POLITECNICO DI MILANO

School of Industrial and Information Engineering

Master of Science in Management Engineering

"Asset Management and Risk Management in Healthcare: Development of a Decisional Framework for an Integrated Perspective"

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ABSTRACT (Italian Version)

Dalla letteratura, molte sono le conferme dell'importanza della gestione del rischio e delle risorse nelle organizzazioni sanitarie. L'attrezzatura medica sta diventando progressivamente sempre più sofisticata, di conseguenza, la sua gestione è una questione fondamentale. Inoltre, poiché le apparecchiature mediche si evolvono continuamente, anche l'impatto sul paziente diventa sempre più significativo. Gestire le tecnologie significa gestire e prevenire i rischi che incidono sul paziente e, come qualsiasi altro tipo di organizzazione, l'ambiente ospedaliero non può essere privo di rischi. Alla luce di queste affermazioni, lo scopo di questa ricerca è di indagare in letteratura lo stato dell'arte, trovando un collegamento tra i due temi. In primo luogo, conducendo una ricerca e una selezione della letteratura, quindi sviluppando una Tassonomia completa e coesa dei fattori, estrapolata dai documenti della letteratura, che incidono sul funzionamento e sulle prestazioni delle apparecchiature mediche; in secondo luogo, creando un Framework che colleghi i due campi. I risultati ottenuti sono sia di tipo qualitativo che quantitativo, mostrando le fasi del ciclo di vita di una risorsa e le aree funzionali della sua gestione che richiedono maggiore attenzione, per quanto riguarda la gestione delle risorse. Per quanto riguarda, invece, la gestione del rischio, vengono fatte le stesse considerazioni sulla interazione componente-componente del modello SHELL e sulla fase del processo di gestione del rischio. La ricerca può essere utilizzata come input per un’analisi di tipo retrospettivo e prospettico. Per quanto riguarda il metodo retrospettivo, analizzando gli errori e impedendone la ricorrenza, mentre per quanto riguarda quello prospettico, anticipando tali errori.

ABSTRACT (English Version)

From the literature, many are the confirmations of the importance of Risk and Asset management in healthcare organizations. Medical equipment is becoming progressively more sophisticated; as a consequence, its management is a pivotal issue. In addition to this, medical equipment continuously evolves, so the impact on the patient does it too. Managing technologies means managing and preventing risk impacting on the patient, and like any other type of organization, the hospital environment cannot be risk-free. In light of these statements, this research aims to investigate in literature state of the art, finding a link between the two themes. Firstly, conducting a literature search and selection, then developing a complete and cohesive Taxonomy of the factors, extrapolated from literature papers, impacting the functioning and performance of medical equipment; secondly, creating a Framework that links the two fields. The results obtained are both qualitative and quantitative type, showing the steps of the asset lifecycle and the Asset Management functional areas that require more considerable attention from the Asset Management point of view. For what concerns the Risk Management, the same considerations are made on the SHELL model's interaction component-component and the phase of the Risk Management process. The research can be used as an input for both retrospective and prospective analysis. Concerning the retrospective method, analyzing errors and preventing their recurrence, while concerning the prospective one, anticipating those errors.

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ACRONYMS

AHP Analytical Hierarchic Process

AM Asset Management

ASHE American Society for Healthcare Engineering

BOL Beginning Of Life

CA Criticality Analysis

CBM Condition Based Maintenance

CE Clinical Engineer

CM Corrective Maintenance

CMMS Computerized Maintenance Management System

DT Downtime

ECRI Emergency Care Research Institute

EOL End Of Life

FDA Food and Drug Administration

IPM Inspection and Preventive Maintenance

ISO International Standard Organization

JCAHO Joint Commission on Accreditation of Healthcare Organizations

MC Maintenance Cost

ME Medical Equipment

MEMP Medical Engineering and Medical Physics

MOL Middle Of Life

MTBF Mean Time Between Failures

PdM Predictive Maintenance

PM Preventive Maintenance

PP Performance Predictive

PV Performance Verification

RBM Risk Based Maintenance

RCM Reliability Centered Maintenance

RM Risk Management

RT Radio Therapy

SJR SCImago Journal Rank indicator

SM Scheduled Maintenance

SPI Safety and Performance Inspection

SRL Systematic Review Model

WHO World Health Organization

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0 EXECUTIVE SUMMARY

The starting point of the present master Thesis unfolds from the relevance of Asset and Risk Management in healthcare organizations. In particular, managing the operative phase of the life of an asset, intended as medical equipment or machinery, under the lenses of risk.

Scientific Relevance

Medical equipment is becoming more sophisticated along time, playing an even more pivotal role. For this reason, its management and, in particular, maintenance are increasing of attention for clinical engineers, practitioners, and stakeholders. Some authors revealed that inadequate maintenance and, more in general, its management are the primary sources of downtime. This latter is only one of the risks for the patient, whose safety is the focus of any healthcare organization. In addition to this, the hospital environment, like any other kind of organization, is not risk-free. So, even if the linkage is implicit, in literature, the gap is on its explicitly, lacking a Framework that combines the two contexts. The actuality and cruciality of the theme underline the relevance of developing research on the topic.

Literature search and selection

A systematic Literature Review is conducted to rigorously and methodologically evaluate the research results. The specific literature review Framework aims at selecting only some papers, for the research, from a multitude of documents on the topic, through the use of research filters.

The focus is, as stated before, on the healthcare field, where Risk and Asset management are treated, and the research questions addressed are the following: “Are they linked in the area of research?”; “To which extent are they linked?”

Defined the topic of the review, the literature search is conducted through the use of science search engines, international bibliographic databases, and specific archives of biomedical and life sciences journals. Through the use of selected keywords, a collection of documents is classified for database, title, author, year, keywords and abstract. Then, through the application of inclusion and exclusion criteria, and a final screening phase of quality of the journal, a total of 37 papers is selected, starting from a total of 153 articles. Results on database, keywords, and per-years contributions are presented at the end of the SLR.

Literature Descriptive Analysis

In this part of the research, the 37 papers are deeply investigated, presenting general summaries of the central Asset management and Risk Management topics, then a general overview on the identification methods of those elements coming from such studies, that represents the basis for the core of the research, is presented.

Starting with the theme of Asset Management, definitions of medical equipment, medical device, and health technology are given and, the role and strategies related to medical equipment are presented too. Furthermore, the description of the stages composing each medical equipment lifecycle is given, as it is the input for the Framework created:

- Planning;
- Acquisition;
- Incoming Inspection,
- Inventory and Documentation;
- Installation;
- Training of Users;
- Monitoring of Use and Performance;
- Maintenance;
- Replacement or Disposal.

Continuing with the part of Risk Management, the section is divided into exposing the theme in these types of organization nowadays: the main trends and findings. Then, offering the concept of Risk management, in particular, its process divided into:

- Communication and Consultation;

- Establishing the Context;
- Risk Assessment: Risk Identification; Risk Analysis; Risk Evaluation;
- Implementation;
- Monitoring and review.

Then, the SHELL model is presented, as considered an essential pre-requisite for the implementation of a meaningful Risk management approach for the description of a healthcare environment. Its architecture puts the Liveware figure at the center of the model, as our analysis wants to do, putting the patient and its safety at the center of the research. The components are listed below, and their interactions with the Liveware figure compose the model (L-L; L-H; L-S; L-E):

- Liveware (L);
- Hardware (H);
- Software (S);
- Environment (E).

Finally, the last paragraph presents the main risk techniques applied in the healthcare field, such as:

- FMEA-Failure Mode and Effect Analysis;
- FMECA-Failure Mode, Effects and Criticality Analysis;
- Fuzzy Logic Model;
- AHP-Analytic Hierarchy Process.

Factor Analysis Framework

In this section, it is presented more deeply the study performed, starting with the identification of the factors, which are all those elements able to demonstrate a direct impact on medical devices' performance and functioning. One of the main trends discovered is that a high percentage of factors, extrapolated from the literature analysis of 26 papers over the 37 of the SLR, come from the Middle Of Life phase, or the operative one. For what concerns the 26 papers, they are equally distributed between Risk and Asset studies, in fact, 13 articles come from one theme, and the rest form the other.

Thanks to the identification of factors and their subsequent analysis, classification, and groupage, a Taxonomy is presented, which can offer a more integrated and precise overview of the whole spectrum of factors analyzed:

NUMBER	FACTOR	TOTAL	NUMBER	FACTOR	TOTAL	NUMBER	FACTOR	TOTAL
1	Availability of tools	10	43	Risk based planning	2	108	Regulatory control of marketing	1
2	Budget management	9	44	Maintenance requirements	8	109	CBM	1
3	Similar tools analysis	5	45	Medical device management database/ID	10	110	Technology obsolescence	1
4	Utilization rate	11	46	Temperature control	2	111	Facility preparation	1
5	Management of spare parts	12	47	Training of personnel in hospital	14	112	Department requirements	1
6	Equipment deterioration	6	48	Reliability and failure analysis	6	113	Strategy for identifying emerging tech	1
7	Maintenance planning	10	49	Risk analysis and management techniques	9	114	Labelling	1
8	Level of personnel	6	50	Equipment lifecycle cost	4	115	Efficiency	2
9	Function	12	51	Vendor service	6	116	Useful life ratio	1
10	Hazard analysis	10	52	Outsourcing	4	117	Availability of operating instructions	3
11	Equipment history	13	53	Supervise installation	3	118	Level of patient satisfaction	2
12	Downtime	10	54	Maintenance policy	3	119	Monitor post procurement performance and operating costs	3
13	Environment	6	55	Physical risk	6	120	Incident response plan	2
14	Electrical safety testing and protection	5	56	Risk monitoring	2	121	Equipment selection criteria	4
15	Medical equipment upgrade	3	57	Vendor negotiation	2	122	Total cost of ownership	3
16	Availability of backup	2	58	Maintenance cost	2	123	Cost of adoption (personal training)	1
17	Workspace analysis	9	59	Infrastructure and transportation	2	201	Training program	2
18	Mission criticality	10	60	Leadership	4	202	Pre-acquisition evaluation	1
19	Multidisciplinary risk management team	4	61	Calibration	4	203	Communication	5
20	Equipment replacement	7	62	Training on installation	2	204	Installation cost	1
21	MTBF	8	63	Maintenance strategy	3	205	Direct labor cost	1
22	Inspection procedures	17	64	Decommissioning	4	206	Degree of acceptance among personnel	1
23	Equipment characteristics	4	65	System integration	4	207	Risk financing	1
24	Process management	2	66	Purchasing management	6	208	Uncertainty and sensitivity analysis	1
25	Recognized guidelines and standards (ECRI, ASHE, FDA)	8	67	Frequency of repairs	2	209	Strategic plan	1
26	Standards/regulation compliance	7	68	Design specifications	4	210	Clinical technology inventory costs	1
27	Administrative person	2	69	Administrative procedures	3	211	Stakeholder collaboration	1
28	Selection and monitoring of different contracts	5	70	Prioritization	5	212	Public relations	1

29	User interface	2	71	PM	13	213	Dashboards	1
30	Performance evaluation	7	72	CMMS	7	214	Joint plan	1
31	Testing of medical equipment	9	73	Age	7	215	Life cycle moment	1
32	Safety testing	9	74	SOD-Severity Occurrence Detection	9	216	Reputation	1
33	Supporting departments	2	75	Clinical experience and knowledge	4	217	Acceptance test	1
34	Testing after repair	3	76	CM	4	218	Planning of new construction and major renovation	1
35	CE service and role	9	77	Number of equipment	2	219	Quality of service	3
36	Equipment planning	9	101	Cost of repair	1	220	Exposure avoidance	1
37	Manufacturers database	8	102	Maintenance system	1	221	Governance	2
38	Assessment methodology	3	103	Institution needs	1	222	Accident Investigation	2
39	Availability of staff	4	104	Standardization of devices	2	223	Staff safety	3
40	Company quality system	6	105	Component information	1	224	Regional variations	4
41	Financial evaluation	5	106	Reconditioned components	1	225	Patient safety	3
42	Recording of processes and activities	14	107	Prioritization of acquisition	1	226	IT systems	3
						227	Personnel survey	1

Table 1-Executive Summary "Taxonomy"

Once developed the Taxonomy, factors have been divided into two main categories according to their nature and capability to influence the decisional process:

- Performance Factors: those elements that are possible to be measured accurately at a specific phase of the medical equipment life cycle;
- Decisional Factors: those indicators that do not present a quantitative or analytical approach, or maybe it is not their primary focus; these elements focus more on the strategic and organizational aspects of a situation.

Then, Framework development and explanation are given. It is developed on double-dimension tables, where such dimensions are represented on the X and Y axis by Asset Management and Risk Management perspectives, respectively. For each aspect, two different classifications are then presented, to create a more integrated and complete overview of the context. Furthermore, within each table, factors are then classified according to their characteristics.

From the Asset Management point of view, the study proposes two main classifications for factors. The first one provides, for the subdivision of the decisional factors according to the medical equipment, life cycle stages they influence, which have been already presented in the Literature Descriptive Analysis. The second subdivision criteria, from the Asset Management point of view, include a classification of the performance criteria according to the healthcare performance area, the factors are connected with. These functional areas are Operations, Finance, Quality, HR, Strategy, Safety and Security, Logistics, Administrative, and External Stakeholders.

In the Risk Management perspective, factors have been catalogued without distinction between decisional and performance ones. The first one recalls the main steps of a Risk management process for healthcare organizations, and the second one the SHELL model's interactions among components; presented in the Literature Descriptive Analysis both of them.

Finally, the four tables, filled with the factors taken from the Taxonomy, representing the final results of the Framework, are presented:

		Asset Management Functional Areas								
		Operations	**Cost**	**Quality**	**HR**	**Strategy**	**Safety & Security**	**Logistics**	**Administrative**	**External Stakeholders**
SHELL	**L-L**		Direct Labour costs	Patient Safety, Quality of service, Level of patient satisfaction	Degree of acceptance among personnel, Communication, Leadership, Level of personnel		Patient Safety, Staff Safety		Administrative Person	Public Relations, Communication
	L-S	Availability of operating instructions	Monitor post procurement performance and operating costs	Standards/Regulations compliance, Vendor service	CE service and role	Mission criticality, Strategic Plan	Standards/Regulations compliance, Accident Investigation		Administrative procedures, Regulatory control of marketing	Regional Variations
	L-H	Availability of tools, Similar tools analysis, Utilization Rate, Function, Occurrence, Detection, Efficiency, Equipment History, Downtime, Availability of backup, MTBF, Performance Evaluation, Frequency of repairs, Age, SOD-Severity	Clinical Technology Inventory Costs, Installation costs, Equipment lifecycle cost, Maintenance cost, Cost of repair, Cost of adoption (personal training), Total cost of ownership	Equipment Deterioration, Equipment characteristics, User Interface, Testing of medical equipment, Testing after repair, Component information, Useful life ratio	Clinical experience and knowledge	Medical equipment upgrade, Life Cycle moment, Standardization of devices, Technology obsolescence	Safety testing, Physical risk	Department requirements		
	L-E		Risk Financing, Financial Evaluation	Workspace analysis, Dashboards, Labelling	Personnel Survey, Availability of Staff		Electrical Safety testing and Protection, Workspace analysis, Exposure Avoidance, Temperature control	Planning of new construction and major renovation, Facility preparation	Supporting departments, System integration, Institution needs	Reputation, Stakeholder Collaboration

Table 2-Executive Summary "Asset Management Functional Areas-SHELL"

		Asset Management Functional Areas								
		Operations	**Cost**	**Quality**	**HR**	**Strategy**	**Safety & Security**	**Logistics**	**Administrative**	**External Stakeholders**
RISK MANAGEMENT PROCESS	**Risk Identification**	Availability of tools	Risk Financing	Patient Safety, Quality of service	Leadership, Availability of Staff	Technology obsolescence	Patient Safety, Staff Safety		System integration	Reputation
	Risk Analysis	Utilization Rate, Function, Equipment history, Downtime, MTBF, Frequency of repairs, Age, Efficiency	Clinical Technology Inventory cost, Installation costs, Maintenance cost, Cost of repair, Cost of adoption (personal training)	Equipment deterioration, Component information, Level of patient satisfaction, Useful life ratio	Level of personnel, Degree of acceptance among personnel	Mission criticality, Life Cycle moment, Standardization of devices	Physical risk	Department requirements	Institution needs	
	Risk Evaluation	Similar tools Analysis, Availability of backup, SOD-Severity Occurrence Detection	Financial Evaluation, Equipment lifecycle cost, Total cost of ownership	Workspace analysis, Equipment characteristics, User Interface, Vendor service	Clinical experience and knowledge	Medical Equipment upgrade	Workspace analysis, Accident Investigation		Administrative Person, Supporting deparments	Regional Variations
	Implementation	Availability of operating instructions		Dashboards, Labelling	CE service and role, Communication	Strategic Plan	Exposure Avoidance	Planning of new construction and major renovation, Facility preparation	Administrative procedures	Stakeholder Collaboration, Communication
	Monitoring and Improvement	Performance Evaluation	Direct Labour costs, Monitor post procurement performance and operating costs	Standards/Regulations compliance, Testing of medical equipment, Testing after repair	Personnel Survey		Electrical Safety testing and Protection, Standards/Regulations compliance, Safety testing, Temperature control		Regulatory control of marketing	Public Relations

Table 3-Executive Summary "Asset Management functional Areas-Risk Management Process"

The first two tables above reflect the classification adopted for Performance factors. In both cases, on the x-axis, subdivision according to functional areas is used, while on the y-axis, risk classification firstly follows SHELL methodology and then Risk Management Process steps.

In the next two tables instead, classification performed on Decisional Factors is presented. In this case, on the x-axis, the subdivision, according to ME, lifecycle stages is adopted, while vertically, it follows the two classifications already discussed above.

Such tables will represent the practical standpoints for further considerations in the next steps of the analysis.

		Asset Life Cycle								
		Planning	**Acquisition**	**Incoming Inspection**	**Inventory**	**Installation**	**User Training**	**Monitoring of Use and Performance**	**Maintenance**	**Replacement**
SHELL	**L-L**	Multidisciplinary risk management team, Communication	Vendor Negotiation			Training on installation	Multidisciplinary risk management team, CE service and role			
	L-S	Budget Management, Process Management, Recognized guidelines and Standards (ECRI, ASHE, FDA), Joint Plan, Strategic Plan, Risk Based Planning, Risk analysis and management techniques, Incident response plan	Assessment Methodology, Vendor service, Purchasing management, Prioritization of acquisition, Pre acquisition evaluation, Strategy for identifying emerging tech, Selection and monitoring of contracts	Inspection procedures	Management of spare parts, Recording of processes and activities	Supervise installation	Training program	Accident Investigation, Uncertainty and sensitivity analysis, Recording of processes and activities	Reliability and failure analysis, Maintenance policy, Maintenance strategy, Prioritization	Decommissioning
	L-H	Maintenance planning, Medical equipment upgrade, Equipment Planning, Standardization of devices	Manufacturer Database, Design specifications, Equipment selection criteria	Acceptance Test	Medical device management database, CMMS, Number of equipment, Reconditioned components		Training of personnel in hospital	Hazard analysis	Testing after repair, Maintenance requirements, Calibration, PM, CM, CBM, CMMS	Equipment replacement
	L-E	Environment, Supporting deparments, Governance, Planning of new construction and major renovation, Outsourcing, Infrastructure and transportation			IT Systems	Facility preparation		Company Quality System, Risk monitoring	Maintenance system	Environment

Table 4-Executive Summary "Asset Life Cycle Stages-SHELL"

		Asset Lifecycle								
		Planning	**Acquisition**	**Incoming Inspection**	**Inventory**	**Installation**	**User Training**	**Monitoring of Use and Performance**	**Maintenance**	**Replacement**
RISK MANAGEMENT PROCESS	**Risk Identification**	Environment, Outsourcing	Vendor Service				Training of personnel in hospital			Environment
	Risk Analysis	Process Management, Standardization of devices	Manufacturer Database, Design specifications, Equipment selection criteria		Number of equipment			Uncertainty and sensitivity analysis	Maintenance requirements, Reliability and failure analysis	
	Risk Evaluation	Budget Management, Maintenance planning, Supporting deparments, Governance, Risk analysis and management techniques, Infrastructure and transportation	Vendor negotiation, Pre acquisition evaluation, Selection and monitoring of contracts		Management of spare parts, IT Systems		CE service and role	Accident Investigation, Hazard analysis	Prioritization, Maintenance system	Decommissioning
	Implementation	Medical Equipment upgrade, Multidisciplinary risk management team, Planning of new construction and major renovation, Joint Plan, Strategic Plan, Equipment Planning, Risk Based Planning, Incident response plan	Purchasing management, Prioritization of acquisition, Strategy for identifying emerging technologies	Inspection procedures	Medical device management database, CMMS, Reconditioned components	Training on installation, Facility preparation	Multidisciplinary risk management team, Training program	Company Quality System	Maintenance policy, Calibration, Maintenance strategy, PM, CM, CBM, CMMS	Equipment replacement
	Monitoring and Improvement	Recognized guidelines and Standards (ECRI, ASHE, FDA), Communication	Assessment Methodology	Acceptance Test	Recording of processes and activities	Supervise installation		Recording of processes and activities, Risk monitoring	Testing after repairs,	

Table 5-Executive Summary "Asset Life Cycle Stages-Risk Management Process"

Analysis

In this section, the main results are shown; the first one is related to the redundancy factors analysis. With redundancy, it is intended the recurrence of factors in other papers, since some of them have been mentioned in literature more than one time. On the one hand, for what concerns the elements coming from the Asset Management papers, preventive maintenance is the factor that appeared the highest number of times followed by downtime of Medical Equipment and training level of personnel. On the other hand, for the Risk Management ones, inspection procedures represent the factor that collects the highest interest, followed by the ability to record processes and activities and to make available equipment history information.

The second group of results is obtained from the analysis of the Framework:

- Performance factors recurrence analysis: Operations Area with 32.7% and Quality Area with 18.8%;
- Performance factors recurrence analysis for SHELL: Liveware-Hardware with 53.1%;
- Performance factors recurrence analysis for Risk Management Process: Risk Analysis with 35.3%;
- Decisional factors recurrence analysis: Planning Phase with 24.9% and Maintenance Phase with 17.2%;
- Decisional factors recurrence analysis for SHELL: Liveware-Software with 42.4%;
- Decisional factors recurrence analysis for Risk Management Process: Implementation with 36.5%.

Then an integrated table analysis is presented to discuss the significant criticalities in terms of individual factors and macro-areas of interest; in fact, the study focuses intensely on the single areas, defined as ‘quadrants”. The approach adopted in this case follows the same of the previous analysis: to evaluate which quadrant has a higher impact on medical equipment’s management-related decisions, factors’ recurrences are considered for ranking areas from the most upper important to the latest.

		ASSET MANAGEMENT FUNCTIONAL AREAS								
		Operations	*Cost*	*Quality*	*HR*	*Strategy*	*Safety & Security*	*Logistics*	*Administrative*	*External Stakeholders*
RISK MANAGEMENT PROCESS	*Risk Identification*	10	1	6	8	1	6		4	1
	Risk Analysis	65	6	10	7	13	6	1	1	
	Risk Evaluation	16	12	21	4	3	11		4	4
	Implementation	3		2	14	1	1	2	3	6
	Monitoring and Improvement	7	4	19	1		23		1	1

Table 6-Executive Summary "Risk Management Process-Functional Areas"

		ASSET MANAGEMENT FUNCTIONAL AREAS								
		Operations	*Cost*	*Quality*	*HR*	*Strategy*	*Safety & Security*	*Logistics*	*Administrative*	*External Stakeholders*
SHELL	L-L		1	8	16		6		2	6
	L-S	3	3	13	9	11	9		4	4
	L-H	98	13	26	4	7	15	1		
	L-E		6	11	5		17	2	7	2

Table 7-Executive Summary "SHELL-Functional Areas"

The two tables presented above report analysis performed on performance factors previously classified. Colors in the tables reflect the degree of importance each quadrant results to have according to factors within it. Numbers reported represent the cumulated recurrence score of each quadrant, resulting from the sum of the single factors’ relevance contained in it.

Then, the following two tables represent the analysis performed on Decisional Factors. Although dimension on the x-axis changes, the analysis follows the same Framework of the tables above.

		MEDICAL EQUIPMENT LIFECYCLE								
		Planning	*Acquisition*	*Incoming Inspection*	*Inventory*	*Installation*	*User Training*	*Monitoring of Use & Performance*	*Maintenance*	*Replacement*
RISK MANAGEMENT PROCESS	*Risk Identification*	10	6				14			6
	Risk Analysis	4	16		2			1	14	
	Risk Evaluation	34	8		15		9	12	6	4
	Implementation	23	8	17	18	3	6	6	35	7
	Monitoring and Improvement	13	3	1	14	3		16	3	

Table 8-Executive Summary "Risk Management Process-Life Cycle Stages"

		MEDICAL EQUIPMENT LIFECYCLE								
		Planning	*Acquisition*	*Incoming Inspection*	*Inventory*	*Installation*	*User Training*	*Monitoring of Use & Performance*	*Maintenance*	*Replacement*
SHELL	L-L	9	2			2	13			
	L-S	34	23	17	26	3	2	17	17	4
	L-H	24	16	1	20		14	10	40	7
	L-E	17			3	1		8	1	6

Table 9-Executive Summary "SHELL-Life Cycle Stages"

Finally, in the last part of the analysis, potential methodology applications are given. Firstly, the discussed Framework can be used as a standpoint for the evaluation of existing policies and procedures, as a retrospective tool for root causes analysis. In the second instance, the methodology is presented as a reference Framework to develop future healthcare management policies and to prioritize decisions, with prospective purposes.

