joint Commission on Accreditation of Healthcare Organization (JCAHO) assumed responsibility for the accreditation of hospitals in 1951. Since 2003, JCAHO has required that accredited institutions incorporate the development of methods for risk analysis as a part of organizational patient safety plans and procedures [6].

In Europe, Union of Medical Specialist (UEMS) suggests to adopt guidelines for Quality Assurance (QA) in every country, showing how to reach reliability goals through the development of structured improvement actions [7].

Nowadays, the Italian healthcare is beginning to apply improvement methodologies in order to obtain an increase of process efficiency and effectiveness. The healthcare sector is looked within and beyond its boundaries, adapting problem-solving strategies already successfully applied to aerospace and other high-risk industrial fields. The use of tools such as root cause analysis, process mapping and FMEA (Failure Mode and Effects Analysis) can be helpful to understand and manage those factors that affect the quality of every process. It is necessary to diffuse improvement techniques and metrics in order to measure and analyze the real performance with a significant impact on service end-users and healthcare institutes. In particular, it is important to create a common metric to communicate and identify the sources of inefficiency.

This paper wants to address this actual issue in healthcare environment, suggesting an integrated approach in managing services and showing a list of effective tools that are useful to reach customer satisfaction. In particular, this study highlights the power of FMEA in order to undertake a risk assessment and a continuous improvement project.

2. INTEGRATED APPROACH ROADMAP

In recent years, continuous improvement and reliability analysis were related only to industrial markets. Here, a high level of quality increased the competitive advantage of a company answering customer requirements.

In the healthcare environment, the quality systems have already provided significant results in organizing procedures and human resources. However, the lack of communication and sharing of know-how and best practices have limited the effects of the obtained results. It is necessary to diffuse improvement techniques and a metric in order to measure and analyze the real performance with a significant impact on service users (patients, families) and healthcare institutes. In particular, it is important to create a common metric to communicate and identify the causes of inefficiency.

In this context, the effectiveness of a service is not always integrated with the efficiency of the processes. The negative aspect is due to a lack of knowledge in managing processes and an incapacity to share the obtained results. The common vision is that a healthcare structure reaches the goal when it is able to provide an effective output. However, this approach does not always consider the improvement of process efficiency. An efficient process consists of a number of activities that are able to provide a service/ product using minimum waste

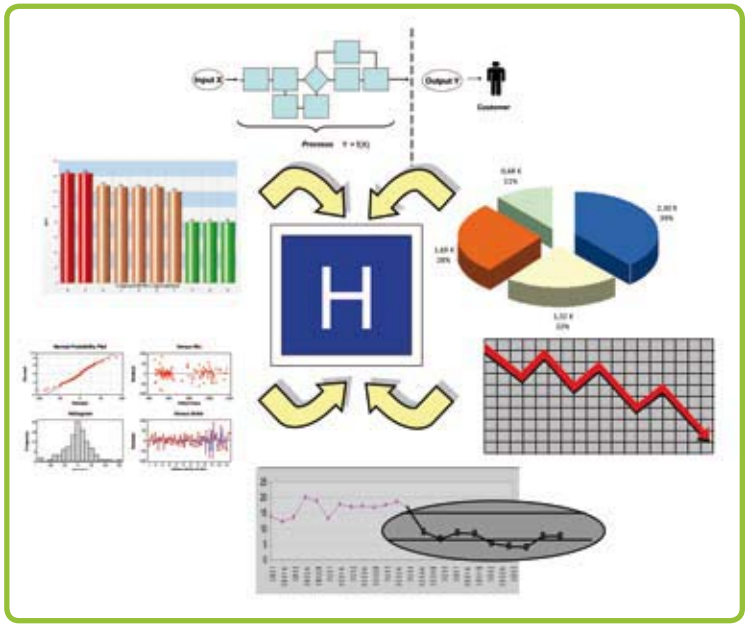


Figure 1: Integrated approach roadmap

of resources (employees, time, equipment, energy) [8, 9].

The introduction of these managerial philosophies means a wide reorganization of the company, by adopting continuous improvement logic and assuring severe changes in business results. Every employee should be an important resource that diffuses a culture and an attitude, underlying the importance of viewing processes and services from the customer perspective.

In order to reach these results, it is important to follow structured and rigorous problem solving methods that are able to lead organization reducing waste, time and resources that are essential for company business, Figure 1.

In this paper, the Authors show the DMAIC problem solving method that makes easier the FMEA application. DMAIC is characterized by five operative phases (Define, Measure, Analyze, Improve and Control) focusing on implementation of smart and effective improvements, reliability and risk analysis [9].

The first step of an integrated approach to enhance quality and reliability is to define clear and ordered goals related to the resources and the business context. If it is necessary, it is suitable to subdivide complex issues into micro-problems: they are easier to reach in a short time.

The project should take eight to twelve months and it should be deployed by a heterogeneous project team. The entire organization has to be involved to achieve excellent results.

In the define phase, it is fundamental to identify who is the client. This step is often neglected. The customer is not only the final user but represents every entity that is downstream of a department or a process. Therefore, a customer can be a person, a company, a function, a process or an activity that can be in different positions of a value stream. It is not possible to understand and eliminate failure modes of a process if the customers are unknown [10, 11]. The customer knowledge allows to understand customer requirements and needs, focusing on what is really critical (VOC - Voice of the Customer) [12].

At the same time, it is necessary to assess the performance level of the involved processes mapping service flow and collecting data and information on process features (VOP - Voice of the Process).

Integrating the VOC into the VOP, it is possible to calculate the CTQs (Critical to Quality features). CTQs are all parts and features of a process or a service that have an immediate impact on customer satisfaction. They are the starting point for a failure mode analysis and an improvement plan offering the greatest opportunity in reducing costs and increasing quality and savings [13].

The Quality Function Deployment (QFD) is an effective tool used in this part of the project. It links the Voice of the Customer directly to the internal processes of a company suggesting prioritization for analysis and improvement [14-16].

Following the DMAIC road map, the second step of the project is the measurement phase. The purpose of this step is gather data that describe the nature of the problem [17]. The team should collect capability indexes and Key Performance Indicators (KPIs) for the main processes focusing on the CTQs identified in the first phase. These information and data must be the input for an effective reliability analysis.

In the third step of the project, the team should identify all causes and sources of a low performance of processes. FMEA is the most powerful tool to understand failure modes and their effect on customer and involved processes. Failure means a total or partial deviation from the functionality of a product/service, activity, process or system [18, 19]. FMEA methodology permits a deep knowledge of the potential failures that can occur in the activities described in the process mapping.

Through the VOC and the VOP analysis it is possible to define a list of possible errors and defects incurred in service delivery.

FMEA should be developed using brainstorming (Ishikawa diagram, kaizen blitz) or quantitative tools (i.e. run chart, capability analysis). For every collected failure, it is possible to identify its effect.

A failure effect is defined as the result of a failure mode on the system function as perceived by the user. Every effect is estimated

by a Severity index (S) (from 1, low severity - to 10, high severity). Then, the team should look at the causes of a failure and how many times it occurs. The failure mode likelihoods can be quantified by an Occurrence index (O) (from 1, low occurrence - to 10, high occurrence). Furthermore, it is necessary to correlate the failure severity and occurrence to a Detection indicator (D) (from 1, high effectiveness - to 10, low effectiveness). This number represents the possible capability of control systems to remove defects or detect failure modes.

By defining the ranking of severity, occurrence and detection, it is possible to calculate the Risk Priority Number (RPN). It is obtained by multiplying the indicators: RPN = S x O x D. Failure modes that have the highest RPNs should be managed with the highest priority for corrective and improvement action [20].

In the light of these considerations, the team should define an improvement plan (i.e. actions, action owners, impact on the system, costs, and investments) and implement the solutions. Analyzing all potential failure modes, FMEA technique impacts directly on the reliability of a process or a system. The last activity of the DMAIC approach is to check that the obtained results can be maintained by the company and if it is necessary to have a recursive use of these tools.

The next sections of this paper show an application of an integrated approach to enhance quality and reliability in healthcare environment.

3. PROJECT STATEMENT

This project was implemented in the radiology department of a healthcare local unit. The main goal was to increase customer satisfaction and service performance of the department using an integrated and rigorous method.

In this context, customer satisfaction has a double meaning. In fact it is important to provide an efficient service; nevertheless, it is fundamental to discover criticalities and priorities for the patient's life. In order to achieve the project goals, the main figures of the department have been involved: the project manager, two physicians, three radiology technologists and two nurses. The study completion took eight months.

The first step was the identification of the voice of the customer. In healthcare environment, customer knowledge is a complex activity. In this project the main customers were the patients (the final users), the patient's families and the healthcare local unit employees (i.e. medical doctors, nurses, technologists, administrative staff) [21]. In particular, the team analyzed a number of customer interviews that the radiology department had deployed in order to measure the customer satisfaction in the last three years. The results of this analysis highlighted that:

- 34% of patients completely satisfied;
- 48% of patients satisfied with the service;
- 18% of patients unsatisfied.