In the first situation, the case study starts from a study conducted in a Radiotherapy and Oncology department in an Italian Hospital by Professor Paolo Trucco, supervisor of this research, and Others. The study is *"Applying failure modes effects and criticality analysis in radiotherapy: Lessons learned and perspectives of enhancement".* The Framework proposed will be used as a standpoint to detect possible causes for failure modes among factors evidenced in the Taxonomy. Once identified factors, their classification into this research's methodology present significant areas of intervention and suggestions for corrective actions.

In the second situation, a potential application of the model is as a reference for supporting the decision about the Selection of a Medical Device used in the Radiotherapy department among different alternatives. In particular, the methodology acts as input for the selection process performed through the AHP. The choice of this application case is due to ensure consistency with the previously analyzed scenario in Radio Therapy and to face the same risks from a different perspective. The *"Radiotherapy Risk Profile"* reported by the World Health Organization serves as technical support to select which factors to take in higher considerations. The hierarchy is presented below:

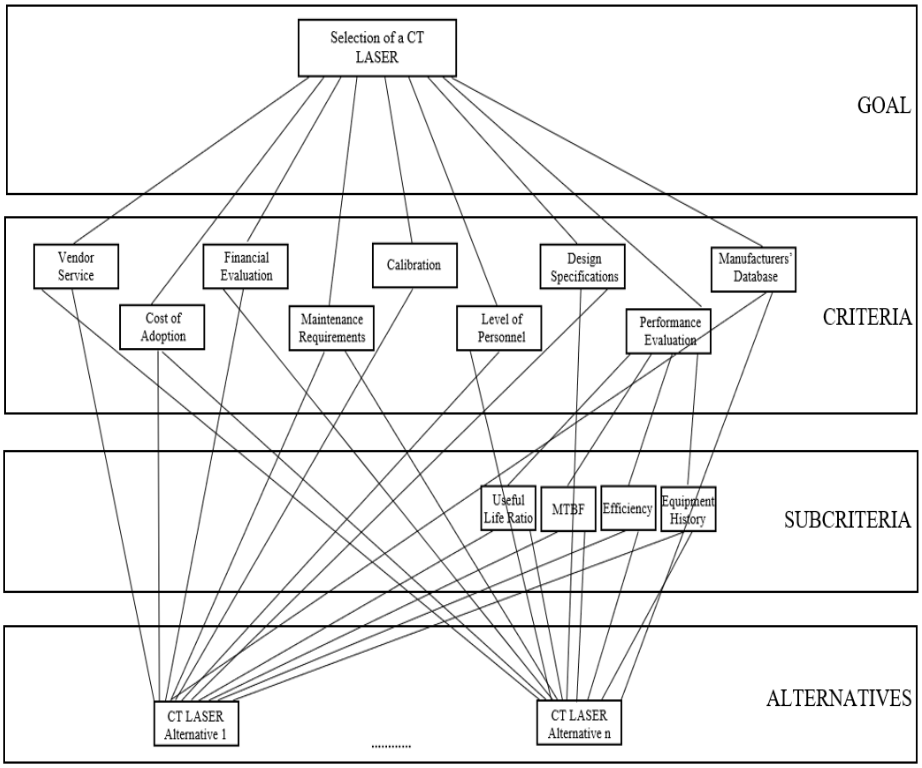

Figure 1-Executive Summary "AHP Hierarchy"

Furthermore, from the AHP tables, it will be possible to obtain the weights of the alternatives concerning each criterium and sub criterium; in such a way, the final weight for each option can be calculated, and the final decision on the selection of the CT Laser can be taken.

Conclusion and Future Developments

The first conclusion, candidates reached, was the lack of an integrated contribute in healthcare literature able to consider potential risks for patient safety connected with medical equipment management. Such absence remains evident since researches were conducted from both Asset Management and Risk Management perspectives. The second conclusion is about the fact that literature concentrates on the middle of the life of Medical Equipment (73% of its overall contribution). Another miss to be evidenced regards an elaborated Taxonomy able to synthesize potential organizational and operational issues that may affect healthcare activities.

In order to overcome those issues, a Taxonomy and a Framework that integrates the perspectives have been created, and the main results obtained are the following:

- The main functional area having a direct impact on the outcome of healthcare performances and their possible implications for patient safety is the one of the Operations, 33% of potential risks come from errors or misunderstandings directly in performing routine activities. The other areas that mostly resulted in representing a risk for healthcare organizations are Quality (19%), Safety & Security (15%), and HR (10%). Those having a lower impact are Logistics and External Stakeholders Influence, both with values below 5%;
- The lifecycle stage having the highest relevance for the implementation of an effective Asset Management policy is the Planning, almost one-fourth of the overall decisions regarding ME management should be undertaken in this stage. High relevance is also attributed to Maintenance and Acquisition stages, 17% and 12%, respectively;
- In general, MOL is confirmed as the medical equipment moment that requires more considerable attention, verifying a trend already existent in literature. However, beginning-of-life activities demonstrated to have a similar impact on the overall performance of ME;
- The step of the Risk Management Process with the highest number of factors evidenced in literature is the Implementation phase (37%). Significant influence is also attributed to factors belonging to the Risk Evaluation stage that counts for 27% of the total. Almost the same is the impact of the other three steps (Risk Identification, Risk Analysis, Monitoring, and Improvement), which is stable between 10% and 15% of the total;
- The interaction of the SHELL model presenting the highest concentration of factors is the Liveware – Software interaction, 43% of factors concentrate, in fact, in this area. 39% is instead related to L - H relationship, while lower interest is registered by L – L and L – E interactions (8% and 11% respectively).
- Table Framework also evidences a more homogeneous distribution of decisional factors influencing patient safety compared to performance factors. In the first

case, areas registering a medium-high interest from experts represent 36% of the total, while for performance elements, such value decreases to 22%.

Finally, the application of the proposed methodology in the real case for the Radiotherapy department offered other insights:

- The retrospective application allowed the RT department to use Taxonomy developed to perform an in-depth root cause analysis, addressing responsibilities to different areas inside the healthcare organizations. Human Resources area resulted as the department major responsible for mistakes in RT with 35% weight: the absence of practical training sessions for personnel and lack of clinical experience are critical factors for this finding. Quality and Administrative issues also represent fundamental aspects to be managed. The Framework also allowed to rank potential risks for patient safety through a different criticality index;
- The prospective application results in the development of a prioritization tool for CT Laser acquisition. The instrument structure follows an AHP approach, whose evaluation criteria have been qualitatively selected among those proposed in the Taxonomy. Manufacturers' database availability, maintenance requirements, and technical level of personnel resulted in being the most relevant variables to be considered.

Potential further applications of the methodology proposed may result in the adoption of a different perspective in assessing risks for patient safety. A new approach to include medical equipment management in risk evaluations. Moreover, the proposed real case application in RT should be considered as a standpoint for further utilizations in other healthcare departments as an instrument for both retrospective and prospective evaluations. Each healthcare institution may decide to readapt or reallocate factors evidenced to suit its needs better. Excellent adaptability and the possibility for continuous updating are crucial elements that may guarantee future developments to the methodology.

1. INTRODUCTION

The present Thesis is intended to investigate the connection between the two macro-areas of "Asset Management" and "Risk Management." In particular, how one influences the other one in the specific context of healthcare, which is, nowadays, growing faster and faster and is under continuous improvement.

The relevance of these two themes in the field of healthcare is implicit: the output is the service for the patient, whose safety depends, also, on the assets adopted for his care. Assets, which must be managed with rigorous precision and attention, which are under sources of risk in every daily situation: "*Organizations of all types and sizes face internal and external factors and influences that make it uncertain whether and when they will achieve their objectives. The effect this uncertainty has on an organization's objectives is "risk." All activities of an organization involve risk.*" (ISO 31000, 2009).

It is of worthwhile importance, for this reason, to introduce the two definitions:

- Risk Management: *coordinated activities to direct and control an organization with regard to risk* (ISO 31000, 2009);
- Asset Management: *the coordinated activity of an organization to realize value from assets* (ISO 55000, 2014).

Before giving other specifications of the present thesis, some milestones must be fixed. The two main themes have been presented, and a definition of each one has been given, the context in which they are treated, too, but the main object in the analysis is still unknown. The candidates have focused the attention on assets, *"items, things or entities that have potential or actual value to an organization"* (ISO 55000, 2014), but it is reductive to say that in general, the focus is on assets, since the hospital is provided with many types of assets that it would have been too wide to consider all of them.

For this reason, it was decided to concentrate on machinery, medical equipment, and technologies with an operative function. This last aspect of the operativity of the asset must be specified. When the topic of Asset Management is considered, a lot of phases and elements must be examined; actually, managing an asset means managing it over different stages of its lifecycle, and about this, it was decided to focus on the management of its middle phase.

1.1. Thesis objectives

All the elements of the object in the analysis are present; *the candidates will treat the relationship between the topics of asset and risk management in the field of healthcare, in particular in managing the operative phase of the life of an asset, intended as medical equipment or machinery, under the lenses of risk*.

But why this theme has been taken into consideration?

From the literature, many are the confirmations of the importance of the theme. Wang and Rice (2003) have designated the poor maintenance, planning, and more in general management of the medical equipment as the primary source of its downtime. Regarding this, medical equipment is becoming progressively more sophisticated and, consequently, is playing a more pivotal role in the healthcare organizations of these times. As a consequence, its maintenance and management, more in general, are an even more difficult issue to be treated, which is increasing attention for clinical engineers, practitioners, and stakeholders generally (Hamdi et al., 2012). Furthermore, as medical equipment continuously evolves, so the impact on the patient, hospital financial resources and operations do it too. As stated before, the capacity to manage this evolution in the healthcare field is one of the significant challenges in these types of organizations. Managing technologies is challenging in managing risk, too; however, like any other type of organization, the hospital environment cannot be risk-free (Corciova et al., 2013).

In addition to this, nowadays, health companies have to face hard economic conditions, in which managers are forced to use resources in the more productive way possible, exploiting them as much as possible, given the increasing costs and restricted budget.

Notably, public hospitals are the ones that are more affected by this situation, and the more the medical equipment resources are better managed, the more the benefits are (Kumru and Kumru, 2013). To cite some benefits, they are the improved financial performances, informed asset investment decisions, managed risk, enhanced services and outputs, and others (ISO 55000, 2014).

For all these reasons, for its actuality, for its cruciality and its increasing interest, the theme has been taken into consideration. In particular, the importance of Asset Management in healthcare organizations, described as *"the systematic and coordinated practices through which organizations optimally and sustainably manage its assets, assets systems, their associated performance, risks and expenditures over the asset's life-cycle for the purpose of achieving the organization strategic plan"* (Chemweno et al., 2015), must be put in combination with the Risk Management essentiality in mitigating and preventing equipment failures, or equipment related risks.

1.2. Studying methodology

After having exposed the objective of the Thesis, in this paragraph, it will be presented the Methodology. First of all, it will be introduced the methodological approach. Secondly, the methods of data collection will be described, then the methods of analysis, and finally, the candidate will evaluate and justify the methodological choices.

For what concerns the methodological approach, it has been opted for a theoretical approach to the literature. The aim has been to collect papers, that in a second moment, have been investigated theoretically: interpreting, contextualizing, and gaining in-depth insights into the specific concept. However, after the first qualitative method used to approach literature, this latter has also been interpreted quantitatively, trying to highlight the main trends of the topic in the literature. So, the methods of data collection used during the analysis have been *Mendeley*, the academic, social network to manage the research and *Excel*. The selection of papers was classified into a table divided into columns used to collect the fundamental notions of each article, as presented in Chapter 2. Proceeding with the third step of the description of the methods of analysis, as introduced before, the candidates categorized and discussed the main topics of the scientific papers taken into study. It has been an analysis of contents, whose objective was to understand the main trends in healthcare about the two fields, trying to find where to cover the present gap, as Chapter 3 will present. In a second moment, the papers have been investigated more deeply, collecting factors contributing to the operative and maintenance phases of medical equipment, and creating a comprehensive view of it through the creation of a Taxonomy. This last point will be presented in Chapter 4, which corresponds to the main body of the Thesis, where the analysis will be treated genuinely.

The reasons behind these choices are the fact that the tools available for the research were databases, such as Google Scholar or Scholar, whose amount of papers reaches large numbers, so thanks to inclusion/exclusion qualitative criteria, it has been possible to reduce the number of them. Then after a qualitative approach to them, this latter has been put beside a quantitative approach to analyze the main trends from a statistical point of view. Moreover, the factors taken from the literature do not have confirmation in reality, however, the fact that a specific element recurs many times, even in different papers, it is a reliable confirmation of the importance of that factor in the reality. In fact, the Taxonomy is put beside an analysis of the recurrence of those factors. In addition to this, the results of the study have been applied to real cases, extrapolated from literature, to confirm the suitability of the investigation from a theoretical point of view.

Indeed, as widely explained the studying methodology approach has been mainly qualitative, but with a substantial contribution of quantitative methods.

1.3. Thesis structure

The objective of the thesis is to investigate the two themes in healthcare organizations in the literature, to have a solid basis for the construction of the analysis. The search and selection of literature papers will represent a crucial point to identify the gap, which connects the two contexts, to study state of the art, and to develop the analysis. From these results, the descriptive literature analysis will be conducted, presenting the main definitions, strategies, techniques, and standards regarding the two topics. Afterward, it will come to the study performed, starting with the factors' identification and the following classification. Factors', that have been extrapolated from literature papers, directly impact on medical equipment performances and functioning. So, as mentioned before, this last aspect underlines the firm reliance on the literature search, selection, and subsequent analysis.

From the factors' classification, a Taxonomy has been created to offer a more integrated overview of the whole collection of factors. Moreover, its development has been the input for the Framework created, which integrates the Asset Management theme with the one of Risk Management. In this way, the gap present in literature can be bridged, and this research can be used as an input for future investigations to increase even more relevance on the topic. Finally, in the last part of the Thesis, two main applications in healthcare organizations will be presented, and conclusive considerations will be developed.

1.4. Thesis results

The results, candidates have reached, are articulated into three different sections. Firstly, findings related to literature analysis, reporting an overview of the current state of the art regarding Asset and Risk management. Secondly, results coming from the proposed Framework of analysis, of both quantitative and qualitative type. Finally, findings emerging from real-case applications of the methodology, extrapolated from the literature.

2. LITERATURE SEARCH AND SELECTION

2.1. General Literature Review Framework

The aim of a Systematic Literature Review (SLR) is to rigorously and methodologically evaluate the research results. Results that are extrapolated from the synthesis of the best quality scientific studies on a specific research question or topic (Kitchenham et al., 2009). The purposes of reviewing the research literature are various, including theoretical background for future research, learning the spaciousness of research on a topic on analysis, or it is carried out to answer practical questions, understanding what the investigation treats on the matter (Okoli and Schabram, 2010). In the specific case, the last one is the objective of the conducted SLR, intending to answer the question, "*What is the relationship between asset and risk management in the healthcare field?*". Performing it, it is possible to identify the state of the art of scientific literature in the research field, synthesizing everything into a Framework and underlying possible future paths of further research in those areas where literature lacks.

Fink (2005) defines the literature review as systemic, because of a methodological approach, comprehensive in including all relevant matters, explicit in justifying all the conducted procedures and reproducible, which stands for being replicable by others who would follow, in investigating topics, the same approach.

To cover all the aspects of the research, an eight steps guide has been followed. Each step must be included if the objective is to obtain a robust SLR (Okoli and Schabram, 2010).

1) *Purpose of the literature review*: identify the goal of the literature review, which must be defined and precise to carry out a proper analysis. In the specific case, the purpose is to identify the relationship that exists between Asset and Risk Management in the healthcare field. In particular, how the practitioners and clinical engineers deal with the

management of assets, intended as machineries, from a Risk Management point of view; since the risk would irreparably affect the patient;

2) *Protocol and training*: in the case of the presence of more than one reviewer, it is fundamental to be aligned and being concordant on the procedure to be followed during the literature analysis, sometimes it is necessary a written and detailed protocol. Considering this case, the steps and procedures have been agreed among the tutors and us throughout a written and precise updating document during the reviews' meeting;

3) *Searching for the literature*: explicit description of the literature search details and explanation of how the search was assured. This is done throughout a clear and methodological analysis of the searching for literature, explained in the further paragraphs;

4) *Practical screen*: this step stands for the screening for inclusion, being explicit in which studies to be considered and which ones to be excluded from the analysis, without any further examination. For what concerns the excluded studies, it must be specified the reasons why they have not been considered. Considering the specific analysis, also the screening phase and the previous step will be further analyzed in detail in the next sessions;

5) *Quality appraisal*: this step, on the other hand, stands for the screening for exclusion, being explicit identifying and specifying the criteria for which some studies are excluded from a quality point of view, depending on the research methodologies used in the articles and the quality of the source. For this step, it is valid what has been written previously;

6) *Data extraction*: data extraction is the step after the identification of all the studies to be deeply analyzed. The reviewer must extrapolate the information from each one. This step has been widely carried out also thanks to a deep reading of each article to include the important aspects of the studies;

7) *Synthesis of the research*: the synthesis is the analysis of the data extrapolated from the studies and combine them through the use of appropriate techniques, either qualitative

or quantitative, but also a combination of them. Carried out in the Literature Descriptive Analysis;

8) *Writing the review*: of course, a fundamental step is the writing of all the aforementioned points in a report. Sufficient details must be included so that the review can be reproduced.

This general Framework of the Systematic Literature Review has been used as a starting point for the specific case. Each step has been covered and treated. In the following paragraph, the Specific Literature Review Framework is treated.

2.2. Specific Literature Review Framework

Starting with the deep procedure conducted to carry out the literature review, the candidates decided to conduct a funnel analysis, as represented in *Figure 2.1*:

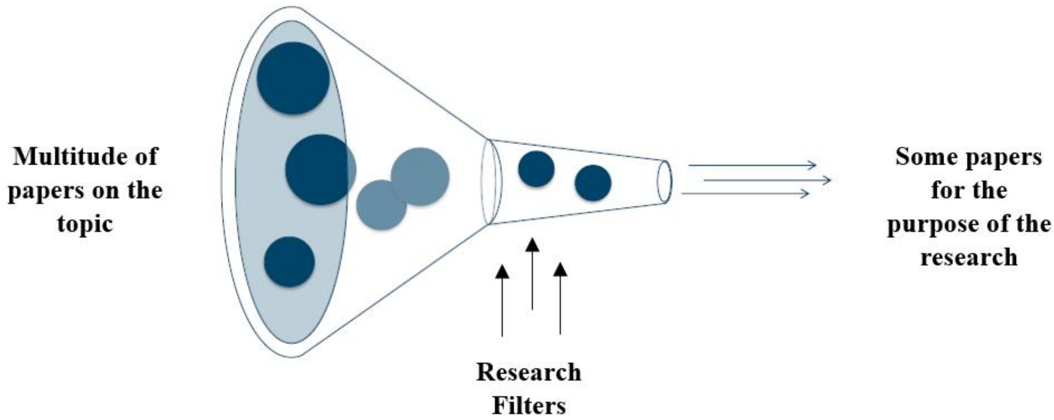

Figure 2 "Literature search and review overview"

Even if it is possible to deal with a multitude of papers, thanks to the infinite sources, it is not also possible to analyze each one in detail. For this reason, it has been decided to apply this technique, through the use of some filters and criteria, to select the papers that best would have described our problem of research.

The following section will discuss more in detail how the literature search has been developed and structured. It is divided into five sections, and the first one clearly states the focus of the review, the second one defines the unit of analysis and the databases or engines used for the literature search. The third section, instead, deals with the collection of papers and how it has been organized and through which instruments. Then the fourth section is about the definition of the inclusion and exclusion criteria and the last one about the final phase of screening, ending up with the total number of peer-reviewed and conference papers, and books' chapters.

2.3.The focus of the review

In order to address the problem proposed, the Framework presented in *Figure 2.2* has been used. The research, in fact, is divided into two main topics: Asset Management and Risk Management. The objective is to find a link, a connection between these two worlds. How they are influenced by each other and connected in the healthcare field. How the assets, intended as machinery, in their operative phase, are managed through the lenses of risk. The importance of the management of the assets, intended in their operative stage, in the healthcare field is obvious, in fact, a lousy control and governance of assets by the organization would permanently affect and injury the patient safety.

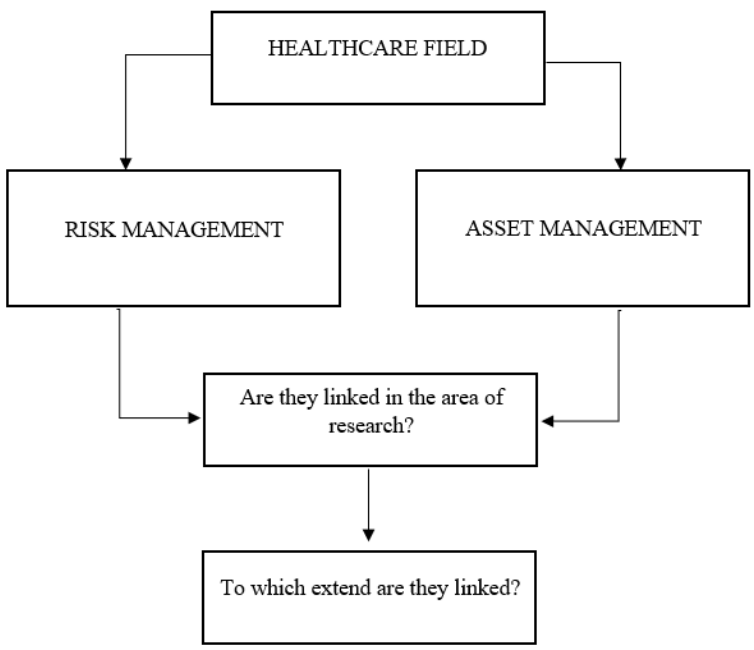

Figure 3 "Literature general Framework"

In the Introduction chapter, it emerges the implicit connection between the two research fields. In particular, as stated in the ISO 55000 (2014), in the Asset management field *"Effective control and governance of assets by organizations is essential to realize value through managing risk and opportunity, in order to achieve the desired balance of cost, risk, and performance."* However, this explicit connection must be found and analyzed in the healthcare area, which is in continuous improvement and growth, in order to assure even more safety to patients.

2.4. Unit of analysis and database definitions

After having selected the defined topic of the review, the unit of analysis definition comes. The candidates opted for international scientific papers from journals, chapters of books, or books themselves and documents from international scientific conferences.

The literature search has been conducted through the use of science search engines (i.e., Google Scholar), international bibliographic databases (i.e., Scopus, Web of Science), and specific archives of biomedical and life sciences journals (i.e., PubMed). The results will show a prevalence of articles from the engine *Google Scholar* and the database *Scopus*. Some articles were selected from the archive *PubMed* and none from the database *Web of Science*. This is because the articles found, in the latter database, were related too much to the biomedical specificities of its practices, avoiding the part of the Asset Management, focusing more on the risk of the procedures. In addition to this, in order to reorganize the significant number of papers, Mendeley has been suggested to be an excellent way to take a trace of all the sources, authors and names of the papers; to share them among the candidates and to restructure the best as possible the literature review.

Moreover, as stated before, the literature search was conducted using several selected keywords. First of all, focusing on *Scopus* "the abstract and citation database of peer-reviewed literature", the chosen keywords were "asset* management", "patient safety", "risk management", "healthcare", "medical device*", "hospital", "clinical technology", "medical equipment", "medical technology", in a second moment of the literature search also a more specific focus was followed, through the use of the keyword "risk-based maintenance". The focus of the analysis is in the management of the operative phase of the assets, avoiding the beginning and the last step of it; otherwise, the literature research would have found a world to discover, too much wide for the unit of analysis. Continuing with the illustration of the keyword's selection, they have been used in combination with each other through the use of the logic connector "AND" to cover a broader spectrum of the inspection. Examples of them are "patient safety AND asset* management", "medical device* AND risk management", or "asset* management AND healthcare". In addition to this, the "*" was used not to lose the articles containing the keyword in both singular and plural form.

Secondly, through *Google Scholar* and *Web of Science*, similar research was conducted, again with a combination of the keywords mentioned above. Finally, when exploring *PubMed*, since it is already related to the healthcare and biomedical field, the keyword "healthcare" has been avoided because useless for the research.

Overall the research, keywords used have always been matched together in order to have at least one keyword belonging to one of the two main research areas, defined as Risk Management and Asset Management. This decision has been taken to maintain the focus on the two main themes of the research, and to make more accessible further classifications upcoming in the next steps of the study.

2.5. Collection of papers

The collection of documents happened through the use of *Mendeley*, the academic, social network to manage the research, collaborate and share the work. However, the use of *Excel* has been fundamental too. In fact, the collection of papers was classified into a table divided into columns used to collect the fundamental notions of each paper:

1) Database, where the scientific, conference paper or book's chapter was found;
2) Title;
3) Author;
4) Year;
5) Keywords used to find that specific paper, chapter or book;

6) Abstract, not the entire one but some meaningful sentences to define the precise content of the selected literature;

In this way, the analysis and the screening phase have been simplified and improved significantly. Moreover, through the use of *Excel*, it has been possible to elaborate on the statistics about the research.

Furthermore, the candidates decided to conduct a parallel literature search, meaning that both searched for articles and papers, using the keywords as mentioned earlier. Then, after having collected them into a single *Excel* file, the elimination of the duplicates took place. In this way, a more comprehensive range of papers was possible to be covered.

2.6. Inclusion/Exclusion criteria definition

As widely explained before, the different combinations of the keywords let to a variety of diverse contributions; as a consequence, some criteria of inclusion and exclusion criteria have been defined to select a smaller group of papers but more significant and representative of the focus in the analysis. The sequence of selection of the papers to be put in the Excel File is the following:

1. Language filter;
2. Title Investigation;
3. Date filter;
4. Abstract Investigation;

The first step has been characterized by the decision to select only articles written in English.

The second step was related to the analysis of the titles, considering valid also articles that from their investigation were omitting one of the two fields, asset or risk ones, but not both. In fact, some keywords must be found in the title; otherwise, they were excluded from the papers gathering.

Thirdly, the last step was related to the fact of including papers of the previous ten years, to avoid literature too much dated. However, during the literature search, the candidates have found the necessity to add five years more because of the interesting insights of some articles, discovered fundamentals for the review.

Finally, also the abstract investigation has been included to have a more precise idea of the main theme in the analysis in the paper. Excluding, in conclusion, the ones which were far away from the focus of the Thesis.

The following *Figure 2.3* shows the steps of the inclusion/exclusion criteria used to obtain the number of papers useful for the literature review:

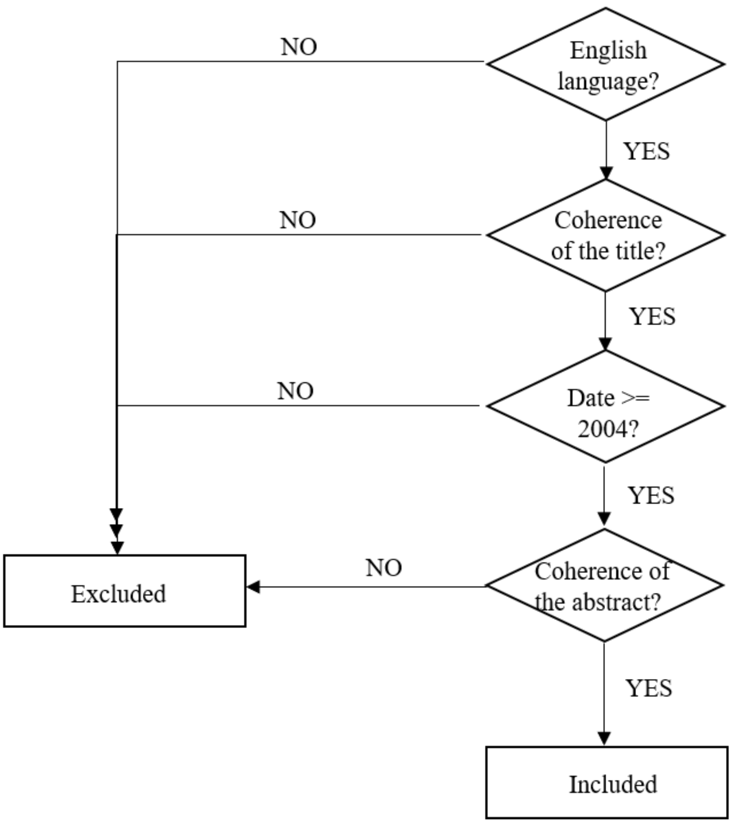

Figure 4 "Inclusion & Exclusion criteria"

2.7. Screening phase

After this first stage of selection of papers, the candidates ended up with a total of 153 papers classified by database, title, year, author/s, keywords, and abstract. The screening phase took place with the analysis of the papers and their focus on the Asset Management or the Risk management topics, respectively. In particular, from the 153 papers, 70 percent of them derive from the research topic of the "Risk management" and the 30 percent, corresponding to 46 papers, from the one of "Asset management."

Since the first selection included articles regarding at least one of the two fields of research, two columns have been included in the *Excel* File, one indicating the link to the Asset Management field and another one for the Risk Management one. At this point in the research, a more detailed analysis has been conducted on each of the 153 papers previously identified. The focus of this step was to verify the coherence of each paper concerning the two main topics of the research, Asset Management, and Risk Management. In particular, by firstly analyzing the documents related to the Risk Management topic, it was verified if also the Asset Management topic was explained within these papers. This first step was performed by searching inside the documents if there were keywords related to Asset Management. Examples of these keywords are "Medical Equipment Management", "Medical Device", "Clinical Technology". At this point, a quantitative approach was introduced by verifying that such keywords were present within the paper in a reasonably significant number. This number has been selected as 5. This step was followed by a qualitative approach, where it was verified that the keywords identified were used in a context useful to pursue the objective of the research. This analysis has been performed by both the candidates independently and, then together if further doubts emerged. If these contexts were considered relevant and consistent with the scope of the research, the papers were definitely included in the analysis. The same analysis has been performed on papers with Asset Management focus, by evidence, in this case, their connection with the Risk Management topic.

The last fundamental step of the screening phase was the check of the quality of the Journal. It was checked through the use of the *Journal Rank or SJR indicator Scimago*.

This has been possible only for the Scientific Journal sources; for the rest of the literature, books, conference papers and peer-reviewed papers, they have been included with a qualitative check. The following *Table 2.1* shows the ranking for the Journal whose quality has been possible to evaluate on the *Scimago* platform. The column "Quality" points out the H value, which is the "Journal's number of articles (h) that have received at least h citations over the whole period".

Source	**Quality (H index)**
International Journal of System Assurance Engineering and Management	*18*
Quality and Reliability Engineering International	*51*
International Journal for Quality in Health Care	*81*
Biomedical Instrumentation & Technology	*25*
International Conference on Control, Decision and Information Technologies (CoDIT)	
Journal of Clinical and Diagnostic Research	*28*
Safety Science	*90*
Industrial and Systems Engineering Research Conference	
Applied Ergonomics	*84*
Journal of Mechanical and Industrial Engineering	*13*
Applied Soft Computing Journal	*110*
American Journal of Applied Sciences	*38*
Archivio Istituzionale della Ricerca	
Annual International Conference of the IEEE Engineering in Medicine and Biology Society	
Journal of Hazardous Materials	*235*
Journal of Clinical Engineering	*11*
BMC Medical Informatics and Decision Making	*59*
Procedia Manufacturing	*18*
Mobile Networks and Applications	*79*
Journal of the Operational Research Society	*94*
Reliability Engineering and System Safety	*119*
International Journal of Production Economics	*155*
Journal of Medical System	*63*
Clinical Engineering Handbook	
Journal of Quality in Maintenance Engineering	*47*
Health Services Administration Commons	
Global Clinical engineering Journal	

International Journal of Medical Informatics	*93*
Congrès International de Génie Industriel	
8th International Symposium on Advanced Topics in Electrical Engineering (ATEE)	

Table 10 "Source Quality Index"

So, from the 33 percent of papers corresponding to 51 of the total number, 37 of them have been selected after this last step of journal quality check, excluding a total of 14. These are, among papers and book chapters, the ones used for the literature analysis. The resuming scheme is shown in *Figure 2.4*.

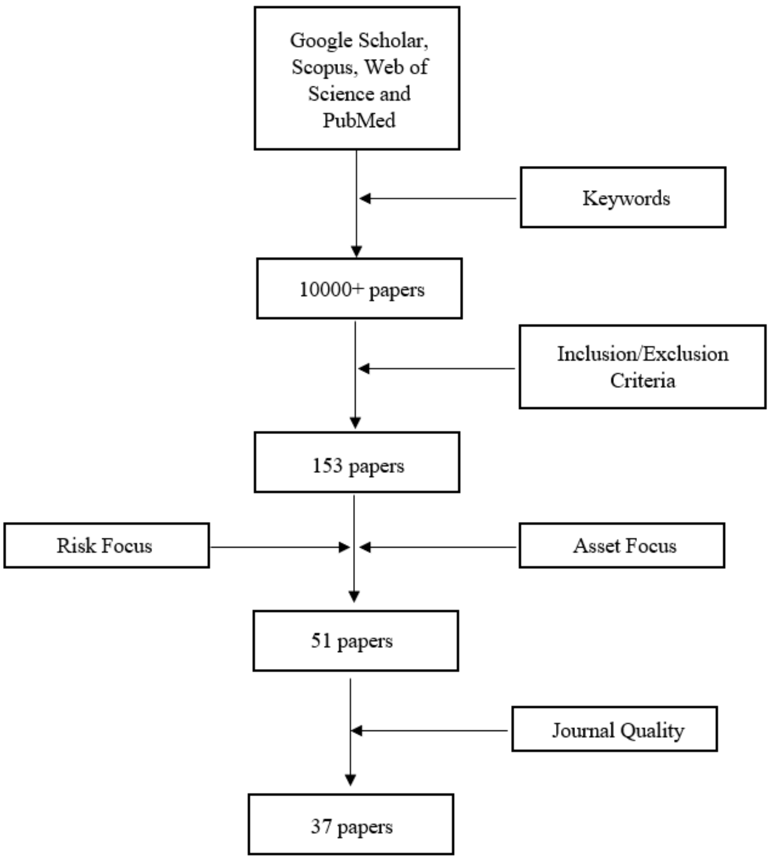

Figure 5 "Literature review process"

2.8.Systematic Literature Review results

It has been fundamental to understand the contributions coming from the 37 selected papers. As the first remarkable point, it was analyzed the database and the research engine, which has contributed the most to the literature review. As it is shown in *Chart 2.1*, *Scopus*, “the largest abstract and citation database of peer-reviewed literature,” contributed the most to this review, with the highest percentage of 73, providing to the candidates the highest amount of scientific papers and book’s chapters. The 22 percent of scientific papers have been found on *Google Scholar* and only two, one scientific and one conference papers, on *PubMed*.

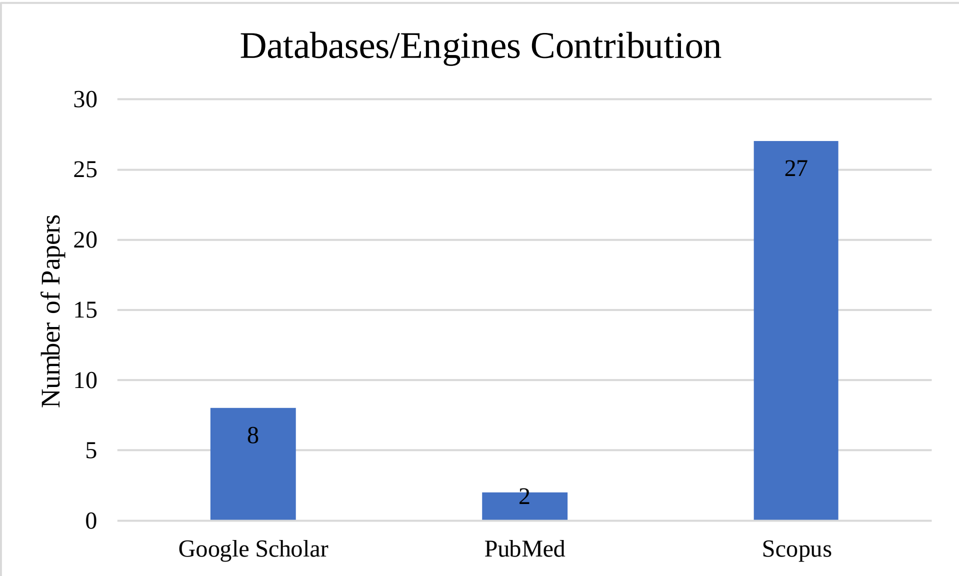

Chart 1 “Database Contribution”

Continuing with the analysis, the candidates wanted to understand also the keywords which contributed the most to the collection of papers, useful for the review. Investigating the Chart below, the combinations of keywords, which showed to be more comprehensive of the topic, have been “medical device* and asset* management” and “medical device* AND risk management”, with respectively 5 and 6 papers found. A good percentage of 11 each, thanks to the contribution of the combined keywords of “medical equipment AND asset* management”, “medical equipment AND risk management” and “risk-based maintenance AND healthcare”. A total of 3 articles were found with the use of “patient safety AND asset* management”. In addition, 20 percent of the articles were found through the utilization of the combinations “asset* management AND hospital”, “medical equipment AND risk-based maintenance”, “medical technology AND asset* management” and “risk management AND healthcare”. Finally, the last three papers with the remaining combinations. Specifically, the candidates decided to use many combinations to cover the broader range as possible of the review, in order to avoid the excluding of some articles.

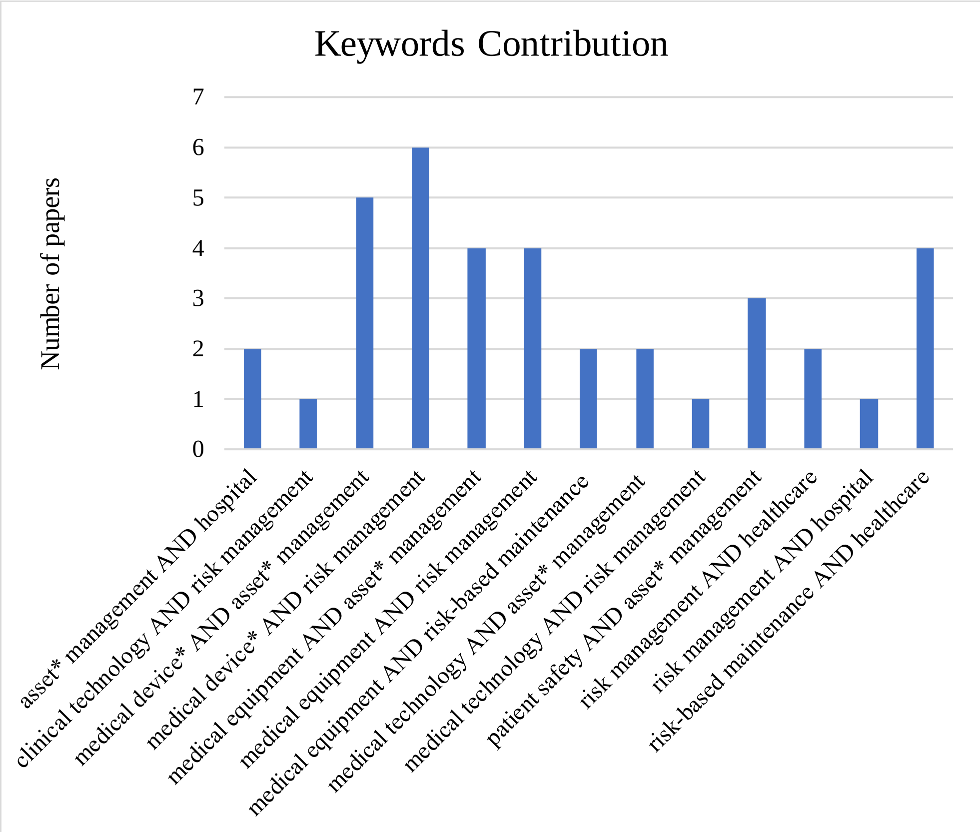

Chart 2 “Keywords Contribution”

The last aspect being analyzed has been one of the years of publication. As mentioned before, it was decided to consider literature with a date of publication of a maximum ten years ago, due to the fact that the candidates want to provide a more recent analysis of the discussed topic, avoiding too old concepts. However, it was realized the necessity to include five years more because of the interesting themes developed in older papers and book chapters. In general, as clearly visible in *Chart 2.3*, the papers are approximately spread out all over the years, apart from the 2012 and 2018, in which five papers each have been published in those years.

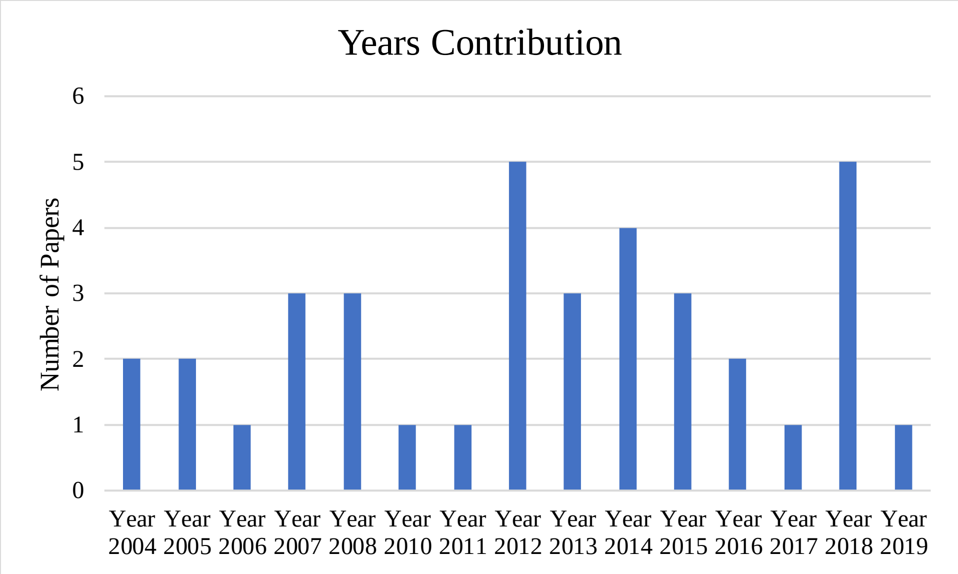

Chart 3 "Per-Year Contribution"

Here is reported the complete Table with all the 37 selected articles used for the Literature review, categorized into *"Succession Number, Website source, Title, Author, Year of publication, Source of the Journal/Book/Conference, Keywords used for the research"*:

No.	***Website***	***Title***	***Author***	***Year***	***Source***	***Keywords***
1	Scopus	*A risk-based maintenance approach for critical care medical devices: a case study application for a large hospital in a developing country*	Vala, S., Chemweno, P., Pintelon, L., & Muchiri, P.	2018	*International Journal of System Assurance Engineering and Management*	risk management AND hospital

2	Scopus	*Reliability analysis of maintenance data for complex medical devices*	Taghipour, S., Banjevic, D., & Jardine, A. K. S.	2011	*Quality and Reliability Engineering International*	medical device* AND asset* management
3	Scopus	*Failure mode and effects analysis applied to the maintenance and repair of anaesthetic equipment in an austere medical environment*	Rosen, M. A., Lee, B. H., Sampson, J. B., Koka, R., Chima, A. M., Ogbuagu, O. U., … Jackson, E. V.	2014	*International Journal for Quality in Health Care*	medical equipment AND risk management
4	Scopus	*Assessing Risk in the Kaiser Permanente Clinical Technology Program*	Davis-Smith, C. E., Painter, F. R., & Baretich, M. F.	2015	*Biomedical Instrumentation & Technology*	clinical technology AND risk management
5	Scopus	*An Integrated Nine-Step Approach to Managing Clinical Technology Risks*	Brady, T. C., & Panagiotopoulos, G.	2017	*Biomedical Instrumentation & Technology*	medical technology AND risk management
6	Scopus	*Medical Equipment Management Strategies*	Binseng Wang; Emanuel Furst; Ted Cohen; Ode R. Keil; Malcolm Ridgway; Robert Stiefel	2006	*Biomedical Instrumentation & Technology*	medical equipment AND asset* management
7	Scopus	*Medical Device Risk-Based Evaluation and Maintenance Using Fault Tree Analysis*	W. P. Rice	2007	*Biomedical Instrumentation & Technology*	medical device* AND risk management

8	Scopus	*Multicriteria decision making for Medical equipment maintenance: Insourcing, outsourcing and service contract*	M. Masmoudi, Z Houria, F. Masmoudi	2014	*Conference Paper*	medical equipment AND risk management
9	Google Scholar	*Factors Affecting Medical Equipment Maintenance Management: A systematic review*	R. Bahreini,L. Doshmangir, A. Imani	2018	*Journal of Clinical and Diagnostic Research*	medical equipment AND risk management
10	Google Scholar	*Human reliability assessment for medical devices based on failure mode*	Qing-Lian Lin, Duo-Jin Wang, Wen-Guang Lin, Hu-Chen Liu	2012	*Safety Science*	medical device* AND risk management
11	Google Scholar	*Medical devices Inspection and Maintenance*	A. Samira, A. Rahimi, D. Ait-kadi	2014	*Proceedings of the 2014 Industrial and Systems Engineering Research Conference*	medical device* AND risk management
12	Scopus	*A comprehensive fuzzy risk-based maintenance framework for prioritization of medical devices*	A. Jamshidia, S. A. Rahimia, D. Ait-kadia	2015	*Congrès Internationa l de Génie Industriel*	medical device* AND risk management
13	Scopus	*QFD: a methodologica l tool for integration of ergonomics at the design stage*	Jacques Marsot	2005	*Applied Ergonomics*	risk management AND healthcare

14	Google Scholar	*Building Medical Devices Maintenance System through Quality Function Deployment*	Adnan Al-Bashir, Mohammed Al-Rawashdeha, Rami Al-Hadithia, Ahmed Al- Ghandoora, Mahmoud Barghashb	2012	*Journal of Mechanical and Industrial Engineering*	medical device* AND asset* management
15	Google Scholar	*Fuzzy FMEA application to improve purchasing process in a public hospital*	Mesut Kumrua, Pınar Yıldız Kumru	2013	*Applied Soft Computing Journal*	asset* management AND hospital
16	Google Scholar	*A Hybrid Decision-Making Model for Maintenance Prioritization in Health Care Systems*	Hassana Mahfoud, Abdellah El Barkany and Ahmed El Biyaali	2016	*American Journal of Applied Sciences*	asset* management AND hospital
17	Google Scholar	*Comprehensive Frameworks for Decision-making support in Medical Equipment Management*	Neven Saleh Khalil Saleh	2014	*Archivio Istituzionale della Ricerca*	medical equipment AND asset* management
18	PubMed	*Medical Technology Management: From Planning to Application*	Y. David, E. G. Jahnke	2005	*Annual International Conference of the IEEE Engineering in Medicine and Biology Society*	medical technology AND asset* management
19	Scopus	*Elements of risk assessment in medical equipment*	Corciova, C., Andritoi, D., & Ciorap, R.	2013	*8th International Symposium on Advanced Topics in Electrical Engineering (ATEE)*	medical device* AND risk management

20	Scopus	*Risk-based maintenance—Techniques and applications*	Arunraj, N. S., & Maiti, J.	2007	*Journal of Hazardous Materials*	risk-based maintenance AND healthcare
21	Scopus	*Risk Classification of Medical Equipment in Alert States*	Florence, G., & Calil, S. J.	2007	*Journal of Clinical Engineering*	medical equipment AND risk management
22	Scopus	*A Fuzzy Logic Model for Medical Equipment Risk Classification*	Tawfik, B., Ouda, B. K., & Abd El Samad, Y. M.	2013	*Journal of Clinical Engineering*	medical equipment AND risk-based maintenance
23	Scopus	*An Estimate of Patient Incidents Caused by Medical Equipment Maintenance Omissions*	Wang, B., Rui, T., & Balar, S.	2013	*Biomedical Instrumentation & Technology*	medical equipment AND risk-based maintenance
24	Scopus	*A multicriteria decision making approach applied to improving maintenance policies in healthcare organizations*	Carnero, M. C., & Gómez, A.	2016	*BMC Medical Informatics and Decision Making*	risk-based maintenance AND healthcare
25	Scopus	*Failure Mode, Effects and Criticality Analysis (FMECA) for Medical Devices: Does Standardization Foster Improvements in the Practice?*	Onofrio R, Piccagli F, Segato F	2015	*Procedia Manufacturing*	medical device* AND asset* management

26	Scopus	*New Engineering Method for the Risk Assessment: Case Study Signal Jamming of the M-Health Networks*	Karoui K, Ftima F	2018	*Mobile Networks and Applications*	patient safety AND asset* management
27	Scopus	*Prioritization of medical equipment for maintenance decisions*	S Taghipour, D Banjevic and AKS Jardine	2010	*Journal of the Operational Research Society*	medical equipment AND asset* management
28	Scopus	*Risk assessment methodologies in maintenance decision making: A review of dependability modelling approaches*	Chemweno, Peter; Pintelon, Liliane; Nganga, Peter; Horenbeek, Adriaan Van	2018	*Reliability Engineering and System Safety*	risk-based maintenance AND healthcare
29	Scopus	*Development of a risk assessment selection methodology for asset maintenance decision making: An analytic network process (ANP) approach*	Chemweno, Peter; Pintelon, Liliane; Horenbeek, Adriaan Van; Muchiri, Peter	2015	*International Journal of Production Economics*	risk-based maintenance AND healthcare
30	Scopus	*An Intelligent Healthcare Management System: A New Approach in Work-order Prioritization for Medical Equipment*	Hamdi, Naser Oweis, Rami Zraiq, Hamzeh Abu Hamdi, Naser; Oweis, Rami; Zraiq, Hamzeh Abu; Sammour, Denis Abu	2012	*Journal of Medical System*	patient safety AND asset* management

		Maintenance Requests				
31	Scopus	*Maintenance and Repair of Medical Devices, Chapter 37*	Joseph F. Dyro	2004	*Clinical Engineering Handbook*	medical device* AND asset* management
32	PubMed	*Applying Risk Management Principles to Medical Devices Performance Assurance Program*	Gaamangwe T[1], Krivoy A, Kresta P.	2008	*Biomedical Instrumentation & Technology*	medical device* AND risk management
33	Scopus	*Equipment control and Asset Management, Chapter 35*	Joseph F. Dyro	2004	*Clinical Engineering Handbook*	patient safety AND asset* management
34	Scopus	*Influential factors on medical equipment maintenance management*	Bahreini, Rona; Doshmangir, Leila; Imani, Ali	2019	*Journal of Quality in Maintenance Engineering*	medical equipment AND asset* management
35	Scopus	*Healthcare Technology: A Strategic Approach to Medical Device Management*	Chad A. Kinley	2012	*Health Services Administration Commons*	medical device* AND asset* management
36	Scopus	*Planning Medical Technology Management in a Hospital*	Yadin David; Ernest Gus Jahnke	2018	Global Clinical Engineering Journal	medical technology AND asset* management

37	Google Scholar	*Human factors engineering in healthcare systems: The problem of human error and accident management*	P.C. Cacciabue, G. Vella	2008	International Journal of Medical Informatics	risk management AND healthcare

Table 11 "Selected literature Table"

3. LITERATURE DESCRIPTIVE ANALYSIS

The literature analysis represented the process where the candidates critically investigated the papers selected to pursue the objectives of the research. For this purpose, candidates analyzed the 37 articles previously mentioned as results of the literature research and screening process. The process has been conducted parallelly among papers coming from both the Risk Management and the Asset Management topic. The first scope of this phase was identifying the main research areas already existent in the literature to verify the relevance of the purpose of our study. Once relevant elements have been identified, they were used to explore the correlation between Asset Management and Risk Management in healthcare. The following paragraphs are organized as follows: firstly, a brief theoretical summary of the main Asset Management and Risk Management topics in healthcare is presented. Then, after presenting a general overview analysis of studies examined, it concentrates on the identification methods of those elements coming from such studies that will represent the basis for the core of the research.