The interviews involved a significant sample of patients. Therefore, the formal goal of the project was to move the patients from the "unsatisfied" class toward

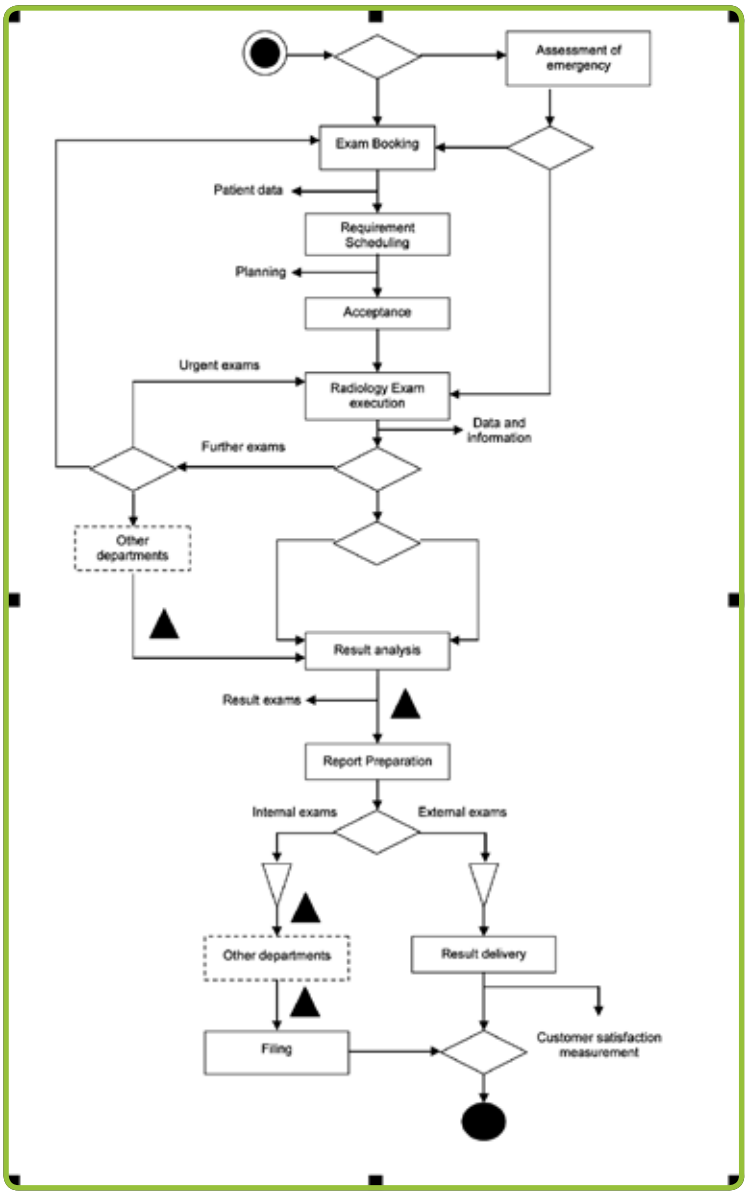
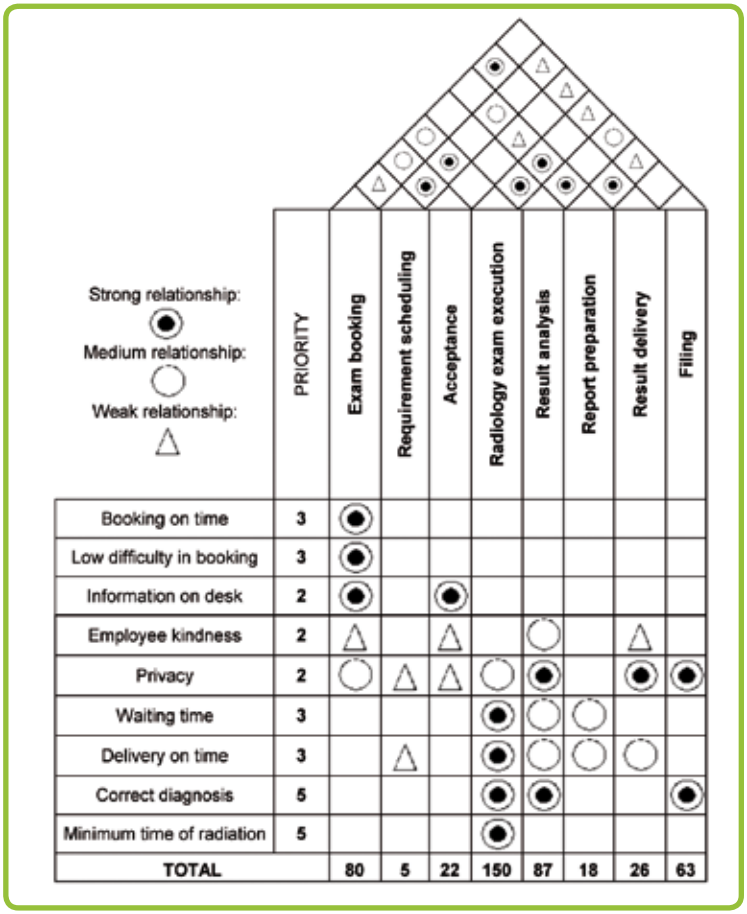