3.1. Medical Equipment Management

This paragraph offers a theoretical overview of what concerns medical device management according to the most quoted documents on the healthcare field. It is structured in two main parts: in the first one, a comprehensive review of the main aspects of medical equipment management is offered, by also presenting different dimensions involved in developing an Asset Management strategy in healthcare. Then the typical medical equipment life cycle is described. Moving from theory each stage will be briefly discussed and analyzed to evidence how it can contribute to the study objective.

3.1.1. Medical Equipment Definition

Literature provides a wide range of definitions for Medical Equipment, differing slightly each other for the application context or the technical specifics. A more complete and detailed definition is that proposed in the World Health Organization publication *"Medical Equipment Maintenance Programme Overview"*, that states as follows:

"*Medical equipment*: medical devices requiring calibration, maintenance, repair, user training, and decommissioning − activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or another piece of medical equipment. Medical equipment excludes implantable, disposable, or single-use medical devices (WHO, 2011)."

In the same publication, different definitions are presented for terms too often abused for identifying medical equipment; however, they have a slightly different meaning. These terms and relative definitions are reported below since their specific use is frequent in the study.

"*Medical device*: An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological, or metabolic means (WHO, 2011)."

"*Health technology*: The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve quality of life. It is used interchangeably with health-care technology (WHO, 2011)."

Medical equipment is so ranked from smaller equipment to complex and big-size machines, as a result of different utilized technologies and intended applications. Their costs as is as their requirements can vary significantly according to these characteristics.

Therefore, it may be misleading considering medical equipment as a unicum because these differences drastically impact the way they are managed.

3.1.2. The Role of Medical Equipment

The increasing centrality of medical technology in delivering healthcare services and in achieving operational and financial objectives constraints healthcare organizations to make the management of its medical equipment more effective and efficient as possible. Medical technology represents one of the most critical segments of the healthcare system. It contributes to the advancement of healthcare in many ways (Dyro, 2004). This contribution is essential for at least five primary reasons: it allows to increase diagnostic, therapeutic and operational efficiency; it improves the health system's cost-effectiveness; it reduces risk exposure and mitigate errors; it attracts high-quality experts; it expands the service area or to better serve the beneficiary base. Therefore, medical equipment plays a crucial role in the healthcare systems and considering the rapid and continuous transformation involving this sector, it is estimated that such importance will further grow over the next years. As the deployment of medical equipment continuously evolves, its impact on hospital operations and the consumption rate of its financial resources increase (David and Consultants, 2018). Healthcare organizations are required to manage their fixed assets better than ever before, and their ability to manage and forecast this continuous evolution and its subsequent consequences has become a significant component in all healthcare decisions.

3.1.3. Medical Equipment Management Strategies

In this scenario, there is a need to understand the potential of technology and the importance of its associated management methodology and tools adequately (Dyro, 2004). Hospitals' rising expenditures over the last decade already demonstrate their belief in the importance and potential benefits from the deployment and efficient management of technology.

At the same time, a wide range of goals and objectives that range from administrative, clinical, financial, and regulatory parameters, must be achieved by healthcare organizations and this integration directly impacts how medical equipment is managed. It interacts with how medical tools are selected, installed, trained for, integrated, safely used, repaired and disposed of by influencing their all life cycle. It is, therefore, essential to the existence of an integrated program able to manage medical equipment effectively and aligned with the global organization strategy. To objectively manage their investment, hospitals are developing medical technology management programs that need pertinent information and planning methodology for integrating new equipment into existing operations as well as for optimizing costs of ownership of all equipment (David and Jahnke, 2006). Successful management methodologies and tools cannot disregard elements able to:

- Provide a guiding strategy for the allocation of limited resources;
- Identify and evaluates technological opportunities and threats;
- Maximize the value created by resources invested in medical technology;
- Meet or exceed standards of care;
- Reduce operating costs;
- Reduce risk exposure;
- Create a better care environment.

Only by applying these methodologies and practices a system can optimize the development of medical technology and the facilities that house it. It is thus evident that these management tools have a direct impact on patient outcomes, hospital operations, and financial efficiency.

However, due to the high complexity where healthcare operates, it is almost impossible to present a base management plan Framework able to fit all the organizations. Each one should develop its unique plan able to integrate its different departments, maximize its resources and achieve its objectives. Besides, although experts agreed on the evidence of how such a unique management plan would be ineffective and too costly and time-consuming suitable, it still lacks an integrated Framework able to describe at least in broad terms how such a Framework may be. Whereas both knowledge and practice patterns of management, in general, are well organized in today's literature, the management of the healthcare delivery system and that of medical technology in the clinical environment is more fragmented and has not yet reached that level of integration (David and Jahnke, 2006).

Although it is complicated to provide a comprehensive Framework, Asset Management literature offers a relevant theoretical background that can be exported to the healthcare field for developing a medical equipment management plan. ISO 55000 - “Asset Management Overview, principles and terminology” - represents the ideal support to start covering this gap in the literature, by evidencing Asset Management requirements that must also be respected in developing a medical technology management plan. These fundamental requirements are:

- *Context of the organization*: in developing and organizing its Asset Management system, an organization should take into account its internal and external context (ISO, 2014). The latter includes the social, cultural, economic and physical context, while the first one refers to the organizational culture and environment;
- *Planning*: principles and activities through which an organization should pursue its objectives should be set out in a Strategic Asset Management Plan (SAMP). In the specific case of the Medical Equipment Management Plan (MEMP). It should represent the guide to achieve asset management objectives by defining the set of activities to be undertaken on assets;
- *Support*: to be implemented, each Asset Management plan requires support and collaboration among different departments of an organization. The high complexity and variety of healthcare structures emphasize this requirement;
- *Operation*: the Asset Management plan should be able to direct, implement, and control Asset Management activities, including those that have been outsourced (ISO, 2014);
- *Performance Evaluation*: the organization should evaluate the performance of its assets. Performance measures can be direct or indirect, financial, or non-financial

(ISO, 2014). Performances should be assessed concerning objectives, by evidencing any opportunities or failures arisen;

- *Improvement*: an Asset Management plan should be always ready to catch any opportunities for development, by dynamically changing activities and objectives;

- *Leadership*: top management, as well as leaders at all levels, should be involved in the planning, implementation, and development of an Asset Management plan. They have a double responsibility in terms of ensuring technical outstanding and knowledge and contributing to creating a motivated and positive working environment.

Regarding this last point, literature often focuses its attention on the role of the Clinical Engineer. The American College of Clinical Engineering (ACCE) provides a profile of the profession, defined as ‘a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology”. The clinical engineer is a role shared between planning for new equipment and optimizing the utilization of the existing inventory. The clinical engineer must be thoroughly familiar with the procurement phase of medical equipment and with the synthesizing of clinical needs into a bid request document (David and Jahnke, 2006). This further includes user training, vendor negotiation, installation preparation, and bid specification. At the same time, the role is familiar with tools and methods for assuring that medical equipment performance and risks are controlled, reported, and managed. Together these technical skills clinical engineers should provide cultural leadership needed to maintain the process in a participatory model. The ability to manage the responsibility that ranges from a strategic technology planning to the planning of its replacement is thus a prerogative of a clinical engineer.

3.1.4. Medical Equipment Management Standards

The past decade has shown a trend toward increased legislation in support of more regulations in healthcare. These and other pressures require technology managers to be familiar with the regulations and to be able to manage a program that demonstrates compliance with these requirements throughout the life cycle of the technology (Dyro, 2004).

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) represents the most influent and recognized organization for International healthcare standards. In its directive in 2002, it firstly requires hospitals to "establish and maintain an equipment management program to promote the safe and effective use of equipment" (JCAHO, 2002).

A literature analysis also, in this case, allowed to explore the principles that are used to determine what medical devices should be included in the equipment control and Asset Management program. Before 1989 JCAHO standards required hospitals to cover all medical devices in the equipment management program. Since that time, JCAHO standards allowed hospitals more flexibility in accepting or excluding some medical devices in their MEMP to focus resources where more needed. Hospitals are left to establish independently risk criteria for identifying, evaluating, and taking inventory of equipment to be included in the management program. Other influent recommendations published by recognized specialist organizations - e.g., Emergency Care Research Institute (ECRI), the Association for the Advancement of Medical Instrumentation (AAMI), and the American Society of Hospital Engineering (ASHE) - can be taken as reference for structuring a medical equipment management program.

3.1.5. Medical Equipment Lifecycle

After presenting a general overview of medical equipment management theory, it seems pertinent to describe the stages composing each medical equipment lifecycle, in order to pursue the objective of this study prefixed. An effective equipment management policy cannot disregard any lifecycle phase of an asset; rather, it should present an integrated approachable to consider each stage as impactful on developing a structured management program. For a comprehensive and more effective way to manage medical equipment, it is useful the system considers the management of the different aspects within the life cycle of a medical device. The typical life cycle of a medical device has the stages shown in the Figure below:

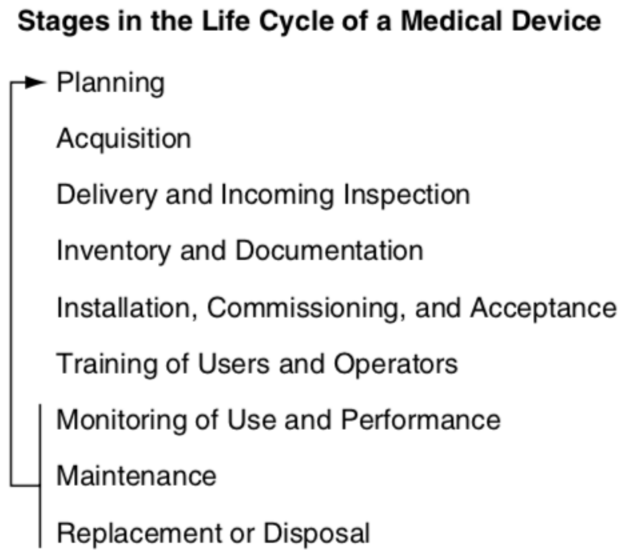

Figure 6 "Essential elements for life-cycle management of medical devices". Clinical Engineering Handbook

In this study, researchers commonly refer to medical equipment Middle of Life (MOL) or operative phase considering all those phases included between the Installation and Maintenance stages. The operative phase of medical equipment is considered to be composed by Installation, User Training, Monitoring of Use and Performance and Maintenance stages.

Now candidates are going to describe more in detail each stage being part of a medical equipment lifecycle.

1) *Planning*

The strategic planning process is the road map for the introduction and development of technology and services, and their related policies into the core business of the hospital to maximize the value outputs of the program (Dyro, 2004). It, therefore, represents the fundamental guideline identifying a shared vision for timely response to structural needs. The following elements are essential and must be present in the planning process to ensure the optimal allocation of funds and the achievement of organizational objectives:

- Creation of a plan to support the facility's vision and communicate its process to staff;
- Periodic review of the alignment between the vision and strategy;
- Identification of areas needed for changes;
- Delineation of clinical goals for road map planning, interaction with operations and capital budgeting processes, acquisition, equipment asset management, and monitoring and evaluation;
- Inclusion of details of specific expectations from information technology, medical technology, and building spaces;
- Determination of priorities and creation of a plan to meet the objectives.

In developing all these elements, a planning process must take into account clinical goals as well as healthcare trends, demographic and market share data, organizational strengths and weaknesses, by also conducting audits of the existing technology base, ensuring compliance with utilization standards, and continuously reviewing technological trends and their operational impact. At the same time, internal working conditions must be evaluated. In this way, the level of qualification of users and interdepartmental support should be adequate to the approved plan.

2) *Acquisition*

The acquisition process subdivided into evaluation and procurement phases. The first one considers some factors such as safety, performance, maintenance, and manufacturer, which should be reviewed to fulfill the requirements. It requires a high degree of collaboration with manufacturers and vendors' databases and information. In the procurement process, conditions can be included in the purchase order to specify that the supplier must apply operating and service manuals, operation and service training, and essential spare part. Other special requirements also can be specified here such as payment (Saleh, 2014). Contract negotiation becomes an essential factor in order to obtain the most favorable conditions as possible.

3) *Incoming Inspection*

Incoming equipment should be carefully checked for possible shipment damages, compliance with specifications in the purchase order, and delivery of accessories, spare parts, and operating and services manuals (Dyro, 2004). The incoming inspection phase is performed on both trial/evaluation products to decide among competitive products and on purchased products to evaluate their useful conformity with operational requirements. Once we overcome the inspection, the inventory stages take place.

4) Inventory and Documentation

The inventory phase refers to a complicated and wide range of situations that involves medical equipment management. Firstly, it considers the physical inventory of equipment such as machineries, spare parts or maintenance tools. On the other hand, documentation, and information storing represent the core activities of a good performed medical equipment inventory. Important parameters to be tracked in association with each device are the model, serial number, warranty expiration date, risk of the device, type of device, ownership information, maintenance scheduling information, and purchase information (Saleh, 2014).

5) Installation

The installation refers to all those activities performed on the workspace to make it available and utilizable. In particular, it takes place when new medical equipment is installed on the care site. Installation and commissioning can be carried out by in-house technical staff if they are familiar with a given item of equipment and represent an excellent way to become familiar and gain experience with the new operative tools (Dyro, 2004).

6) Training of Users

Training of users and operators is essential in ensuring the safety and effectiveness of medical devices. Users' errors still represent the leading cause of medical equipment accidents and risk for patient safety. Incorrect use of equipment may also have an impact on maintenance and repair activities. Training of users should be monitored from the vendor to ensure the maximum skill level that is required for operating a device. The training should include all user's staff as needed, such as clinical staff and technical staff (Saleh, 2014).

7) Monitoring of Use and Performance

To perform effective and efficient Asset Management and Risk Management program, monitoring of use and performance, it is probably the most crucial phase of all medical equipment lifecycles. It is characterized by scheduled inspections and parameters testing, conducted with defined frequency and methodologies. These analyses are performed mainly on the operating phase of the equipment but have a direct impact on all the decision-making processes. Therefore, information and data gathered at this stage influence the overall medical equipment management process. The types of metrics evaluated depend on the function and the characteristics of the technology.

8) Maintenance

Equipment maintenance involves all activities relating to providing an adequate level of service and limiting downtime of medical devices. Maintenance and service activity is required in order to ensure the devices are kept functioning within limits imposed by the test criteria and to return devices to the required level of working after breakage or other failures (Saleh, 2014). For this reason, the first goal of any maintenance activity is to eliminate, if possible, any future failures or reduce the need for repairs. Traditionally, equipment maintenance is categorized as Preventive Maintenance (PM) and Corrective Maintenance (CM). Preventive maintenance procedures are actions that are necessary or desirable in order to extend the operational intervals between failures to extend the life of equipment or to detect and correct problems that are not apparent to the user. Corrective maintenance procedures are any services that involve medical equipment repair (Saleh, 2014).

9) Replacement or Disposal

All equipment reaches the point in its life where the cost-benefit ratio goes to the negative because of decreased reliability, increased downtime, safety issues, compromised care, increased operating costs, changing regulations, or simply obsolescence (Saleh, 2014). Disposal of equipment must follow safety procedures (Dyro, 2004). The choose for disposing of machinery must always be taken after a mix of economic, operative, and safety evaluation.

3.2. Risk Management papers analysis

This other paragraph proposes a theoretical overview of what concerns Risk Management in the healthcare field. It incorporates a general overview of Risk Management in this type of organization and its underlying process stages and techniques, to give to the reader a broader spectrum of the analysis. It is organized in subparagraphs, the first one explores the theme in healthcare organizations nowadays, the main trends and findings, the second one offers the concept of Risk Management, in particular its process, continuing with the third one, which deals with the SHELL model and finally, presenting the main risk techniques used in the field, thanks to the analysis of the literature.

3.2.1. Risk Management in Healthcare Organizations

The healthcare systems have always been involved in different changes, varying from technological to normative ones, the reason why it happens is because of a continuous request of efficiency and efficacy in processes and outputs of them (Cagliano et al., 2011). The complexity of these organizations has risen through the years, and nowadays, they are complex dynamic systems that focus on improving the quality of care since an error or mistake in the specific field is not tolerated. In fact, because of the potential risks, the area is hugely regulated by agencies that assure standards of quality, and the evaluation of services' performances is becoming even more important through the lenses of risk (Ahmed et al., 2013). In addition to this, The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and The World Health Organization (WHO), which are only two of the international healthcare organizations, have developed and started to adopt the concept of Clinical Governance (Cagliano et al., 2011). This last one aims to ensure that healthcare organizations mature methods of the way of working and culture that guarantee the quality of care, changing the way people work, from communication, teamwork, and leadership to the clinical effectiveness and Risk Management (Tait, 2004). To confirm the importance of Risk Management in healthcare, Kuhn and Youngberg (2002) state that it merged in the 1970s as an answer to the malpractice crisis in the US and managing risks that contributed to the patient harms, it was the key to overcome that crisis. Indeed, patient safety, as the avoidance, improvement, and prevention of injury events on patients from the process of healthcare, is the main objective of the intended Risk Management.

3.2.2. Risk Management process

Continuing with the analysis of the Risk Management branch of the thesis, the ISO definition has been provided in the introductory chapter. Its process always refers to the ISO 31000, and the Figure is provided below:

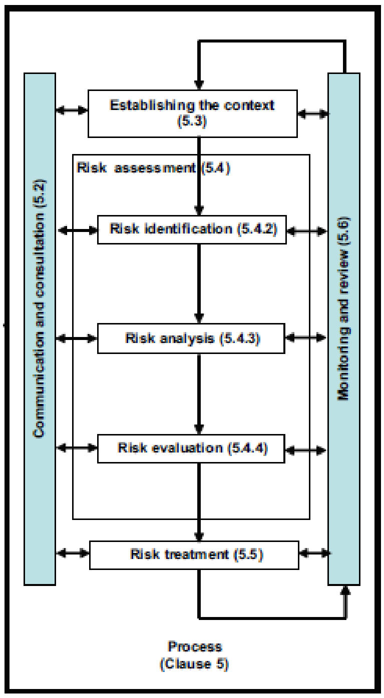

Figure 7 "Risk Management process". ISO 31000

Investigating the process, as stated in the ISO 31000, it should be an integral part of the management of an organization, with strong roots in its culture and operations based on its business processes.

It is structured in establishing the context, then in assessing the risk, which is subsequently divided into identification, analysis, and evaluation of risk, and finally, in treating it. Everything must be linked thanks to secure communication and consultation, and continuous monitoring and review of each phase of the process. Proceeding with its illustration, each stage of the Risk Management process will be described:

1) *Communication and consultation*

With this first phase, it is intended the communication and consultation on each step with the external and internal stakeholders. To accomplish this stage, plans should be developed both of them, treating the risk itself, its causes and consequences, and the measures are taken. This should be done to inform each stakeholder on the decisions taken and the reasons why they have been taken.

2) *Establishing the context*

This stage stands for defining the objectives, the internal and external context, and in particular, the risk criteria and the scope for the risk management process. In the definition of the external context, the social, cultural, political, economic, technological are only some of the examples of environments that must be included in it. On the other hand, with the definition of the internal context, the organization must define the internal boundaries in which it seeks to achieve its objectives, spacing from the governance and organizational structure to the culture and internal capabilities. Then comes the establishment of the following risk management process, where it should be addressed, to which activities of the organization, the resources, responsibilities, and authorities accomplish the process. Finally, for this stage, the last issue is the definition of the criteria used to evaluate the risk, which must be consistent and always reviewed.

3) *Risk Assessment*

3.1) Risk Identification

Risk identification is the identification of the potential sources of risk, areas where it can impact, events that could arise, causes, and consequences. The risk identification phase should be implemented through the use of tools and techniques.

3.2) Risk Analysis

The analysis stage means understanding the risk and should be used as an input for the following phases. Causes and sources should be analyzed, and their positive or negative consequences followed, but also the likelihood of occurrence and the level of impact, the severity with which it can occur.

3.3) Risk Evaluation

The result of the precedent stage should be used in the assessment and the formulation of decisions, decisions made on the treatment, and priority of risks. These decisions are based on the criteria previously established.

4) *Implementation*

The treatment phase is applied to select the options for working on risks. The process is assessing the treatment, understanding the tolerability of the level of risk, if too high, considering another solution, and finally, evaluating the effectiveness of the action.

5) *Monitoring and Review*

The actions that must be executed in parallel with the others are the ones of monitoring and analysis, to control the process itself, obtain further information for present and future actions, learn lessons, perceive changes and primarily identify emerging risks.

(ISO 31000, 2009)

3.2.3. SHELL Model

An essential pre-requisite for the implementation of a meaningful Risk Management approach is the availability of models and taxonomies for the collection of data and the description of environments. In the specific case, the model used for the environment description is the SHELL one. For what concerns the Taxonomy, a paragraph in the next sessions will be dedicated to this aspect.

SHELL model is a widely used and standard model for the representation of working contexts and its principal actors. In particular, in the healthcare field, it is gaining attention, even if originally developed in the aviation domain. The model describes each component of the working systems and their interactions. Its architecture puts the Liveware figure at the center of the analysis, as our analysis wants to do, putting the patient and its safety at the center of the research. *Figure 3.3* shows the architecture:

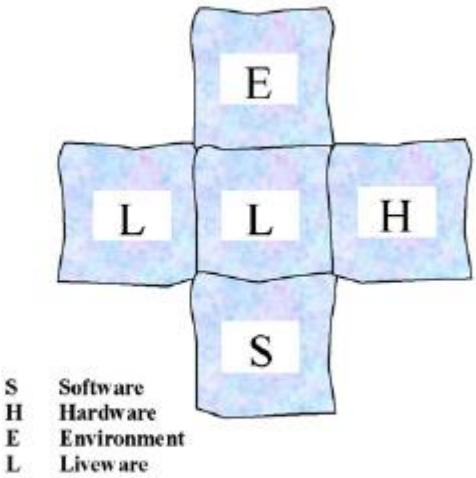

Figure 8 "SHELL Architecture". Human factors engineering in healthcare systems: The problem of human error and accident management

1) *Liveware (L)* who is the human being who operates in various working contexts;
2) *Environment (E)* which is the social and physical working domain where liveware operate and operations are carried out, in particular, as mentioned it stands for the physical context where people work and for the social one, meaning all the interactions and interpersonal situations that people have to deal with;
3) *Hardware (H)* intended as machinery, components, and instruments, the medical equipment that people use to carry out operations;
4) *Software (S)* expressed as norms and rules, generally all the procedures used to regulate the people's behaviors.

The model does not only concentrate the analysis on each actor but also on their interactions, in the specific case, on the Liveware-Environment, Liveware-Hardware, Liveware-Software, and Liveware-Liveware ones. The human being, in fact, in the working context, has to deal with other human beings; he has to utilize tools and machinery being affected by social and physical situations and, being regulated by specific training and regulations for his daily duties.

It is clear the applicability of the SHELL model in the medical environment, as similar requirements exist. For this reason and for the centrality of the liveware figure, while analyzing the literature, it has been dutiful to include the model in the presented analysis. Its importance will be cleared with the proceeding of the Thesis (Cacciabue and Vella, 2010).

3.2.4. Risk Management techniques

As disclosed in the introductory chapter, in the last ten years, industrial Risk Management has been applied and adapted more and more in clinical contexts. Nowadays, several techniques of Risk Management are used in healthcare settings to control risky and adverse events and to respond to international standards (Onofrio et al., 2015).

A parallel analysis has been conducted on the primary techniques used in the specific field. As a result of the investigation, prospective analysis such as the Failure Mode and Effect Analysis (FMEA) and its derivative techniques, Failure Mode, Effects and Criticality Analysis (FMECA) and Failure Mode, Mechanisms and Effects Analysis (FMMEA), are the most widespread techniques in the healthcare industry. Moreover, also retrospective analysis, such as Root Cause Analysis and Ishikawa diagram ones are applied, but with a lower spread in the context. FMEA's aim is to identify potential sources of risks related to products or processes and their consequences. It is a bottom-up technique whose main measures are the Severity (S), Occurrence (O) and Detectability (D). The severity is the consequence of the failure, the occurrence, the frequency of that failure and the detection is the possibility to detect the specific failure mode (Franklin et al., 2012). In the analyzed case, it is a helping instrument for manufactures to prevent errors in design and accidents, but also for clinical engineers to detect changes in the use of the device and consequently to take measures to avoid failures. In fact, it is performed at any stage of an asset's lifecycle. Even if widely used, it has one primary fault which is dealing with the subjectivity derived from the consultancy of a multidisciplinary Risk Management team. On the other hand, the main advantage is the possibility to mitigate and prevent failures on medical devices that can impact both patients and healthcare providers (Aguas and Sobral, 2019).