Figure 2:
Radiology system mapping

Figure 3:
Radiology Quality Function Deployment



	PRIORITY	Exam booking	Requirement scheduling	Acceptance	Radiology exam execution	Result analysis	Report preparation	Result delivery	Filing
Booking on time	3	◉							
Low difficulty in booking	3	◉							
Information on desk	2	◉		◉					
Employee kindness	2	△		△		○		△	
Privacy	2	○	△	△	○	◉		◉	◉
Waiting time	3				◉	○	○		
Delivery on time	3		△		◉	○	○	○	
Correct diagnosis	5				◉	◉			◉
Minimum time of radiation	5				◉				
TOTAL		80	5	22	150	87	18	26	63

the 'satisfied' one and increase the percentage of the 'completely satisfied' category. Assessing historical data and information, customer complaints, interviews and surveys, the team determined the main customer needs and requirements:

- correct diagnosis;
- minimum time of radiation;
- booking on time;
- clear and correct information on desk;
- privacy;
- employee kindness;
- short waiting time;
- delivery on time.

The team had to focus on these aspects for an immediate increase of the system performance level.

In order to define the voice of the process of the radiology system, it is important to map all processes and activities using simple tools such as SIPOC (Suppliers-Inputs-Process-Outputs-Customers) or flow charts. For more clarity, Figure 2 shows the mapping of the radiology system.

In a radiology service, the first step is the exam booking, where a prioritization of patients is defined.

This phase can be executed by phone or directly at the department desk. The critical situations are processed immediately, while the normal cases are scheduled, assessed and planned for the exam execution following the standard procedures.

The core of the system is the exam execution at the radiological laboratory and the analysis of the results. The preparation of the reports and the delivery of the results to the patients complete the system mapping.

Further activities can support the main processes: the movement of vulnerable patients from/to the radiology department, the transportation of radiological equipments, the execution of exams in other sites, the control of the expiration date and the storage of drugs.

As defined, it was fundamental to determine prioritizations in order to safeguard the patient's life, the radiology technologist safety and increase the department performance level.

By involving the customer service department, it was possible to select a list of critical to customer features (CTCs). For every feature, the team defined a weighting of importance (from 1, low – to 5, high).

In order to correlate the main CTCs with the radiology processes and services the team applied the Quality Function Deployment tool.

Quality Function Deployment (QFD), Figure 2, relates the voice of the customer directly to the process, creating and suggesting prioritization for improvement. Different functional teams can apply this technique in order to resolve problems in providing products, processes or services [22].

The relationship matrix identifies the most important CTQs features that represent the best opportunity of improvement. The relationships are shown at the intersection of the 'what' (VOC and CTCs) and 'how' (VOP), using different symbols. In this way, the team should calculate 'how much' for each 'how', multiplying every symbol rank with the importance of weightings in each column [23].

In this study, QFD was a customer-driven process for planning services. Figure 2 shows a number of CTQs that include both simple booking activities and the critical procedures of the radiology laboratory.

For example, the matrix highlights that the exposition time of radiation had a significant impact on patient and technologist's health. The team completed the whole matrix for every CTC, identifying the critical area on which to develop an FMEA analysis.

4. KPI DEFINITON

An improvement analysis needs appropriated indicators to know objectively and synthetically the current situation and system performance.

For this reason, it is necessary to introduce an accurate measurement system, in order to know the behaviour of critical activities. Using appropriate KPIs (Key Performance Indicators) every process and activity can be analyzed in a simple and objective way.