In addition to this technique of Risk Management, the fuzzy logic model could be another answer to the identification of equipment risk. Originally it was a tool used to support human decisions in sectors such as the automatic control or time-series prediction ones; however, as for the FMEA, this technique is progressively being used in the healthcare context. The logic behind is to convert the input into a linguistic variable, then the inference engine, which together with the set of rules, fuzzifier, and defuzzifier compose the system, searches for information and relationships and delivers answers in the way a human being would do. Finally, with the defuzzification, the output of the engine is converted back into a crisp state. The main advantage of the model is the possibility to have variables that are not fixed but can vary during the time, updating the risk scores for the same device continuously. In this way, risk scores are not more static but dynamic, and the MEMP can be improved over time (Tawfik et al., 2013).

One last remarkable technique, which has been mentioned in some of the papers analyzed, is the Analytic Hierarchy Process (AHP). The proposed methodology is utilized in order to prioritize the criticality of an asset, helping in the decision-making processes. Its development is to define the problem and to mature a hierarchy; in fact, the problem must be broken down into three levels, the goal, the criteria to consider and the possible alternatives. Then, pairwise comparison matrices are computed, and each element in an upper level is used to compare the elements in the level immediately below concerning it. Consequently, the priorities obtained from the comparisons are used to weigh the priorities in the level immediately below.
Moreover, for each element in the level below it is added its weighted values and it is obtained its overall or global priority. Continuing this process of weighing and adding, the final priorities of the alternatives at the bottom-most level will be accomplished. The final steps are the ranking of the options, the computing of a sensitivity analysis to check the robustness, and then to choose (Salem and Elwakil, 2018). The use of the AHP makes excellent sense when it is dealing with multiple criteria used to prioritize medical equipment and to support the decision-making process in managing the critical devices. In particular, the AHP methodology will be retaken into account in the next chapters as a pivotal instrument for the application of the following presented analysis.

4. FACTOR ANALYSIS FRAMEWORK

In this paragraph, candidates will present more deeply the study performed. The analysis started with the factors' identification process and their subsequent classification in different subclasses according to their nature and analysis requirements. As mentioned in the previous chapter, candidates consider as factors all those elements able to demonstrate a direct impact on medical devices' performance and functioning from their installation to the replacement phase.

4.1. Factors Definition

Analyzing the whole set of researches collected, one of the first results candidates reached was to evidence how almost the overall documents obtained at the end of the screening process were related to the Middle Of Life (MOL) or the operative phase of the assets. This trend is partially confirmed also by considering the whole *Excel* database before the screening phase. Examining all the documents coming from the Asset Management research field, more than 80% have a focus on the MOL phase of the asset. Of course, this portion includes a wide range of researchers, many of whom have been then cataloged as not useful for our analysis.

Nevertheless, a first conclusion can be made about the operating phase as the stage of the equipment lifecycle that captures the highest interest from researchers. The same trend is confirmed by papers coming from Risk Management research. Risk management techniques and prevention analysis focus their attention on the operative phase of the medical equipment. For this reason, candidates decided to focus their research on the operative phase of the equipment life cycle.

Moving from these initial considerations, candidates decided to focus their analysis on factors that have a powerful influence on the medical equipment MOL. In doing so, it was necessary to integrate the contributions given to the research by papers that had a focus on both the Asset Management and Risk Management topic. Candidates analyzed documents that resulted from the literature review to find factors considered impactful for the medical technology operating phase. Factors can impact on several ways the MOL of medical equipment: by reducing its performance, by compromising its maintenance program, or by decreasing its useful life cycle. All these factors have a substantial impact on the way a healthcare entity can use its medical technology and rely on it. As an immediate effect, an unsafe or underperforming utilization of this equipment can represent a direct threat to patient safety and workers' security. Factors affecting the MOL of medical equipment have a direct impact on patient safety and healthcare organizations' ways to dispense their services.

This research has individuated and extracted all the elements and factors contributing to the operative and maintenance phases of medical equipment and has created a comprehensive view.

4.2. Factors Identification

The identification process for factors extraction was performed on studies coming from both Risk management and Asset Management perspective. In particular, among the 37 studies that emerged from the literature review, only 26 were analyzed to directly extrapolate such factors, equally distributed among Risk Management and Asset Management Studies (13 types of research each). From this analysis, candidates identified 287 different elements. Among these 287 factors, 59% comes from Asset Management papers while the remaining 41% from studies with a focus on Risk Management. To better clarify how these factors have been collected, *Appendix 1* is attached to this study. Each of the 26 studies analyzed is classified, as well as the research field (Risk/Asset) it comes from. Then for each paper, the relevant factors that emerged from its analysis are explicitly reported and cataloged according to the medical equipment life cycle stage they belong to.

4.3. Taxonomy

A large number of factors identified in the previous analysis and the full range they cover in the medical equipment life cycle suggested candidates develop a specific Taxonomy able to offer a more integrated and precise overview of the whole spectrum of factors analyzed. The development of such Taxonomy helped the researchers to comprehend the nature of each element better, to classify them with higher precision, and to quickly decide on which of them focus in the further steps of the analysis. The Taxonomy creation process follows a precise approach defined at the beginning of the investigation. In the beginning, all the factors coming from both the Asset Management and Risk Management areas have been listed together. Then a short description has been associated with each factor to explain and clarify its main characteristics and the context it came from. After completing this step, candidates grouped all factors having similar names, by creating new integrated factors and renaming them. Since the number of factors was still elevated, and there was also margin for further reclassification; therefore, candidates proceeded to join together all those elements having a similar description or used in a similar context inside reference papers. At the end of the process, a short and definitive definition has been associated with each factor, to facilitate its comprehension. To assure total transparency to the process, the reference paper number from which each factor comes is reported as well as the way each factor has been grouped over the process. This further classification allows reducing the total number of factors by 56%, from the original 287 to 127, streamlining the whole process and creating a more detailed and focused perspective. The results of the previous Taxonomy process are exhaustively presented in the table at the end of the following paragraph. The original factors grouped together are instead listed in *Appendix 2*, making possible to trace from which study they come from as well and their grouping.

From a preliminary analysis of the 127 factors identified, it turned out how 77 of these factors were mentioned in both studies of Asset Management and Risk Management, representing 61% of the total. In the remaining part, 23 factors emerged only from Asset Management related studies, while 27 from Risk Management studies, respectively the 18% and 21% of the total. The following Chart reports these preliminary results.

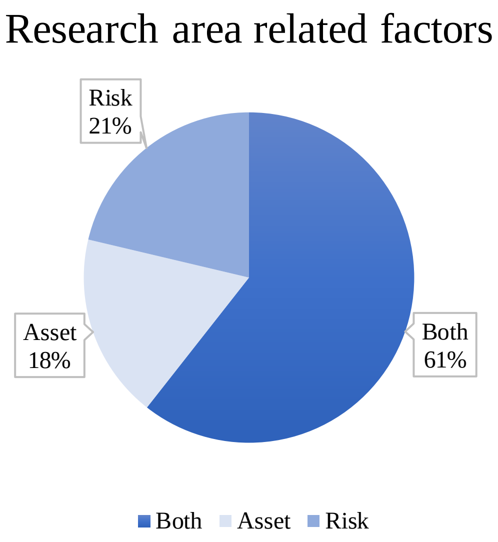

Chart 4 "Research Area related factors"

4.4. Decisional and Performance Factors

Once developed the Taxonomy, factors have been divided into two main categories according to their nature and capability to influence the decisional process:

- Performance Factors;
- Decisional Factors;

As Performance Factors, we refer to all those elements that are possible to be measured accurately at a specific phase of the medical equipment life cycle. These factors express in a quantitative way how a medical device is performing about a particular parameter, making previsions about future scenarios, and receive feedback from past situations. These numerical factors can be the result of a specific analysis or study performed on the medical equipment or the simple result of a routine test. In each case, they represent the analytical basis for moving forward to any organizational decisions and planning. Therefore, it is crucial to evidence how the difference between these two groups of factors is only superficial since they are directly connected. No decision can be undertaken without a quantitative basis. For this reason, each performance factor can also be considered a decisional one. However, for the objective that this paper wants to pursue, this structural approach is respected over all the studies.

Oppositely, Decisional Factors are those indicators that do not present a quantitative or analytical approach, or maybe it is not their primary focus. These elements focus more on the strategic and organizational aspects of a situation, representing the qualitative bottom for successive analysis. Their importance relies on the subjective interpretation of conditions and data, and the consequences that their implementation can have on the whole organization. Examples of this kind of factor can be budget decisions, maintenance strategies, or acquisition/dismissal plans. For their nature, these indicators occupy a central role in the decision-making process of any organization. While all the performance factors are also decisional factors at the same time, decisional factors are not performance factors too. They represent the result of previous strategic analysis and not the numerical result of a specific measuring. However, due to the complexity and vastity of the studies examined, it has not been possible for some factors to be categorized in just one group. For this reason, during the research, candidates decided to add a further class for classifying factors. In this third group, all those decisional factors that also presented a performance verification and quantitative nature have been included.
According to these definitions, all the factors identified have been divided into the mentioned categories.
The following *Chart 4.2* shows the distribution of these three categories of factors.

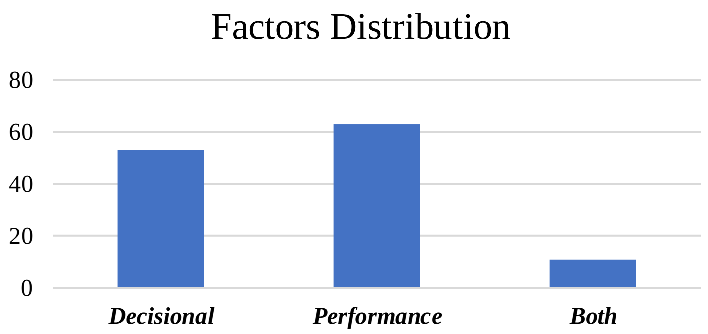

Chart 5 "Factors Distribution"

Performance factors represent the majority, even if there is not a relevant difference with decisional ones. Low mentioned are instead those decisional factors that also present a performance nature.

The following *Table 4.1* summarizes the data mentioned in the previous paragraphs, including Factors' Legend, Names, Description, Category, and Reference Papers.

TAXONOMY

NUMBER	***NAME***	***DESCRIPTION***	***PERFORMANCE/ DECISIONAL***	***REFERENCE PAPER***
1	Availability of tools	Number of identic tools and ME available	Performance	2,4,15,18, 10,16,19,22
2	Budget management	Set of procedures, strategies and activities to manage financial resources in a healthcare organization	Decisional	4,5,9,13, 1,16,19,21
3	Similar tools analysis	Identification of potential similar tools and ME equivalent to those utilized	Performance	3,4,5, 16
4	Utilization rate	Percentage of use of a ME with respect to its total availability	Performance	2,4,6,8,9,15,18, 1,10,22
5	Management of spare parts	Set of procedures, strategies and activities to manage spare parts in a healthcare organization	Decisional	4,5,6,8,18, 16,19,25
6	Equipment deterioration	Level of deterioration of a ME with respect to predetermined standards	Performance	4,18, 10,24
7	Maintenance planning	Development of an integrated plan to coordinate maintenance activities in a healthcare organization	Decisional	4,5,11,18, 7,16,22,26
8	Level of personnel	Degree of education of hospital personnel with respect to predetermined standards	Performance	8,17, 16,22,23
9	Function	Role of a specific ME in a process	Performance	2,4,11,15,17,18, 1,10,22,24,26
10	Hazard analysis	Development of an integrated study able to predict and estimate potential hazards within the healthcare organization	Decisional	2,3,6,13,15, 16,21,22,24
11	Equipment history	Development of an integrated study able to trace and verify previous failures and repairs on a specific ME	Performance	2,6,8,11,14, 10,12,16,22,26
12	Downtime	Amount of time a specific ME is not available	Performance	2,4,5,6,17,18, 10,16
13	Environment	Characteristics of the working context where personnel operate with respect to specific parameters	Decisional	2,15,17, 12,19,24
14	Electrical safety testing and protection	Level of prevention and safety in the use of electrical equipment and tools	Performance	8,18, 10,16,26
15	Medical equipment upgrade	Level of upgrade of ME and potential opportunities for upgrading	Both	9,17,18, 26
16	Availability of backup	Number of personnel instructed, and time required	Performance	18, 1
17	Workspace analysis	Development of an integrated study of the workspace operating conditions	Performance	13,18, 1,23
18	Mission criticality	Relative importance of a specific tool or ME in a determined process	Performance	2,3,4,6,11,18, 1,7,22
19	Multidisciplinary risk management team	Level of cross cutting competences developed in working teams	Decisional	3,17, 7,1
20	Equipment replacement	Easiness in replacing ME	Decisional	6,9,17, 16
21	MTBF	Estimation and ongoing monitoring of Mean Time Between Failures	Performance	2,4,5,17,18, 16,22
22	Inspection procedures	Development of specific procedures and plans to perform inspection activities	Decisional	2,6,8,13,14,15, 7,10,12,16,22,24,26

23	Equipment characteristics	Characteristics and technical specifications of a ME	Performance	5,18, 1,11
24	Process management	Set of procedures, strategies and activities to manage processes in a healthcare organization	Decisional	13, 21
25	Recognized guidelines and standards (ECRI, ASHE, FDA)	Set of strategies and activities to ensure compliance with standards	Decisional	3,11,14,17, 7,16,21
26	Standards/regulation compliance	Level of compliance with International guidelines and Standards	Performance	5,11,13,17,18, 1,2
27	Administrative person	Existence of an administrative person/office	Performance	18, 16
28	Selection and monitoring of different contracts	Development of a methodology for the analysis of different contracts in the acquisition process	Decisional	4,5, 16,21
29	User interface	Level of development of the user interface for ME	Performance	17, 23
30	Performance evaluation	Level of performance of ME with respect to specific parameters	Performance	9,11,13,14, 10
31	Testing of medical equipment	Routine tests to verify ME conditions	Performance	2,4,8, 10,16
32	Safety testing	Level of performance of ME with respect to specific safety parameters	Performance	5,6,8,13, 12,16
33	Supporting departments	Existence of specif supporting departments and relative evaluation	Both	17, 16
34	Testing after repair	Level of performance of ME with respect to specific parameters after maintenance	Both	5,8, 16
35	CE service and role	Existence of a Clinical Engineer	Both	5,6,9, 7,16,19,20
36	Equipment planning	Development of an integrated plan to coordinate ME operating activities in a healthcare organization	Decisional	6,9,11,14, 1,7,12,16
37	Manufacturers database	Free access to manufacturers' databases and relative structure	Decisional	3,4,11,14,15, 10,12,16
38	Assessment methodology	Creation of an integrated methodology for evaluating ME	Decisional	8,17, 10
39	Availability of staff	Number of personnel available	Performance	5,17, 16,21
40	Company quality system	Development of an integrated plan to monitor quality performances in the healthcare organizations	Decisional	3,4,9,13, 16,24
41	Financial evaluation	Evaluation of economic and financial performances of a healthcare organization	Performance	9,15, 20,22
42	Recording of processes and activities	Development of a specific procedure and plan to record ME information and data	Decisional	3,13,14,18, 7,16,21,24
43	Risk-based planning	Development of an integrated plan to evaluate potential risks in healthcare organizations	Decisional	14, 16
44	Maintenance requirements	Development of an inegrated plan to support maintenance activities	Decisional	2,8,11,15,18, 1,10,22
45	Medical device management database/ID	Development of a specif ME database	Decisional	2,3,6,8,9,13, 12,16,21
46	Temperature control	Level of temperature in the workspace with respect to specif standards	Performance	14, 26
47	Training of personnel in hospital	Development of a specif training activities for personnel	Decisional	4,5,6,8,9,13,14, 7,10,16,19,23,25
48	Reliability and failure analysis	Development of comprehensive analysis for ME reliability	Decisional	2,6,8,14, 12,16
49	Risk analysis and management techniques	Choose of most suitable RM techniques to adopt	Decisional	3,8,11, 7,10,16,21,24
50	Equipment lifecycle cost	An economic evaluation of ME costs overall its lifecycle	Performance	9,11,13, 16
51	Vendor service	Process for the selection of the best vendor service and relative on-going evaluation	Both	6,8,9, 16,2
52	Outsourcing	Integrated plan to evaluate potential outsourcing opportunities	Decisional	13,14, 10,12
53	Supervise installation	Development of specific procedures to coordinate installation activities	Decisional	9,16
54	Maintenance policy	Development of a specific and integrated organizational maintenance policy	Decisional	8,20,25
55	Physical risk	Level of risk due to physical and working environment conditions	Performance	11,18
56	Risk monitoring	Development of a specific methodology to evaluate and monitor risk	Decisional	9, 10
57	Vendor negotiation	Development of a specific methodology to negotiate and select vendors	Decisional	9, 21

58	Maintenance cost	Continous evaluation of maintenance costs	Performance	8, 12
59	Infrastructure and transportation	Creation of integrated transportation systems and infrastructures to optimize logistics	Decisional	5, 16
60	Leadership	Level of leadership spread among personnel	Performance	9, 16,21,23
61	Calibration	Planning calibration of ME	Decisional	5,8,13, 16
62	Training on installation	Development of a specif training program for personnel on the installation	Decisional	5, 16
63	Maintenance strategy	Development of a specific strategy for maintenance activities	Decisional	4,6, 12
64	Decommissioning	Evaluation of potential decommissions	Decisional	13, 20,21
65	System integration	Level of integration among hospital departments	Performance	17, 16,23
66	Purchasing management	Creation of an integrated methodology for ME acquisition process	Decisional	8,13, 10,16,25
67	Frequency of repairs	Number of repairs occurred in a specif period	Performance	14, 16
68	Design specifications	Integrated system to provide manufacturers with the design specification	Decisional	3,17, 23
69	Administrative procedures	Acceptance and consistency of existing administrative procedures	Performance	5, 16,23
70	Prioritization	Prioritization strategy used for maintenance activities in healthcare organizations	Decisional	2,4,11, 1,12
71	PM	Planning Preventive Maintenance activities	Decisional	2,4,5,6,11,13,14,15,18, 7,10,12,16
72	CMMS	Development of a CMMS	Decisional	2,11,14, 16, 20, 21, 26
73	Age	Number of years in service for a ME	Performance	2,3,15,18, 12, 16, 22
74	SOD-Severity Occurrence Detection	Estimation of parameters for prioritization issues	Performance	2,3,4,6,15, 7, 20, 23, 24
75	Clinical experience and knowledge	Level of experience and technical capabilities of the clinical engineer	Performance	3,13,17, 21
76	CM	Planning Corrective Maintenance activities	Decisional	4,13,15, 16
77	Number of equipment	Number of different ME to be managed	Decisional	18, 20
101	Cost of repair	Evaluation of repairing costs for a specific maintenance activity	Performance	2
102	Maintenance system	Development of an integrated manage maintenance activities in the healthcare organizations	Decisional	5
103	Institution needs	Level of satisfaction of institutional and administrative standards	Performance	6
104	Standardization of devices	Development of potential standardization strategies and relative evaluation	Both	8,14
105	Component information	Level of information about ME components	Performance	8
106	Reconditioned components	Development of a plan to manage reconditioned parts	Decisional	8
107	Prioritization of acquisition	Implementation of an integrated plan to prioritize ME acquisitions	Decisional	9
108	Regulatory control of marketing	Level of control on marketing activities and relative compliance with standards	Performance	11
109	CBM	Planning Condition-Based Maintenance activities	Decisional	15
110	Technology obsolescence	Level of obsolescence of ME	Performance	15
111	Facility preparation	Strategy to develop facility management and relative implementation and evaluation	Both	17
112	Department requirements	Degree of satisfaction of departments requirements	Performance	17
113	Strategy for identifying emerging tech	Development of a strategy for identifying emerging technologies	Decisional	17
114	Labeling	Level of standardized labeling across the workspace	Performance	18
115	Efficiency	Level of efficiency of ME	Performance	8,18
116	Useful life ratio	Number of working years of a specific ME	Performance	18
117	Availability of operating instructions	Presence of operative working instruction in the workspace	Performance	13,18

118	Level of patient satisfaction	Degree of satisfaction for healthcare services among customers	Performance	17
119	Monitor post procurement performance and operating costs	Development of a methodology for monitoring post procurement on-going costs	Performance	9,17
120	Incident response plan	Implementation of a set of procedures and activities to face a potential hazard	Decisional	14
121	Equipment selection criteria	Selection of criteria to prioritize ME maintenance	Decisional	6,9,11
122	Total cost of ownership	Evaluation of the total costs of ownership of a specific ME	Performance	8,14,17
123	Cost of adoption (personal training)	Evaluation of costs for training personnel in using a specif tool	Performance	17
201	Training program	Development of a scheduled training program for personnel	Decisional	7, 16
202	Pre-acquisition evaluation	Development of a specific methodology to evaluate ME before the acquisition	Decisional	7
203	Communication	Implementation of integrated communication systems, rules, by monitoring its efficiency	Both	10, 19, 21, 23, 26
204	Installation cost	Evaluation of installation costs for a specific ME	Performance	25
205	Direct labor cost	Evaluation of specific set of activities for performing a task	Performance	25
206	Degree of acceptance among personnel	Compliance with organizational rules among personnel	Performance	25
207	Risk financing	Evaluation of financial risk	Performance	10
208	Uncertainty and sensitivity analysis	Development of an analysis to evaluate potential threats and opportunities	Decisional	24
209	Startegic plan	Development of a strategic plan and relative monitoring	Both	21
210	Clinical technology inventory costs	Evaluation of ME inventory costs	Performance	21
211	Stakeholder collaboration	Degree of collaboration among stakeholders	Performance	21
212	Public relations	Level of cooperation with public entities	Performance	21
213	Dashboards	Presence of regulatory and operative dashboards in the workspace	Performance	21
214	Joint plan	Development of a integrated plan for risk reduction	Decisional	21
215	Life cycle moment	Level of adaptability of procedures and activities to life cycle stage of ME	Performance	20
216	Reputation	Level of external reputation of the healthcare organization	Performance	20
217	Acceptance test	Ste of procedures and activities to evaluate ME during incoming inspection	Decisional	16
218	Planning of new construction and major renovation	Planning of new construction and major renovation	Both	16
219	Quality of service	Quality level of services erogated	Performance	24,25
220	Exposure avoidance	Level of exposure to risk among personnel	Performance	10
221	Governance	Type of governance and management policy adopted	Decisional	16,21
222	Accident Investigation	Development of a specific methodology to investigate accident root causes	Both	20,26
223	Staff safety	Level of Staff safety	Performance	12,16,20
224	Regional variations	Compliance with regional standards and social variations	Performance	20
225	Patient safety	Level of patient safety	Performance	20,21,22
226	IT systems	Implementation of an integrated IT system	Decisional	16,21
227	Personnel survey	Analysis of surveys filled on by personnel	Performance	10

Table 12 "Taxonomy"

4.5. Framework of analysis

Once completed the previous classification, candidates developed the final Framework that allows them to carry on their study. This Framework is developed on double-dimension tables, where such dimensions are represented on the X and Y axis by Asset Management and Risk Management perspectives, respectively. For each perspective, two different classifications are then presented, to create a more integrated and complete overview of the context. Such divisions created four different tables where the analysis is structured on. Within each table, factors are then classified according to their characteristics, developing the basis for the following steps.

4.5.1. Asset Management Axis

From the Asset Management point of view, the study proposes two main classifications for factors. The first one provides for the subdivision of the decisional factors according to the medical equipment life cycle stage they influence. In particular, a decisional factor is classified depending on when the decision related to that factor should be undertaken. The medical equipment life cycle stages where it is possible to organize decisional factors are those presented in Chapter 3: planning, acquisition, incoming inspection, inventory and documentation, installation, user training, monitoring of use and performance, maintenance, and replacement. This decision is related to the high degree of differentiation that characterizes the medical technologies' life cycle. Factors are equally distributed along ME life and change consistently from one phase to another. It is, therefore, essential to distribute them to understand when most impactful decisions are taken and what characterizes them. The second subdivision criteria from the Asset Management point of view include a classification of the performance criteria according to the healthcare performance area the factors are connected with. These functional areas are Operations, Finance, Quality, HR, Strategy, Safety and Security, Logistics, Administrative, and External Stakeholders. The classification of performance factors depending on functional areas allows having a complete overview of the whole healthcare organization and bettering catalog elements affecting its performances.

4.5.2. Risk Management Axis

In the Risk Management perspective, factors have been catalogued without distinction between decisional and performance ones. On the ordinate axis, a Risk Management perspective is again adopted with two different classifications. The first one recalls the main steps of a Risk Management process for healthcare organizations. Therefore, factors are classified into five main blocks represented by Risk Identification, Risk Analysis, Risk Evaluation, Implementation, and Monitoring and Improvement. Through this subdivision, candidates firstly integrated Risk Management and Asset Management perspectives in a unique Framework, by evidencing which steps of an RM process require particular interest and attention. The second classification includes the SHELL model for Risk Management, as defined in Chapter 3. Factors are so analyzed from this innovative point of view, classified according to the four main areas this Framework proposes: Liveware-Liveware (L-L), Liveware-Hardware (L-H), Liveware-Environment (L-E), Liveware-Software (L-S). This further classification was expected to verify how Asset Management practices may complement a specific methodology that assigns the human factor a central role.