KPI system must include all the performance parameters related to service lead time, savings and costs [24]. In this project the critical areas were radiology exam execution, result analysis and exam booking process. The main identified performance indicators were:

- Percentage of operators that use PPEs (Personal Protection Equipments) [%].
- Percentage of operators that use dosimeter [%].
- Number of patients exposed to unnecessary radiation [# operators / year].
- Number of inspections on drug expiration date [# inspections / week].
- Percentage of over time exams [%].
- Percentage of infected patients [%].

The Analyze phase had to take into account these indicators to identify and plan improvement actions.

5. HEALTHCARE FMEA

The analysis phase has been performed using the FMEA methodology. In this case study, the team applied the Process FMEA approach that focuses on potential failures due to inefficiency of processes.

The project team deployed the PFMEA involving the department employees in a brainstorming meeting. Focusing on the critical area, the team identified the main failures for every process and their effects on the customers. Table 1 shows a part of the FMEA document. In particular, four failure examples are listed: the patient is not able to book the required exam, the drug dosing is wrong, the radiology operators do not use the PPEs and ra-

Process	Failure	Customer	Effect	S	Cause	O	D	RPN
Exam booking	Patient does not book the exam	Operator	No effect	1	The call centre is out of service or busy	6	7	42
		Patient	Failed Booking	4				168
Exam execution	Wrong dosing	Operator	Exam Repetition	4	Incorrect parameters	3	3	36
		Patient	Death or Permanent Damage	10				90
Exam execution	Operator does not use PPEs and dosimeters	Operator	Serious damage	9	PPEs are not available or adequate	7	5	315
		Patient	Serious damage	9	Unclear procedures			315
Exam execution	Use of expired drugs	Operator	No effect	1	Lack of procedures	5	6	30
		Patient	Serious damage	8				240

Table 1: Healthcare FMEA

Figure 4:
Pareto Chart of Process Failures

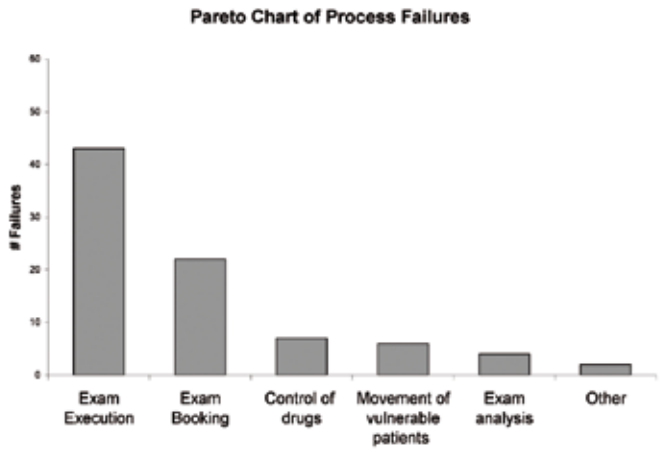


Figure 5:
Pareto Chart of Exam Execution RPNs

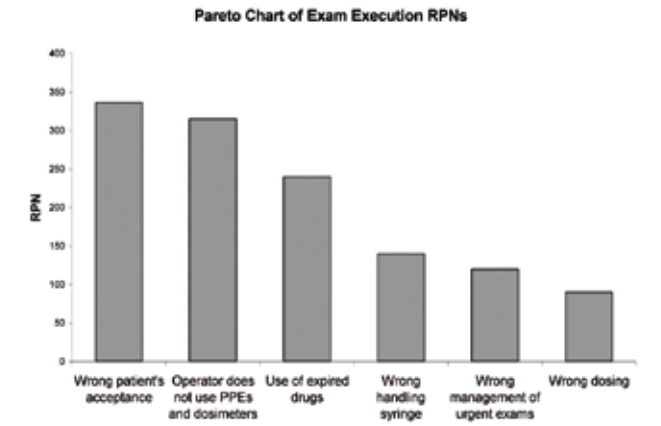


Table 2:
KPI Improvement

KPI	Before Project	After Project
Operators that use PPEs	73.60%	96.80%
Operators that use dosimeter	79.60%	95.50%
Inspections on drug expiration date	1	3
Over time exams	26.20%	6.50%
Declared Infected patients	78.00%	98.00%

diation dosimeters, the drugs are expired.

For every failure the team identified the Severity, the Occurrence and the Detection indexes, calculating the RPN indicator.

The failures with highest RPN represented the critical aspects on which the team had to focus for an immediate improvement. In particular, the RPN indicators suggested where, who, when, how to implement suitable improvement actions.

For example, a critical potential failure was that the operators did not use PPEs during the exam. This failure could impact strongly on employee and patient's safety (S=9). The main investigated causes were a lack of a clear procedure that explained the necessary equipment of operators and patients, and the serious effects of radiation emissions on the user health. With some accuracy and conviction, radiologists could tell themselves, their colleagues, and their patients that X-ray exposures cause deleterious changes to one's health [25, 26]. In the same time the PPEs (i.e. protective gloves, glasses and mask) protected employees and patient from disease-spreading. In order to calculate the occurrence and detection indicators the team verified the frequency and the controls of the radiation emission (O=7; D=5) in the radiology room. Following this way, the team deployed the FMEA analysis considering all potential process failures identifying customer effects, severities, occurrences, control system effectiveness and RPN indicators. This evaluation suggested an improvement plan that defined priorities, solution actions, owners and costs.

6. IMPROVEMENT ACTIONS AND RESULTS

In the light of the FMEA considerations, the team identified 84 potential failures of radiology service.

Figure 4 underlines the number of failures stratified per process.

The exam execution process had the highest number of failures and the highest RPN values, confirming the QFD analysis, see Figure 5.

In order to increase the system yield, the team performed brainstorming sessions, root cause investigations and collected data

Table 3:
RPN Reduction

Process	Failure	RPN Before Project	Improvement action	Action owner	RPN After Project
Exam booking	Patient does not book the exam	168	More information for the patients on booking process, focusing on the call centre activities	Administrative Staff	80
Exam execution	Operator does not use PPEs and dosimeters	315	Continuous control of the level of the radiation Adoption of new leaden equipments to protect further on patient health	Medical Doctors, Technologists, Nurses	90
Exam execution	Use of expired drugs	240	More effective inspection drug expiration date	Nurses	72

assessing possible solutions to reach the declared goals.

The main suggested actions were:

- More efficient management of the urgent exams and emergencies.
- More effective inspection drug expiration date.
- Adoption of new leaden equipments to protect further on patient health.
- More effective procedures and guidelines for operators in order to improve the result analysis and filing process (emergencies, filing database, privacy, order processing, etc…).
- Continuous control of the level of the radiation in order to preserve the health of the patients and operators.
- More information for the patients on booking process, focusing on the call centre activities (guidelines, emergency management, kindness, etc…).
- Improvement in the relationship between the radiology unit and other departments.

In order to obtain an effective application of the suggested solution, the project team defined an action log document identifying improvement action owners, solution completion, costs, investments and necessary resources.

Table 2 shows the KPIs improvement after the implemented actions. It is possible to note a global increase of the system performance level.

In particular, the new results of customer interviews, collected after the improvement action implementation, highlighted the following customer satisfaction percentage:

- 36% of patients completely satisfied;
- 58% of patients satisfied with the service;
- 6% of patients unsatisfied.

The obtained results allowed a reduction of the RPN indicators for the main critical failures, as shown in Table 3.

7. CONCLUSIONS

This paper underlines the effectiveness of an integrated approach to enhance quality and reliability of healthcare processes.

The application of rigorous and structured methodologies can help to involve whole resources of an organization to improve the performance level of a service system.

In implementing a problem solving method, every process at every level of detail can be measured and, as a consequence, it is possible to approach the management of the variability in the same way.

In this project, identifying the customer needs and requirements it was possible to determine the CTQs (Critical to Quality) features. They are the starting point for an improvement plan and they offer the greatest opportunity for improvement in cost, quality capital and lead time.

At the same time it was fundamental to calculate the performance level of the system at start of the project and the potential gap [27,28]. The possibility to involve a heterogeneous project team enabled to understand the different critical aspects of the radiology systems.

The FMEA methodology suggested a structured analysis of failures and defect causes. In particular, the RPN calculation defined prioritizations of the improvement actions focusing immediately on the critical area. The identification and implementation of the solutions and the improvement actions allowed obtaining an increase of customer satisfaction (patients, employees, and opera-

tors) and the performance level of the radiology department.

In this project there are no significant investments, but the team took advantage only of resources that already existed in the company. This aspect represents a further advantage of this improvement approach. Finally, the application of advanced tools to model and simulate the healthcare processes will be able to optimize the performance level suggesting a structured analysis of failures and defect causes [29,30].

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