Once this whole set of criteria is established, it is possible to summarize the Framework used as the standpoint for the analysis. It is represented by four two-dimensions tables integrating Asset Management and Risk Management perspectives, with a binary classification each. Within each Table, specific and pre-defined factors have been classified according to their nature, to identify possible criticalities and areas of interest. Such Tables are presented below:

		Asset Management Functional Areas								
		Operations	**Cost**	**Quality**	**HR**	**Strategy**	**Safety & Security**	**Logistics**	**Administrative**	**External Stakeholders**
SHELL	**L-L**		Direct Labour costs	Patient Safety, Quality of service, Level of patient satisfaction	Degree of acceptance among personnel, Communication, Leadership, Level of personnel		Patient Safety, Staff Safety		Administrative Person	Public Relations, Communication
	L-S	Availability of operating instructions	Monitor post procurement performance and operating costs	Standards/Regulations compliance, Vendor service	CE service and role	Mission criticality, Strategic Plan	Standards/Regulations compliance, Accident Investigation		Administrative procedures, Regulatory control of marketing	Regional Variations
	L-H	Availability of tools, Similar tools analysis, Utilization Rate, Function, Occurrence, Detection, Efficiency, Equipment History, Downtime, Availability of backup, MTBF, Performance Evaluation, Frequency of repairs, Age, SOD-Severity	Clinical Technology Inventory Costs, Installation costs, Equipment lifecycle cost, Maintenance cost, Cost of repair, Cost of adoption (personal training), Total cost of ownership	Equipment Deterioration, Equipment characteristics, User Interface, Testing of medical equipment, Testing after repair, Component information, Useful life ratio	Clinical experience and knowledge	Medical equipment upgrade, Life Cycle moment, Standardization of devices, Technology obsolescence	Safety testing, Physical risk	Department requirements		
	L-E		Risk Financing, Financial Evaluation	Workspace analysis, Dashboards, Labelling	Personnel Survey, Availability of Staff		Electrical Safety testing and Protection, Workspace analysis, Exposure Avoidance, Temperature control	Planning of new construction and major renovation, Facility preparation	Supporting departments, System integration, Institution needs	Reputation, Stakeholder Collaboration

Table 13 "Asset Management Functional Areas - SHELL Table of Factors"

		Asset Management Functional Areas								
		Operations	**Cost**	**Quality**	**HR**	**Strategy**	**Safety & Security**	**Logistics**	**Administrative**	**External Stakeholders**
RISK MANAGEMENT PROCESS	**Risk Identification**	Availability of tools	Risk Financing	Patient Safety, Quality of service	Leadership, Availability of Staff	Technology obsolescence	Patient Safety, Staff Safety		System integration	Reputation
	Risk Analysis	Utilization Rate, Function, Equipment history, Downtime, MTBF, Frequency of repairs, Age, Efficiency	Clinical Technology Inventory cost, Installation costs, Maintenance cost, Cost of repair, Cost of adoption (personal training)	Equipment deterioration, Component information, Level of patient satisfaction, Useful life ratio	Level of personnel, Degree of acceptance among personnel	Mission criticality, Life Cycle moment, Standardization of devices	Physical risk	Department requirements	Institution needs	
	Risk Evaluation	Similar tools Analysis, Availability of backup, SOD-Severity Occurrence Detection	Financial Evaluation, Equipment lifecycle cost, Total cost of ownership	Workspace analysis, Equipment characteristics, User Interface, Vendor service	Clinical experience and knowledge	Medical Equipment upgrade	Workspace analysis, Accident Investigation		Administrative Person, Supporting deparments	Regional Variations
	Implementation	Availability of operating instructions		Dashboards, Labelling	CE service and role, Communication	Strategic Plan	Exposure Avoidance	Planning of new construction and major renovation, Facility preparation	Administrative procedures	Stakeholder Collaboration, Communication
	Monitoring and Improvement	Performance Evaluation	Direct Labour costs, Monitor post procurement performance and operating costs	Standards/Regulations compliance, Testing of medical equipment, Testing after repair	Personnel Survey		Electrical Safety testing and Protection, Standards/Regulations compliance, Safety testing, Temperature control		Regulatory control of marketing	Public Relations

Table 14 "Asset Management Functional Areas - Risk Management Process Table of Factors"

		Asset Life Cycle								
		Planning	**Acquisition**	**Incoming Inspection**	**Inventory**	**Installation**	**User Training**	**Monitoring of Use and Performance**	**Maintenance**	**Replacement**
SHELL	**L-L**	Multidisciplinary risk management team, Communication	Vendor Negotiation			Training on installation	Multidisciplinary risk management team, CE service and role			
	L-S	Budget Management, Process Management, Recognized guidelines and Standards (ECRI, ASHE, FDA), Joint Plan, Strategic Plan, Risk Based Planning, Risk analysis and management techniques, Incident response plan	Assessment Methodology, Vendor service, Purchasing management, Prioritization of acquisition, Pre acquisition evaluation, Strategy for identifying emerging tech, Selection and monitoring of contracts	Inspection procedures	Management of spare parts, Recording of processes and activities	Supervise installation	Training program	Accident Investigation, Uncertainty and sensitivity analysis, Recording of processes and activities	Reliability and failure analysis, Maintenance policy, Maintenance strategy, Prioritization	Decommissioning
	L-H	Maintenance planning, Medical equipment upgrade, Equipment Planning, Standardization of devices	Manufacturer Database, Design specifications, Equipment selection criteria	Acceptance Test	Medical device management database, CMMS, Number of equipment, Reconditioned components		Training of personnel in hospital	Hazard analysis	Testing after repair, Maintenance requirements, Calibration, PM, CM, CBM, CMMS	Equipment replacement
	L-E	Environment, Supporting deparments, Governance, Planning of new construction and major renovation, Outsourcing, Infrastructure and transportation			IT Systems	Facility preparation		Company Quality System, Risk monitoring	Maintenance system	Environment

Table 15 "Asset Lifecycle - SHELL Table of Factors"

		Asset Lifecycle								
		Planning	**Acquisition**	**Incoming Inspection**	**Inventory**	**Installation**	**User Training**	**Monitoring of Use and Performance**	**Maintenance**	**Replacement**
RISK MANAGEMENT PROCESS	**Risk Identification**	Environment, Outsourcing	Vendor Service				Training of personnel in hospital			Environment
	Risk Analysis	Process Management, Standardization of devices	Manufacturer Database, Design specifications, Equipment selection criteria		Number of equipment			Uncertainty and sensitivity analysis	Maintenance requirements, Reliability and failure analysis	
	Risk Evaluation	Budget Management, Maintenance planning, Supporting deparments, Governance, Risk analysis and management techniques, Infrastructure and transportation	Vendor negotiation, Pre acquisition evaluation, Selection and monitoring of contracts		Management of spare parts, IT Systems		CE service and role	Accident Investigation, Hazard analysis	Prioritization, Maintenance system	Decommissioning
	Implementation	Medical Equipment upgrade, Multidisciplinary risk management team, Planning of new construction and major renovation, Joint Plan, Strategic Plan, Equipment Planning, Risk Based Planning, Incident response plan	Purchasing management, Prioritization of acquisition, Strategy for identifying emerging technologies	Inspection procedures	Medical device management database, CMMS, Reconditioned components	Training on installation, Facility preparation	Multidisciplinary risk management team, Training program	Company Quality System	Maintenance policy, Calibration, Maintenance strategy, PM, CM, CBM, CMMS	Equipment replacement
	Monitoring and Improvement	Recognized guidelines and Standards (ECRI, ASHE, FDA), Communication	Assessment Methodology	Acceptance Test	Recording of processes and activities	Supervise installation		Recording of processes and activities, Risk monitoring	Testing after repairs,	

Table 16 "Asset Lifecycle - Risk Management Process Table of Factors"

These Tables represent the final results where factors are accorporated together, and a definitive Taxonomy has been developed. In the next chapter, the analysis developed on this Framework is established and the results presented. In particular, in the last paragraph of the next chapter, two applications of the study conducted by candidates are introduced and developed.

5. ANALYSIS

In this chapter, candidates present their analysis and the results they achieved. The report follows the Framework presented and discussed in Chapter 4, and it continues with a critical discussion about the main findings obtained. The chapter is structured in different paragraphs. The first one will briefly present the principal outcomes resulting from analysis performed on Asset Management and Risk Management perspectives separately. Secondly, candidates focused on both the axis composing the reference Framework, to identify on which segments and macro-areas factors presence concentrate more. Thirdly, the focus of the study will focus on the integrated scenario, where each of the four tables previously presented will be analyzed in detail and critically discussed to evidence criticalities. Finally, two applications in healthcare organizations are proposed, in particular, in two different ways: one application with a prospective purpose and the other one with a retrospective purpose.

5.1. Preliminary Factors Analysis

Before to adopt an integrated approach for identifying possible criticalities among the different perspectives, candidates decided to analyze factors identified from both an Asset Management and Risk Management perspectives separately. This method allowed to evaluate the development stage of AM and RM practices on their own, before to evidence their potential shortcomings into a more integrated healthcare organization.

Therefore, the proper investigation of the 127 identified factors started from the Asset Management point of view. Among these factors, 100 were directly mentioned in AM related studies and will be the main focus of this section. 77% of them are also mentioned in Risk Management studies, while 23 are reported only in AM papers. In the following chart, AM factors are reported ranked according to the redundancy in studies analyzed. Only those factors that appear at least three times are reported due to clearness reasons. preventive maintenance is the factor that appeared the highest number of times in Asset management related papers, followed by downtime of Medical Equipment and training level of personnel, as those factors that have a higher impact on the operative phase of the medical equipment life cycle.

Chart 6 "Asset Management factors redundancy"

Only four of the factors reported belong to those mentioned only in AM papers. In particular, these factors are: equipment selection criteria, the availability of operating instructions, the monitoring of post procurement and operating costs, and the total cost of ownership, with a redundancy value not higher than four. Therefore, the most substantial majority of most cited factors are mentioned in both AM and RM studies, although with different scores among the two research fields.

The same analysis has been performed over Risk Management factors to identify possible trends after their identification. In this case, out of 104 factors identified, 27 emerged only form Risk Management related studies. In the following Chart, only elements with at least three mentions are reported.

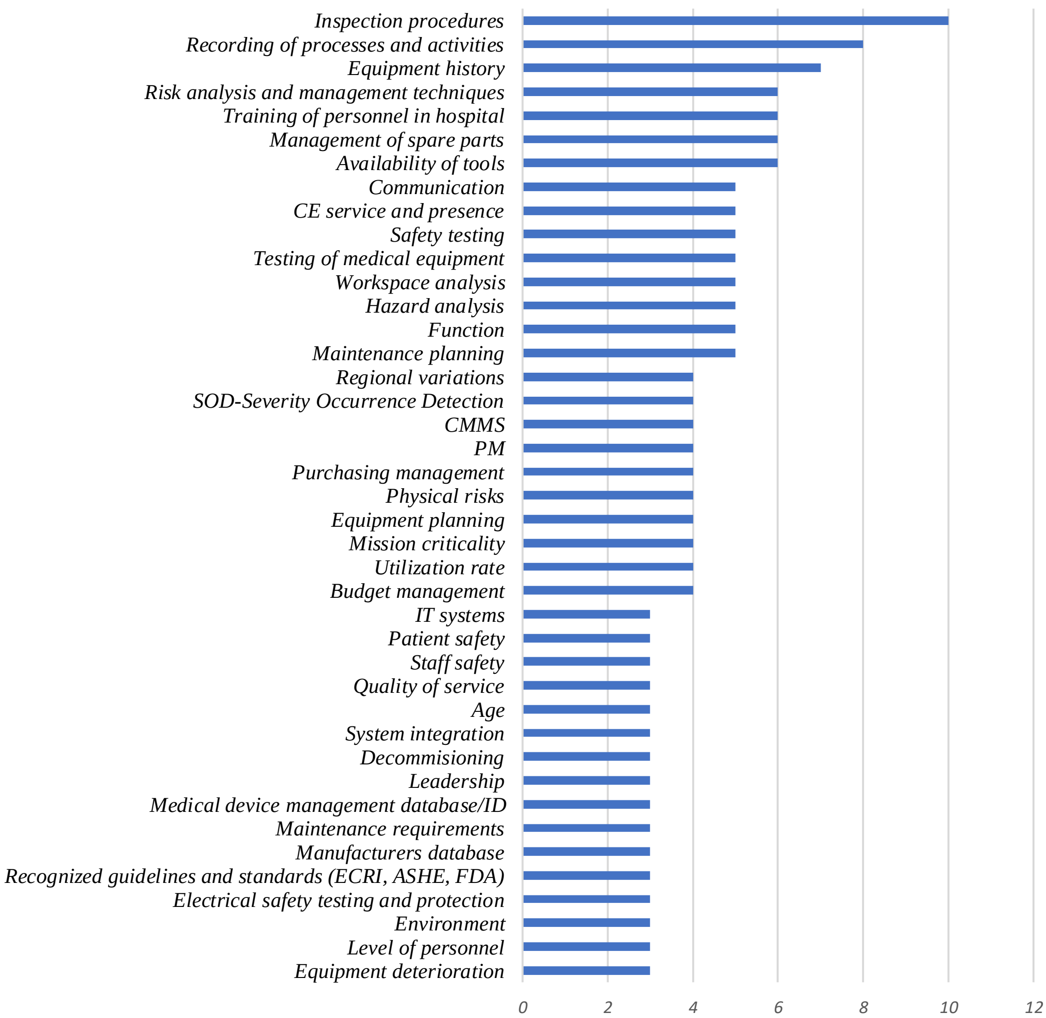

Chart 7 "Risk Management Factors Redundancy"

From this analysis, inspection procedures represent the factor that collects the highest interest from RM studies, followed by the ability to record processes and activities and to make available equipment history information. As in the AM case, just a few numbers of reported factors are mentioned only in RM studies (5), with an average redundancy value of 3.

Some initial considerations can be addressed regarding the differences among factors that emerged from Asset Management and Risk Management studies. The number of factors identified is almost the same, as well as the average redundancy of elements, which is around 2.5 repetitions for both categories. Risk Management factors present the overall highest redundancy value, with the ten repetitions of the Inspection Procedures.

Another data showed how performance and decisional factors were equally distributed between both Asset Management and Risk Management perspectives. Among the 77 factors mentioned in studies related to both research areas, 43% are classified as performance factors (33), while 51% as decisional ones. The remaining 6% (5 factors) are represented by factors cataloged as both decisional and performance. On the contrary, this trend is reversed by considering only the factors mentioned in studies belonging to just one of the two research areas. In this case, performance factors count for almost 60% of the factors identified in both single areas, while the decisional ones are assessed at 31% and 26% for Asset Management and Risk Management Studies, respectively. The following Charts summarize the overall distribution of factors among the two research areas.

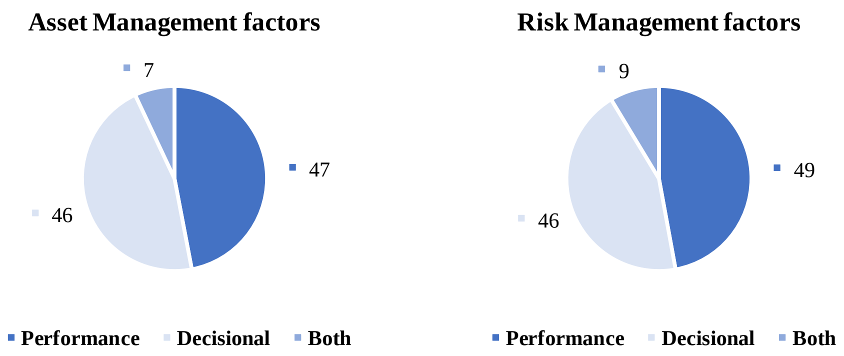

Chart 8 "Asset Management Factors Distribution" and *Chart 9 "Risk Management Factors Distribution"*

Besides quantitative findings, it is interesting to focus also on the qualitative insights that differentiate the two sets of factors. Although it is possible to dwell on this kind of analysis at this point, candidates preferred qualitative reserve considerations up ahead in the study once a broader picture of the research has been already provided.

Once briefly discussed AM and RM related factors separately in this first section, they will be considered as a whole set in the following chapters, since their origin is considered no more relevant for this study purposes. Consequently, in the following table is offered a complete overview of the factors identified and associate recurrences regardless they came from asset or Risk Management research areas. These data are fundamental for the next steps since repetitions will represent the standpoints for any further calculations in estimating the relevance of a particular area. In particular, *Table 5.1* presents the columns that indicate: the factor identification number, the factor name, and the number of recurrences for each factor over all the 26 papers analyzed. Among these elements, the one that counts the highest number of repetitions is the incoming inspection, confirming the trend of RM factors. The necessity to establish a training program for personnel and a recording procedure for data and information are often mentioned as well as the need for planning preventive maintenance activities.

NUMBER	FACTOR	TOTAL	NUMBER	FACTOR	TOTAL	NUMBER	FACTOR	TOTAL
1	Availability of tools	**10**	43	Risk based planning	**2**	108	Regulatory control of marketing	**1**
2	Budget management	**9**	44	Maintenance requirements	**8**	109	CBM	**1**
3	Similar tools analysis	**5**	45	Medical device management database/ID	**10**	110	Technology obsolescence	**1**
4	Utilization rate	**11**	46	Temperature control	**2**	111	Facility preparation	**1**
5	Management of spare parts	**12**	47	Training of personnel in hospital	**14**	112	Department requirements	**1**
6	Equipment deterioration	**6**	48	Reliability and failure analysis	**6**	113	Strategy for identifying emerging tech	**1**
7	Maintenance planning	**10**	49	Risk analysis and management techniques	**9**	114	Labelling	**1**
8	Level of personnel	**6**	50	Equipment lifecycle cost	**4**	115	Efficiency	**2**
9	Function	**12**	51	Vendor service	**6**	116	Useful life ratio	**1**
10	Hazard analysis	**10**	52	Outsourcing	**4**	117	Availability of operating instructions	**3**
11	Equipment history	**13**	53	Supervise installation	**3**	118	Level of patient satisfaction	**2**
12	Downtime	**10**	54	Maintenance policy	**3**	119	Monitor post procurement performance and operating costs	**3**
13	Environment	**6**	55	Physical risk	**6**	120	Incident response plan	**2**
14	Electrical safety testing and protection	**5**	56	Risk monitoring	**2**	121	Equipment selection criteria	**4**
15	Medical equipment upgrade	**3**	57	Vendor negotiation	**2**	122	Total cost of ownership	**3**
16	Availability of backup	**2**	58	Maintenance cost	**2**	123	Cost of adoption (personal training)	**1**
17	Workspace analysis	**9**	59	Infrastructure and transportation	**2**	201	Training program	**2**
18	Mission criticality	**10**	60	Leadership	**4**	202	Pre-acquisition evaluation	**1**
19	Multidisciplinary risk management team	**4**	61	Calibration	**4**	203	Communication	**5**
20	Equipment replacement	**7**	62	Training on installation	**2**	204	Installation cost	**1**
21	MTBF	**8**	63	Maintenance strategy	**3**	205	Direct labor cost	**1**
22	Inspection procedures	**17**	64	Decommissioning	**4**	206	Degree of acceptance among personnel	**1**
23	Equipment characteristics	**4**	65	System integration	**4**	207	Risk financing	**1**
24	Process management	**2**	66	Purchasing management	**6**	208	Uncertainty and sensitivity analysis	**1**
25	Recognized guidelines and standards (ECRI, ASHE, FDA)	**8**	67	Frequency of repairs	**2**	209	Strategic plan	**1**
26	Standards/regulation compliance	**7**	68	Design specifications	**4**	210	Clinical technology inventory costs	**1**
27	Administrative person	**2**	69	Administrative procedures	**3**	211	Stakeholder collaboration	**1**
28	Selection and monitoring of different contracts	**5**	70	Prioritization	**5**	212	Public relations	**1**

29	User interface	**2**	71	PM	**13**	213	Dashboards	**1**
30	Performance evaluation	**7**	72	CMMS	**7**	214	Joint plan	**1**
31	Testing of medical equipment	**9**	73	Age	**7**	215	Life cycle moment	**1**
32	Safety testing	**9**	74	SOD-Severity Occurrence Detection	**9**	216	Reputation	**1**
33	Supporting departments	**2**	75	Clinical experience and knowledge	**4**	217	Acceptance test	**1**
34	Testing after repair	**3**	76	CM	**4**	218	Planning of new construction and major renovation	**1**
35	CE service and role	**9**	77	Number of equipment	**2**	219	Quality of service	**3**
36	Equipment planning	**9**	101	Cost of repair	**1**	220	Exposure avoidance	**1**
37	Manufacturers database	**8**	102	Maintenance system	**1**	221	Governance	**2**
38	Assessment methodology	**3**	103	Institution needs	**1**	222	Accident Investigation	**2**
39	Availability of staff	**4**	104	Standardization of devices	**2**	223	Staff safety	**3**
40	Company quality system	**6**	105	Component information	**1**	224	Regional variations	**4**
41	Financial evaluation	**5**	106	Reconditioned components	**1**	225	Patient safety	**3**
42	Recording of processes and activities	**14**	107	Prioritization of acquisition	**1**	226	IT systems	**3**
						227	Personnel survey	**1**

Table 17 "Cumulated Factor Recurrences"

5.2. One Dimension Factors Analysis

Proceeding with the analysis, the section's aim is to investigate the results obtained from the Framework developed, analyzing the factors' recurrence numbers, finding out the reasons behind this outcome. It is organized in the following way: firstly, it is investigated the recurrence of factors through three bar charts, starting with the performance factors, it is presented the analysis for the Asset management functional areas, then the other two charts for the SHELL and Risk Management process analysis related to the functional areas in Asset management; secondly, through three more charts, the decisional factors are analyzed, one of the asset lifecycle stages and the other two that connect the topic with the SHELL and the Risk Management process, again.

5.2.1. Performance Factors Recurrence Analysis

The first bar *Chart 5.5* "Factors Recurrence analysis for Asset Management Functional Areas" shows the areas classified for a total number of factors recurrences. As mentioned before, this analysis does not distinguish between asset and risk fields, but in this case, it is referring to factors that have been classified as performance ones. As clearly visible, the area with the highest percentage of factors recurrences is one of the operations, in particular with a percentage of 32.7. This data shows the specific relevance of the operations area, whose aim is to direct, implement and control Asset Management activities, as explained in Chapter 3. This confirms the Thesis' interest in focusing the attention of the operative phase of the asset, since the operations area comprehends all that factors of performance that give a feedback on the operativity of the machine, which includes its frequency of repairs, function, utilization rate, efficiency, severity-occurrence-detection of a failure analysis and availability of tools or similar/identical machines. These factors have been mentioned in papers many times, also because of their importance in the analysis of Risk Management, as inputs for many related techniques, such as FMEA or FMECA (treated in the third paragraph).

The second highest area with a considerably huge percentage in terms of factors recurrence is the quality one, with 18.8%. In this case, it is understandable the importance of the area, as for quality, it is referring to the output for the patient, with factors of performance such as the level of patient satisfaction and the quality of the service, and to the quality of the machine, so, factors referring to the deterioration rate, the general characteristics, the life ratio and the tests after repairs. The last impacting area is the safety and security one, with a percentage of 15.2. Safety and security area includes performance factors such as staff and patient safety, which are obviously of extreme importance in the healthcare field, but also standards and regulations compliance which are them too fundamental in the context analyzed. Regarding this particular point, healthcare organizations are strictly regulated, and they must be compliant with severe standards to prevent patients and also staff risks. For this reason, the presented area is the third one in order of importance, even if it probably should be the first one. However, since it is something considered in some way obvious, it is thought to be just after the operations and quality areas, for the percentage of the number of factors recurrence, just because its performance factors must be granted for sure.

Other considerations can be made on the reason why the other areas do not account for a great percentage. The Chart shows a low percentage of relevance for the performance factors of the logistic and external stakeholders' areas. These two, in fact, present performance factors such as facility preparation and stakeholder collaboration respectively, which are factors indirectly connected to Asset Management. With facility preparation it is intended the strategy to develop facility management and relative implementation and evaluation, therefore something that is not directly connected to the asset but influences it. On the other hand, with stakeholder collaboration, it is intended also the relationship with suppliers of medical equipment, which again influences the choices of the best performing medical equipment, and on future guarantees and availability of suppliers.

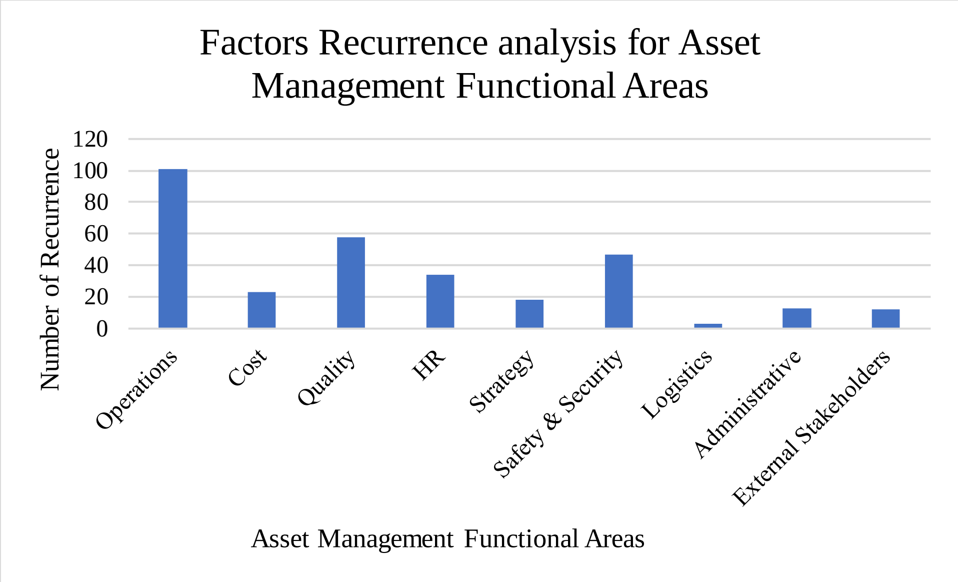

Chart 10 "Factors Recurrence analysis for Asset Management Functional Areas"

The second bar *Chart 5.6* presents the "Factors Recurrence analysis for SHELL" related to the Asset Management functional areas. In this way, performance factors have been classified for their impact on the four combinations of the SHELL model, based on their belonging to one functional Asset Management area. So, if before it has been analyzed the columns of the Table, in this case, the analysis moves on the rows of it. The chart evidences a considerable percentage of factors recurrences from the L-H component of the SHELL model. Again, also, in this case, the data is expected since the focus of the thesis itself is concentrated on the management of assets, intended as medical equipment. So, the result of a majority, in particular, of 53.1% of recurrence factors belonging to the Liveware-Hardware component was supposed from the beginning. In fact, under this interface, safety can be guaranteed when people are aware of all the functions of hardware components. Some factors that belong to this class have been mentioned before for the areas of operations and quality, some others are equipment lifecycle costs and installation costs for the cost area and clinical experience and knowledge for the HR area, to cite some of them. Therefore, from a performance point of view, this interface presents the majority of recurrences in literature.

However, it is essential not to underestimate the relevance of the other three components, because it is precisely in the moment when the focus is only on the Liveware-Hardware component that, forgetting the other three, it is possible to incur into errors. It is important to take into account the other factors belonging to the Liveware-Liveware, Liveware-Environment and Liveware-Software branches, such as the patient safety for the L-L, the availability of operating instructions for the L-S, or the availability of staff and workspace analysis for the L-E. These are only some of the factors that can be cited, and everyone is linked to the other one and can have an impact on Asset Management.

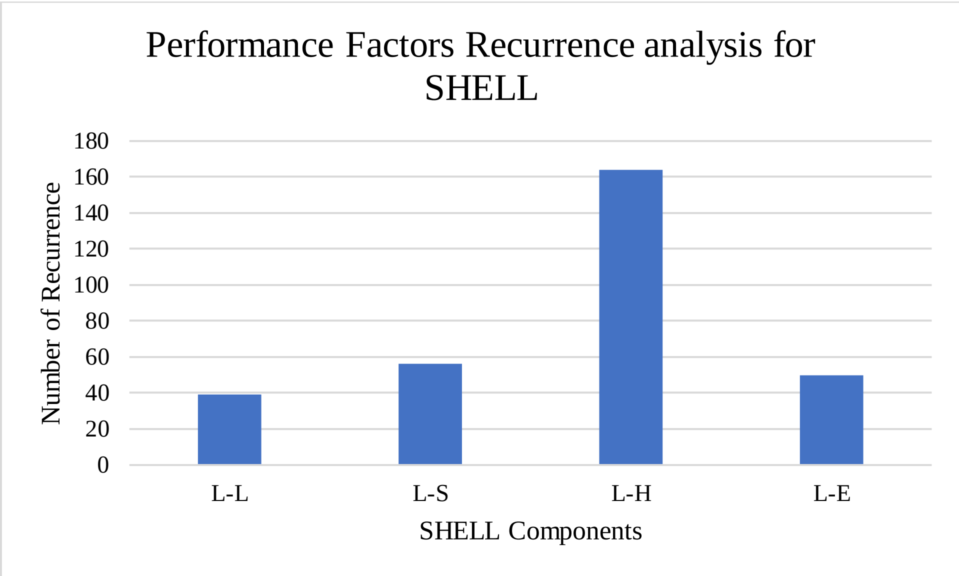

Chart 11 "Performance Factors Recurrence analysis for SHELL"

Continuing with the performance factors analysis of recurrences, the third bar *Chart 5.7* shows a prevalence of factors recurrences belonging to the process of risk analysis. Investigating the factors in this category, again, it is possible to find the factors cited before; some of them are utilization rate, downtime, frequency of repairs or installation costs, equipment deterioration, and level of patient satisfaction and personnel. Taking into consideration the recurrence numbers of just three of them, in particular, utilization rate, level of personnel, and downtime, they are very high concerning the average; to be precise 11, 6, and 10, respectively.

As a consequence, the overall category presents a high percentage. This phase of risk analysis intends to investigate the causes and the sources of risk, and the consequences that derive from them, in addition to this, also the frequency and the impact of the risk. It is a huge step in the Risk Management process, which must be driven carefully as it is the input for all the following stages. For this reason, it impacts the analysis with a percentage of 35.3. The risk evaluation accounts for a considerable percentage too, of the 24.3. In this phase, the formulation of decisions on treatment and priority of risk is made. Factors which belong to this process stage are similar tools analysis, for example, as a decision on the substitution of the machine with a similar one, or workspace analysis, developing a study on the usage of workspace and a better utilization in order to prevent errors. Another one, being part of the administrative area, is the presence of an administrative person and of supporting departments as possible countermeasures evaluation of the employment of supporting functions.

Another interesting aspect is why the implementation phase accounts only for 10.4%. Factors, affiliated to this part of the process, have been recurred fewer times than the others, even if the implementation is the put-in practice of countermeasures, so a relevant part of the process. However, the factors are few, and some of them are administrative procedures to be taken, planning of new construction, and a significant renovation and better communication. The reason behind this is probably the lack of implementation solutions because each case is specific in its own right, and the countermeasures determined based on the precise risk. The other phase with a lower percentage of factors recurrences is the risk identification one; this could be explained by the fact that some risks can be hidden and difficult to be identified, so factors belonging to this stage might be less treated in literature. Finally, the monitoring and improvement phases are considered relevant as in this way actions, and lessons can be learned for future events. Tests of medical equipment and after the repair is just some factors characterizing this process stage.

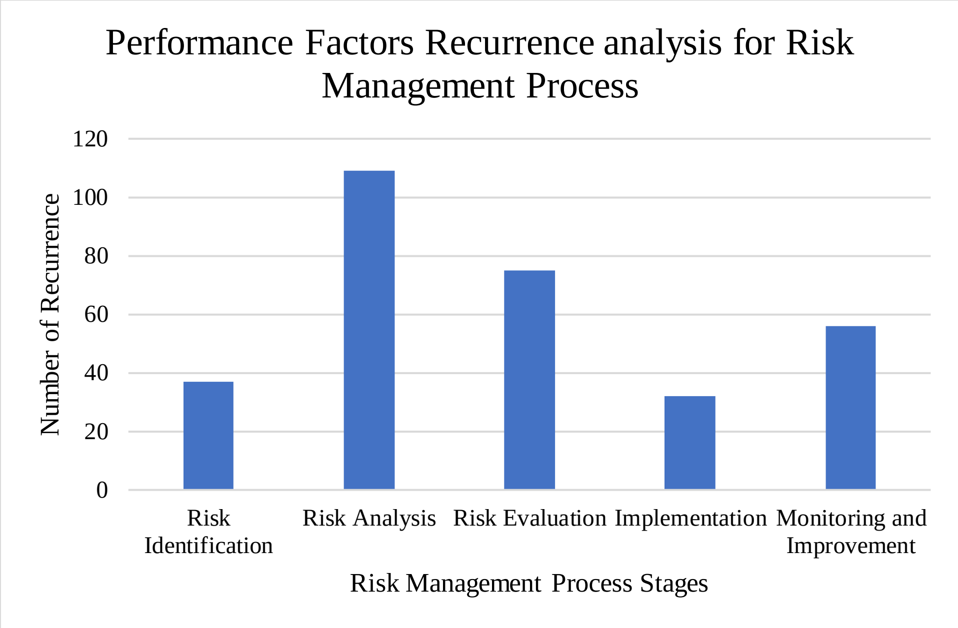

Chart 12 "Performance Factors Recurrence analysis for Risk Management Process"

5.2.2. Decisional Factors Recurrence Analysis

In this second section of the factors' recurrence analysis, the decisional factors classified into asset lifecycle phases are presented. In fact, the investigation starts with *Chart 5.8* of the asset lifecycle phases. Three are the categories that catch the eyes: planning, inventory, and maintenance phase. The planning phase reaches the 24.9%, the inventory 14.5% and the maintenance one, the 17.2%. A consideration that can be made on these results is the fact that even if the literature focuses on the majority on the maintenance phase, considered as the most critical and needy of control and monitoring, it is not the first one in the number of factors recurrences. It is worthwhile to mention that it is the second one, after the planning phase and, this latter one plays a crucial role in the lifecycle of a medical equipment and, in general, of an asset. It is, in fact, the road map for the introduction and development of the technology and services and their linked policies, to cite Chapter 3. It represents the general guideline for the overall lifecycle, and it has to take into account goals and many variables. The reason for this significant percentage is linked to this aspect since many are the factors to be considered in this phase.

The second big category is, as written before, the maintenance one, in fact, the implementation of a maintenance strategy that maximizes the availability and efficiency of medical equipment is fundamental. It must control the rate of equipment deterioration, ensuring safety, and environmentally friendly operations. Some of the decisional factors that are part of this phase are maintenance strategies, requirements, and calibration of the machine. Analyzing the acquisition phase, it is another crucial step, as the choice of proper medical equipment influences all the other stages after, so the average percentage that represents is reasonable. In this category, it is possible to find decisional factors such as vendor negotiation and service, design specifications, and manufacturer database to choose suppliers with whom to tighten a trustable and long-lasting relationship.

A question that arises spontaneously is why the installation and replacement phases are so low in terms of the number of recurrences. Referring to the installation stage, it relates to the activities performed to make available the machine, and since it is not such a long and crucial phase, the factors belonging to this stage are few, and low are the numbers of recurrences. Finally, surprising data is the one related to the replacement phase; however, it worthwhile to mention that the papers, to which it has referred to, have been chosen for their implication in general Asset Management. To clarify better, they are not related to the last phase of medical equipment, like the ones that were to have been deleted from the first part of the research. For this reason, the factors that can be associated with this category are less than the others, as less is the number of recurrences. Decommissioning and equipment replacement decisional factors are two of them, with 4 and 7 repetitions found in the literature.

Considerations have been made on the x-axis of the Table and the respective distribution of factors recurrences for stages of the asset lifecycle; in the following steps, the SHELL and Risk Management process for decisional factors examinations will be conducted.

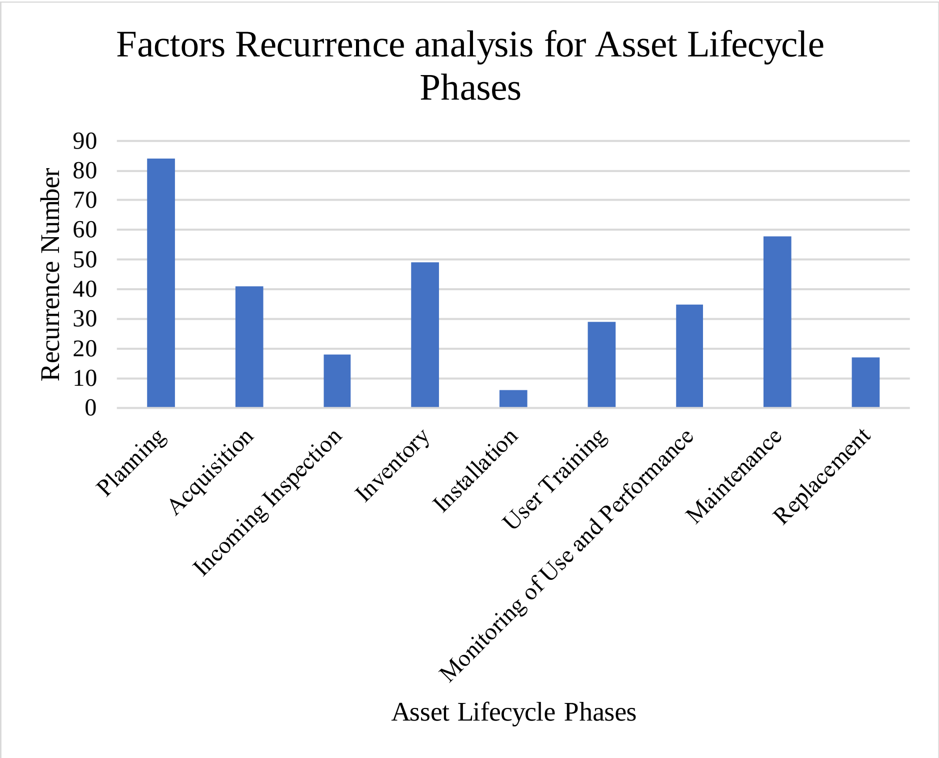

Chart 13 "Factors Recurrence analysis for Asset Lifecycle Phases"

Taking into consideration the SHELL bar Chart for the functional areas of Asset Management, it is interesting to note that again the L-H component represents a massive percentage in *Chart 5.9*. However, the biggest one is one of the L-S interfaces. Taking into consideration the fact that it is referring to decisional factors, so not quantitative but, of strategic and organizational nature, it has been supposed that, in this case, the Liveware-Software interface is reasonably high. Explaining the concept better, in a situation where it is considering factors of performance, which give a parameter and a quantitative result, it is more comprehensible than the category to find the most is the human-machine one, since the parameters expected are an output of the medical equipment.

On the other hand, mentioning the decisional factors, it is more understandable a high percentage of recurrences for the Liveware-Software component, since the human formulates decisions on rules, norms, and procedures, used to regulate the organization. To give some data, the L-S is 42.4%, and the L-H interface 39.2%. Decisional factors associated with these categories are process management, recognized guidelines, also belonging from the planning phase, management of spare parts for the inventory one and the acquisition phase, purchasing management, and vendor service. These are related to the L-S interface. On the other hand, maintenance planning, standardization of devices, and the medical device management database are only three of the human-machine components.

The other two couples, Liveware-Liveware and Liveware-Environment, are in both of the cases lower concerning the others. This is again justifiable from the literature taken into the analysis since the focus was on the asset and not on the human error, and as a consequence not on the Liveware-Liveware interaction. So, the papers related to the relationship between physicians and patients have been excluded from the analysis. Multidisciplinary Risk Management teams and training on installation are part of the category mentioned above. The last remarkable point is the interaction between humans and the environment, in general, not so investigated in the literature analyzed, probably because considered as a boundary and not directly related to the delivery of excellent service.

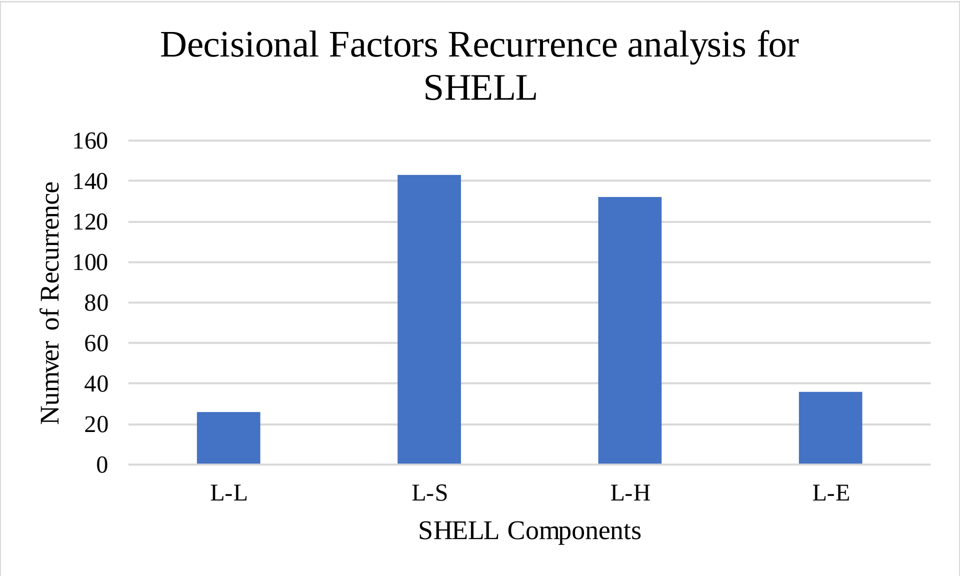

Chart 14 "Decisional Factors Recurrence analysis for SHELL"

The last figure to analyze is the "Decisional Factors Recurrence analysis for Risk Management Process," show by *Chart 5.10* The implementation process is represented by the 36.5%, going to be the highest in the number of recurrences. Decisional factors are well suited for this stage, as this latter is the putting into actions risk treatment measures, based on the consideration done in the previous steps, where performance factors were fundamental in order to carry out them. This is the reason why in this second Chart, risk identification and analysis present lower numbers of recurrence. The given phase presents factors such as strategy for identifying emerging technologies, prioritization for acquisition, inspection procedures, of course belonging to the inspection phase of the asset lifecycle, CMMS for the inventory phase, and training programs for the user training.

For what concerns the risk evaluation process stage, it is still reasonably high, with a percentage of 26.1. In fact, in this phase, both quantitative and qualitative data are necessary, because evaluation and formulation of decisions are made. Belonging to this category, it is possible to find budget management and Governance for the planning phase, pre-acquisition evaluation and selection and monitoring of contracts for the acquisition phase, and CE service and role best suited for a specific situation, for the user training.

Finally, in both decisional and performance factors recurrence analysis, the monitoring and improvement stage is at a medium level, as it is the last step of the Risk Management processes. Probably it is undervalued and considered not so important as the other stages of the process. However, it is precisely from this latter that it is possible to control the process itself and obtain further information for present and future actions, especially to create a pro-active behavior towards risks.

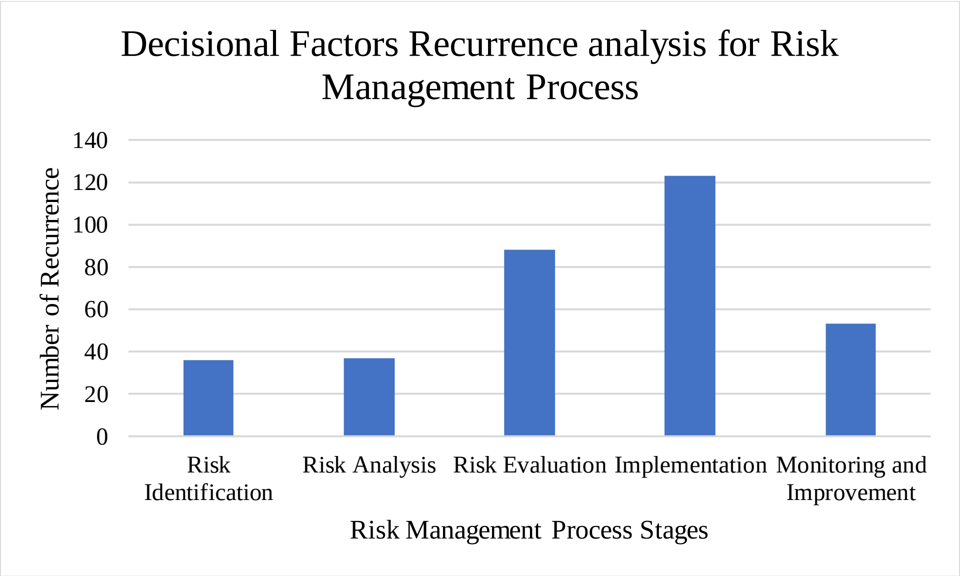

Chart 15 "Decisional Factors Recurrence analysis for Risk Management Process"

These are the considerations extrapolated from the Framework developed. The aim is to give quantitative shortcomings on the analysis and qualitative comments on the main differences and results. The following paragraph will go deeper in the analysis of every single quadrant, presenting the four Tables of the Framework filled with the recurrence numbers, obtained from *Table 5.1,* where each final factor of the Taxonomy study is associated with its recurrence number in literature.

5.3. Integrated Perspective Analysis

Once evidenced and discussed the significant criticalities in terms of individual factors and macro-areas of interest, in this paragraph, the study focuses intensely on the single areas, defined as 'quadrants,' that more captured the attention of the experts according to this research Framework. The scope of this analysis is to integrate the Risk Management and Asset Management approach from a unique perspective, able to synthesize critical issues that may emerge. The approach adopted in this case follows the same of the previous analysis: to evaluate which quadrant has a higher impact on medical equipment's management-related decisions, factors' recurrences are considered for ranking areas from the most upper important to the latest. In the case of different elements in a single quadrant, the overall repetition of the domain is obtained by summing together recurrences of individual factors present in it. It will be referred to this score as a Relevance score. Once completed this step for all the four tables considered, it is possible to perform qualitative and quantitative evaluations on the results obtained. In order to facilitate the comprehension and the linearity of the analysis, each table will be presented separately from the others as well as relative considerations will be made.

Furthermore, a legend is provided to immediately evidence areas that result in higher interest in the research scope.

- Top Relevance Area
- High Relevance Area
- Medium Relevance Area
- Medium-low Relevance Area
- Low Relevance Area
- Null Relevance

Figure 9 "Tables' Legend"

5.3.1. Risk Management Process - Functional Areas Analysis

The first Table presented considers performance factors classified on the x-axis according to the Risk Management Process and on the y-axis according to the Functional Areas composing a generic healthcare organization.

		ASSET MANAGEMENT FUNCTIONAL AREAS								
		Operations	*Cost*	*Quality*	*HR*	*Strategy*	*Safety & Security*	*Logistics*	*Administrative*	*External Stakeholders*
RISK MANAGEMENT PROCESS	*Risk Identification*	10	1	6	8	1	6		4	1
	Risk Analysis	65	6	10	7	13	6	1	1	
	Risk Evaluation	16	12	21	4	3	11		4	4
	Implementation	3		2	14	1	1	2	3	6
	Monitoring and Improvement	7	4	19	1		23		1	1

Table 18 "Risk Management Process - Functional Areas Analysis"

As previously described in the last paragraph, *Table 5.2* confirms the Operations department as the one able to concentrate on the highest number of factors and significant interest from researchers. Such data appears consistent with the main focus of this study, that focalizes its attention on the operative phase of the medical equipment. The fact that this table takes into account only performance factors supports one more time such data, due to the operative definition of performance factors themselves. At this point, it is possible to make observations on the distribution of these factors over the Risk

Management Process phases. Over the 45 quadrants, it is possible to register an average recurrence value of 6.86. Therefore, just 14 quadrants have a value higher than the average. It may suggest unequal factors' distribution over the areas. This fact is confirmed by the following data: the 33.3% of the areas present an almost null relevance score (0-1), among whom even ten areas, representing more than 22% of the overall table, register no relevance at all from the integrated perspective. If low-relevance areas distribution appears consistent in departments like Logistics, External Stakeholders, and Administrative, characterized by lower relevance average scores due to the weak global interest in these areas, such distribution appears still more unequal considering the higher interest areas. In particular, for the Strategy department, it is unexpected to discover how three quadrants out of five present no relevance for researchers. The one concentrating on the monitoring phase for the on-going strategies is even not mentioned at all in all the studies analyzed. This fact emphasizes a lack of attention for strategic parameters needed to evaluate vital elements' outstanding Asset Management decisions. The same could be affirmed for the financial department. It is unexpected to register such low interest in two areas as risk identification and the implementation of countermeasures in the cost area. In particular, the adoption of particular and specific measures to face possible financial under-performance should be taken into account and provided by the management to overcome potential issues faster.

On the other side, it is confirmed the trend that shows the risk analysis phase as that able to concentrate higher interest from researchers. More than one-third of the overall performance factors indicated in this table is used for risk analysis considerations. This is in part due to the operative and quantitative nature of both performance factors and risk analysis phase, but also to the high importance that this step plays in the Risk Management process. The ability to select the right elements to analyze and focus on allows healthcare organizations to monitoring with more efficiency the on-going performances of different areas of the structure; to intervene with greater rapidity and effectiveness once unexpected events take place, and to better predict possible issued and threats in the long term.

Such importance is, therefore, reflected by the average recurrence value in risk analysis quadrants. In particular, that for the Operations departments registered the highest score in the overall table, almost ten times higher than average. In such quadrant reside, in fact, performance factors essential to monitor the operating status of the medical equipment: utilization rate, MTBF, function, downtime, frequency of repairs. The high score is so justified by both the single relevance of each factor as well as by the vast number of factors included in this quadrant. It is then essential to evidence how other high-relevance areas are mostly spread over the Quality and Safety and Security departments. This immediately reflects the increased attention that healthcare organizations pose on the quality of service provided to patients as well as their safety and that of its personnel. The risk evaluation and monitoring stages are those that captured higher interest for both the departments. The workspace analysis and vendor service evaluation on one side and the level of compliance with standards and regulations and related testing activities on the other are those factors that significant contribution to such relevance. Finally, both departments accounted for their lowest score in the implementation phase. This unsatisfactory result is attributable to the methodological difficulties in identifying potential relationships and consistency among performance factors and the implementation phase of a Risk Management process. Twelve quadrants registered a relevance value approximately around the average score (between 4 and 10) and are equally distributed over the nine departments, while the remaining five quadrants in the upper-middle class are distributed among the Operations, Cost, Strategic, Safety & Security, and HR areas. The last mention is for the following area that surprisingly collected a great interest. In particular, it represents the only department where the implementation phase received the highest relative relevance score. This is due to different factors as communication implementation and the greater responsibility assigned to Clinical Engineer. The deployment of such elements and their comparative evaluation represent the more effective way for the human resources to have a significant impact on the Asset Management procedures. Clinical engineer's experience and technical capabilities may have a central role in developing and spreading rapidly and effectively further competences in new human resources, creating a more pleasant working climate; impact productivity and efficiency of services in a positive way. At the same time, the implementation of sophisticated communication systems and procedures may contribute to achieving better performance results.

5.3.2. SHELL - Functional Areas Analysis

In the following Table, instead, performance factors are still considered but classified according to SHELL methodology on the y-axis. On the x-axis remains the classification following the healthcare departments. This allows us to insert the previous findings from a different point of view but still maintaining the advantages of the integrated Asset-Risk Management perspective.

		ASSET MANAGEMENT FUNCTIONAL AREAS								
		Operations	*Cost*	*Quality*	*HR*	*Strategy*	*Safety & Security*	*Logistics*	*Administrative*	*External Stakeholders*
SHELL	**L-L**		**1**	**8**	**16**		**6**		**2**	**6**
	L-S	**3**	**3**	**13**	**9**	**11**	**9**		**4**	**4**
	L-H	**98**	**13**	**26**	**4**	**7**	**15**	**1**		
	L-E		**6**	**11**	**5**		**17**	**2**	**7**	**2**

Table 19 "SHELL - Functional Areas Analysis"

As in the previous Table, also, in this case, the highest relevance value is registered in the Operations department. The difference relies on the different distribution of performance factors in the categories proposed. If all the Risk Management process stages recorded a minimum degree of interest, even if unequally shared, in the case of SHELL classification performance factors for operations department concentrate basically in just one segment: the interaction between humans and machines. Only a miserable 3% is left to the Liveware - Software interaction. Such a discrepancy represents out of any doubts a criticality that must be investigated to find causes and possible alternative deployments.

First of all, it needs to consider the high relevance of L-H as something reasonable and amply predictable. This segment includes performance factors that inevitably represent the core element for any Risk Management activities performed on operating medical equipment. The availability of tools and backup, risk parameters, medical equipment age, and deterioration are standpoints to evaluate routine activities in a healthcare organization. What surprises is the misalignment with other components essential as machines and human factors to complete tasks.

Considering the Liveware – Liveware segment, it completely lacks the consideration of how the interactions and relationships among personnel may affect routine operating activities and represent, therefore, a relevant source of risk for patients. Candidates' analysis invites to focus more attention on this issue, by starting to consider the following elements: to introduce performance analysis to evaluate the personnel working environment. Parameters that could be taken into account may refer to: level of satisfaction among staff reported, the existence of possible conflicts, unwillingness in working as a team. Instruments adaptable to prevent these phenomena may be represented by personnel surveys, mandatory technical training courses, team group evaluation, or to activate regular job rotation inside operations departments.

A similar review is performed for the Liveware – Environment segment. The introduction of tools to evaluate the workspace and working environment in operative departments is something required, and that should be considered in order to prevent risk. It includes the periodic evaluation of temperature, electrical instruments, ventilation, brightness, and noise as potential factors affecting human and medical equipment performances.

Although it is not null, also the Liveware – Software score is considered unsatisfactory. For this reason, the implementation of accurate operating instructions is promoted, including specific indications on how to utilize medical equipment if it requires particular treatments, the sequence of activities to be performed for a determined task, and the detailed and explicit responsibilities of each role in the department.

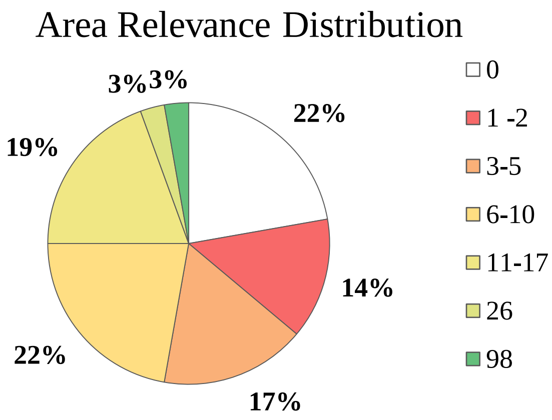

Chart 16 "Area Relevance Distribution"

Besides these considerations, it can be observed how areas that show the lowest concern still represent almost one-third of the overall quadrants, with a moderate increase of those characterized by a null interest. This last group increased in fact to eight quadrants. If those included in the Logistics do not represent a problem due to the low general attention put on the department, and the ones in Operations have already been discussed, different considerations may be made about the others. In particular, as evidenced in the previous analysis, it should analyze the under consideration of factors attributable to the strategic department in L-L and L-E. It may suggest a focus of healthcare organizations on strategic aspects related just to procedures and machines, by neglecting environmental and interpersonal working conditions.

Another mention is about the disregard for the L-H segment in the Administrative and External Stakeholders, even if Liveware – Hardware interaction always represented the most mentioned topic. It is satisfactory the attention posed in the L-L area by those departments that aim to ensure ordinary quality and safety to daily operations.

In the end, although it has already been discussed the surprising medium-low interest for financial and economic dynamics, it seems opportune to underline the need for more decisive factors able to provide a complete financial evaluation of healthcare activities. If for some segments as the L-L, it may be difficult to identify performance factors, it is more comfortable doing so for L-H and L-S areas that would require more considerable attention from Cost departments, by implementing, for example, tools to better monitor operational costs or manufacturers' services.

5.3.3. Risk Management Process – Medical Equipment Lifecycle Analysis

In the following two paragraphs, the research will adopt on the x-axis the classification based on medical equipment lifecycle stages, while on the y-axis again, the SHELL Framework and the Risk Management Process steps will alternate. In the following *Table 5.4*, this latter classification is adopted.

		MEDICAL EQUIPMENT LIFECYCLE								
		Planning	*Acquisition*	*Incoming Inspection*	*Inventory*	*Installation*	*User Training*	*Monitoring of Use & Performance*	*Maintenance*	*Replacement*
RISK MANAGEMENT PROCESS	*Risk Identification*	10	6				14			6
	Risk Analysis	4	16		2			1	14	
	Risk Evaluation	34	8		15		9	12	6	4
	Implementation	23	8	17	18	3	6	6	35	7
	Monitoring and Improvement	13	3	1	14	3		16	3	

Table 20 "Risk Management Process – Medical Equipment Lifecycle Analysis"

The first finding in analyzing the distribution of decisional factors influencing medical equipment performances is a higher average relevance score than for performance factors. It is obtained through equal distribution of influencing factors among different quadrants. There are not relevant discrepancies between the most mentioned areas and the lowest ones: the most significant difference is equivalent to 35 points, almost a half of the difference evidenced in *Table 5.3* and only a third of that in *Table 5.2*. This is an essential standpoint for this analysis since it manifests an already integrated and ramified approach in the decision-making process for medical equipment management. Even though this data, it must be registered a significant increase by 7% of those areas that present null relevance from the studies analyzed. Among those requiring specific attention, candidates focused on:

- *Risk Identification / Maintenance area*: Regarding medical equipment management, maintenance represents the area able to guarantee higher performance improvements in both efficiency and economic terms. Comprehensive literature focuses on confirming this hypothesis; however, neglecting factors may contribute to the risk identification process. The following steps are full of techniques and parameters to evaluate performing maintenance activities. Still, it lacks a theoretical analysis able to evidence what characterizes each approach: what conditions may prevent from using a specific method, a detailed Taxonomy of potential risks in determined contexts, or which elements should be monitored to identify potential hazards. Even if complicated, approaching maintenance problems with a more general perspective, starting to identify potential hazards that may manifest in a healthcare organization, would help in preventing potential risks and considering a more extensive range of threats in a more effective way;
- *Monitoring and Improvement / User Training area:* If generally high relevance is attributed to user training factors in the Risk Management process, not the same can be affirmed regarding the Monitoring & Improvement phase, which should act as guidelines for the evaluation of countermeasures implemented. To decide which standards of personnel performance must be achieved, to present a long-term plan for clinical staff professional growth, and to set out a clear guideline to establish core responsibilities may represent starting points to define precise evaluation tools and monitoring methodologies;
- *Risk Identification / Inventory area:* Another criticality is represented by the absence of contingent factors that help in the identification of potential risks for inventory management. In this case, also, a specific Taxonomy of potential hazards should be implemented as well as an active collaboration with manufacturers to anticipate possible issues;

- *Risk Identification & Analysis / Monitoring of Use quadrants:* In this case, the proactive monitoring of the operating phase of medical equipment represents an effective way to achieve more significant results in terms of quality and quantity of services provided to patients. Operational management should focus more on factors that may help in the identification of potential hazards, as well as provide specific indications on which kind of performance values must be monitored after conducting a particular analysis of the workspace conditions, activities performed, personnel skills and level of performance required.

Due to the low attention involved and relative lower impact of installation and incoming inspection activities, their limited relevance has not been considered as significant and critical in this analysis. Oppositely, it is relevant to emphasize how the planning phase is the object of much attention from researchers as the lifecycle stage that more impacts on the success of an Asset Management strategy. To this stage belongs, in fact, the area that registered the most significant relevance score in the Risk Evaluation step. Almost the same relevance is attributed to the implementation of effective countermeasures in the maintenance phase. In general, it is important to outline how many quadrants reported a relevance score almost doubled than average, to demonstrate the importance of adopting an integrated view in developing an effective Asset Management policy.

5.3.4. SHELL – Medical Equipment Lifecycle Analysis

The last level of analysis refers to the classification of decisional factors in the relative medical equipment lifecycle according to the SHELL methodology. In *Table 5.5*, the outcomes of such an analysis are reported.

The general considerations made for *Table 5.4* remains pertinent, with decisional factors presenting a wide distribution among different areas. It would confirm the high level of interest healthcare organizations provide considering many steps of the asset lifecycle from different perspectives. Such data is approved by the difference between the most upper relevance area and the lowest relevance area in the table, 40 points, slightly increased respect to the previous decisional factors' analysis, but still significantly below values from performance factors.

		MEDICAL EQUIPMENT LIFECYCLE								
		Planning	*Acquisition*	*Incoming Inspection*	*Inventory*	*Installation*	*User Training*	*Monitoring of Use & Performance*	*Maintenance*	*Replacement*
SHELL	**L-L**	**9**	**2**			**2**	**13**			
	L-S	**34**	**23**	**17**	**26**	**3**	**2**	**17**	**17**	**4**
	L-H	**24**	**16**	**1**	**20**		**14**	**10**	**40**	**7**
	L-E	**17**			**3**	**1**		**8**	**1**	**6**

Table 21 "SHELL – Medical Equipment Lifecycle Analysis"

The two quadrants reflecting the highest interest from researchers are the Maintenance / L-H and the Planning / L-S areas, also this data aligned with what presented in the previous paragraph, where again planning and maintenance areas had recorded the most relevant scores. This is due to the presence of factors that have a direct impact on the implementation of an effective Asset Management policy for ME, such as the definition of Corrective and Preventive Maintenance activities as well as testing after repairs in one case, and the budget management and process management actions in the other.

Furthermore, concerning the previous analysis, it must be registered a decrease of 25% of areas that had expressed a null interest, from 12 quadrants to 9. In part, this result can be referred to as the different Framework, that presents a lower number of quadrants and may suggest a more concentration of interest, but this did not happen for the performance factors classification, demonstrating that the methodology used should be the leading cause for such a discrepancy.

Although this reduction, some null areas still need to be deeper analyzed in order to evidence possible criticalities. Attention focused in general of the low interest demonstrated by decisional factors in L-L dynamics that are globally recognized as decisive to provide excellent services and prevent errors. In a human-centered methodology as SHELL, it is essential to evidence how and why Liveware conditions are neglected.

In many lifecycle stages, this neglection was highly foreseeable: because these stages do not present an overall high relevance for the analysis, for the Incoming Inspection phase, or because methodology applied is not the best option to represent dynamics underlying that lifecycle stage, as it may be for replacement. In other cases, anyway, the low interest is seen as a point to be focused on. Monitoring of use & performance and maintenance stage little attention should be investigated due to the high importance such stages cover in a medical equipment lifecycle. In the first case, directives to manage overcome potential risk as leadership absence, lack of working experience, time pressure, or emotional stress may be implemented since these elements represent relevant sources of uncertainty in the operative phase. The same may be suggested for routine maintenance activities where poor decision making, absence of coordination, and failed communication are recognized potential hazards that affect the L-L sphere in healthcare organizations.

Another area that requires attention is the user Training / L-E. It is underestimated the impact that working environmental aspects may have on an effective training program of personnel. It should be encouraged the spread of a safety culture and safety climate able to make it clear for staff the importance they play in the healthcare process. Training programs and sessions represent the best options to create awareness about this topic. The same reasoning can be applied for the maintenance step, where maintenance planning lacks consideration for working context aspects.

To offer a broader representation of this analysis, the following chart summarizes the relevance score distribution among areas. As mentioned, relevant discrepancies can be identified with respect to SHELL - performance factors analysis. This comparison is made in order to empirically point out the differences between performance and decisional factors, by underlying how they both are essential to managing assets with a focus on patient safety effectively.

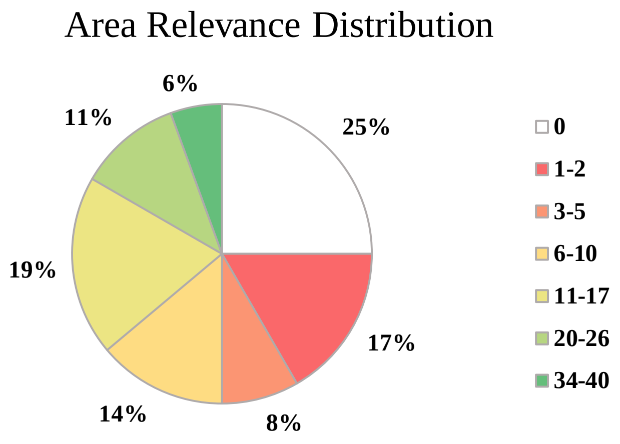

Chart 17 "Area Relevance Distribution"

Compared to *Chart 5.11*, it can be seen a slight increase in null relevance and lowest areas, by 4%. This data is immediately compensated by the higher number of quadrants that had registered a common interest, between 3 and 10 points. They account for more than 20% of the overall healthcare potential management areas. The most relevant increase regards the number of quadrants that showed relevance for studies analyzed. Quadrants moved from just 25% of the total to a significant 36%, with a particular change in those with a relevance value of around 23 points. This data would confirm how decisional factors are more equally spread among different stages of ME life, while performance factors concentrate more on a restricted number of elements. Liveware – Software interaction is the SHELL segment that can count on the highest and relevant increase: significant importance is so attributed to decisions undertaken about the purchasing procedures and contract monitoring in the acquisition phase. The storage of ME information and management of spare parts represent situations offering more extensive opportunities for growth, while different are those elements to monitor in the operative phase: the accident investigation methodology adopted, the maintenance policy as well as the selection of the right prioritization criteria and techniques in order to improve reconditioning activities. Different interest distribution in the L-H segment is instead considered consistent with the different classification proposed on the x-axis.

The scope of this paragraph was to qualitatively analyze data emerging from the application of methodology proposed on decisional and performance factors identified. At the end of Chapter 4 are reported Tables with all factors inserted within quadrants of the four tables presented. It is then possible to verify which factors are responsible for a determined value in a quadrant.

5.4. Potential Methodology Applications

The methodology described can find a wide range of applications in healthcare organizations. Among them, candidates decided to propose two different ways of application that differ from each other for their purposes. Firstly, the discussed Framework can be used as a standpoint for the evaluation of existing policies and procedures, as a retrospective tool for root causes analysis. In the second instance, the methodology is presented as a reference Framework to develop future healthcare management policies and to prioritize decisions, with prospective purposes.

5.4.1. Retrospective Application

In the first case, the Asset Management – Risk Management integrated methodology can represent an instrument to assess the effectiveness of Risk Management and Asset Management policies currently applied in the healthcare structure.

A healthcare institution can use the proposed methodology as a Framework to verify if the factors it is considering in developing its asset/risk management policies correspond where necessary to those presented in this study. The Taxonomy developed and described in Chapter 4, in fact, takes into account a wide range of factors, most of whom appreciable from the majority of healthcare structures and its departments. Not all the factors may be relevant, but it would be in charge of the single structure evaluating which one to consider. It may represent an important standpoint and evaluation tool, since it allows to verify if the institution is missing something, or, more in general, if a specific functional area requires more attention. Considering its asset lifecycle management, a healthcare institution may discover, for example, it is giving too low emphasis on the acquisition process. The methodology not only would allow the hospital to identify such a gap easily but also would give immediate suggestions about what elements to focus on. The implementation of a methodology for contract monitoring and selection, a proactive negotiation with manufacturers, or setting a strategy for acquisition prioritizations may represent good starting points.

Additionally, it may represent an excellent Framework for developing root cause analysis inside a healthcare organization. In a complex and multifunctional scenario such as a healthcare institution, it may be challenging to trace potential sources of errors due to the high correlation among different factors that may contribute to error generation. The wrong allocation of responsibilities and the neglection of possible causes represent severe threats to the Risk Management process since they do not allow developing effective countermeasures. In this way, again, having access to an instrument able to integrate different perspectives and to directly identify causes and allocate duties represents a great opportunity. Through its integrated perspective, the Framework can provide key areas where intervene and the primary instruments to do it.

In order to offer a potential practical application of such an instrument, a hypothetical utilization scenario is here presented in the Radiotherapy (RT) department. The choice for the RT process is due to the high interaction between completely automated functions, performed by innovative hardware and software equipment, and human activities. At the same time, such a process requires high interaction between patients and professionals. All these components make radiotherapy activities at risk for the patient, shifting on the consequences that Risk Management and Asset Management may have for patient safety.

The case study starts from a study conducted in a Radiotherapy and Oncology department in an Italian Hospital by Professor Paolo Trucco, supervisor of this research, and Others. The study, *"Applying failure modes effects and criticality analysis in radiotherapy: Lessons learned and perspectives of enhancement"* after an accurate analysis of RT processes, focuses on the identification of possible failure modes of the process aimed at identifying priorities of intervention (Trucco et al., 2010). This research takes away the failure modes list and description identified during the original study. At this point, the Framework proposed will be used as a standpoint to detect possible causes for failure modes among factors evidenced in the Taxonomy. Once identified factors, their classification into this research's methodology will present significant areas of intervention and suggestions for corrective actions.

In the following Table, a list of potential failures modes extracted from *"Applying failure modes effects and criticality analysis in radiotherapy: Lessons learned and perspectives of enhancement"* is presented, associated with candidates' correlated factors and the cumulated relevance obtained by summing recurrences of factors identified.

Failures modes	***Factors***	***C.R.***
Patient Administrative Errors	Process Management, IT systems, Administrative Procedures	8
Incomplete or inadequacy of the first medical examination	Equipment deterioration, Clinical Experience and knowledge, Multidisciplinary risk management team, Training Program	16
Error in patient positioning	Level of Personnel, Training of Personnel in hospital	20
Error in the choice of the immobilization system	Training Program, Availability of tools, Technology obsolescence, Facility preparation	14
Administration of the contrast medium without checking blood tests	Level of Personnel, Availability of operating instructions	9
Inadequate contouring of the target volume	Level of Personnel, Availability of operating instructions	9
Incomplete filling of treatment form	Communication, Administrative procedures	8
CT laser out of alignment	Inspection procedures, Calibration, Testing of ME, Training of Personnel in hospital, Maintenance requirements	52
Error in markers position on the patient	Training of personnel in hospital, Clinical Experience and knowledge, Labelling	19
Error in dose entry during treatment planning	Communication, Equipment deterioration	11
Data entry error during treatment plan scheduling	IT systems, Communication, Medical device management database/ID, Administrative Person	20
Missing transcription of the new isocenter	Process Management, Recording of processes and activities	16
Incomplete scheduling of treatment plan	Administrative Procedures, Administrative Person, System Integration, Dashboards	10
Error in gantry angle	Equipment Deterioration, Calibration, Training of Personnel in Hospital, Availability of operating instructions	27
Treatment plans having the same name	Administrative Procedures, Process Management	5
Missing or wrong patient scheduling on the time planner	Administrative Person, Supporting departments	4

Incomplete or erroneous filling of the informed consent	Administrative procedures, Institution needs	4
Patient identification error	Level of Personnel, Administrative procedures, Communication	14
Error in patient positioning during treatment	Clinical Experience and knowledge, Training of Personnel in hospital, Availability of operating instructions	21
Error in the portal vision verification at the beginning of the treatment	Technology obsolescence, IT systems, Medical device management database, Training Program	16
Linear accelerator not calibrated	Calibration, Inspection procedures, Workspace analysis, Component information, Maintenance system	32
The incompleteness of the check medical examination	Clinical Experience and knowledge, CE role, Performance evaluation, Level of Personnel, Multidisciplinary risk management team	30
Error in drug administration	Level of Personnel, Supporting departments, Administrative procedures	11

Table 22 "Radiotherapy FM, factors contributing and Cumulated Relevance"

Once calculated CR for each failure mode, it can be used as an instrument for the prioritization of interventions. As a result of the process, major potential risks for patient safety are represented by CT Laser out of alignment, the incompleteness of the Check Medical Examination, and the Linear Accelerator not Calibrated. It is important to underline how the medical equipment focus of methodology applied impacted the final results of the case study.

At the same time, factors identification allowed to evidence functional areas where a higher number of risks originate, by suggesting corrective and preventive actions. Candidates classified each factor within a specific area according to how explained in the methodology presentation. Then, each factor has been assigned a value equal to the *Number of Repetitions* times the *Recurrence Score*. The sum of different factors scores established the relevance of each area, presented as the *Cumulated Relevance*. The results are summarized in the following chart:

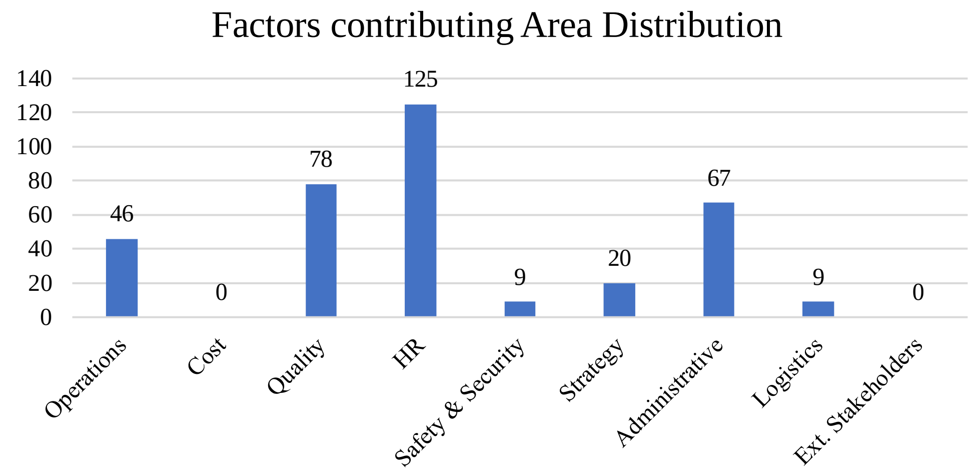

Chart 18 "Factors Contributing Area Distribution"

Areas requiring significant interventions and special monitoring is represented by the Human Resources department, which counts for 35% of the total factors. Relevant impact is given by the need for the creation of precise scheduling for personnel training as well as the establishment of specific practical training sessions on operating activities, able to reproduce real working situations. Clinical experience and technical know-how of staff also represent elements that contribute to increasing patient safety. Countermeasures should also focus on Operational aspects by focusing on the availability of tools, technology obsolescence, as well as the presence of operating instructions and dashboards in the workplace. Quality area impacts 22%, almost two times more than the operational area, while the department that surprisingly results from having a massive impact on the success of RT activities is the administrative. It accounts for more the 25% of the overall sources of risk for RT, and an essential contribution in determining such a value is given by the set-up of appropriate administrative procedures and the presence of an administrative person that ensures its observance. Ability to implement and use effective communication among personnel also impacts the overall results of the RT process.

5.4.2. Prospective Application

Once completed the discussion about the potential retrospective application of the methodology, this paragraph presents its prospective use. As mentioned above, the

Framework proposed can be applied as a standpoint for developing new Asset Management and Risk Management policies that take into account both perspectives.

Factors presented cover a wide range of potential risks and situations may happen in healthcare organizations. Therefore, the Taxonomy proposed could be a reference model for implementing healthcare strategic plans and creating an integrated network involving manufactures and external stakeholders. Furthermore, a great advantage of such methodology consists in the possibility to be continuously updated. This allows healthcare structures to exclude any factors that may not be relevant, and to include new factors that may emerge from a new scenario. It is a precious advantage expendable also for retrospective applications. A second advantage offered by such methodology is represented by the possibility to be scalable. It can be, in fact, applicable to the wide project, as for the implementation of a new policy, but also as a guideline for more restricted decisions, that may refer to just some stages of medical equipment lifecycle or a few healthcare functional departments. This would be without affecting the overall effectiveness of the methodology.

Referring to this aspect, it is now presented a potential application of the model as a reference for supporting the decision about the Selection of a Medical Device used in the Radiotherapy department among different alternatives. In particular, the methodology will act as input for the selection process performed through the AHP. The choice of this application case is due to ensure consistency with the previously analyzed scenario in RT and to face the same risks from a different perspective. In this case, in fact, an Asset Management issue (the selection of specific ME) will be solved moving from risk parameters. The RT device to be acquired is the CT Laser used to obtain the highest precision by reducing collateral effects for the patient and by delivering the right dose during treatment, ensuring such a global efficiency and security to the process.

Failure Modes extrapolated above, and the *"Radiotherapy Risk Profile"* report by the World Health Organization will serve as a technical support to select which factors to take in higher considerations (Gantchew, 2010). The evaluation has been conducted by candidates based on both qualitative and quantitative information. The analysis of previous contributing factors and relative weights inside the Taxonomy presented allowed candidates to identify the following criteria as crucial to select the optimal CT laser device, with comparable relevance scores given by Table in Chapter 4.

Selected Criteria	***Description***	***Relevance Weight***
Vendor Service	Characteristics and quality of services offered by the supplier after purchasing the CT Laser	**6**
Cost of Adoption	Amount of economic resources require for facility preparation, installation, and training of operators.	**1**
Financial Evaluation	Sum of the direct and indirect costs that may manifest in the ME lifecycle after adopting a specific device.	**5**
Maintenance Requirements	Maintenance specifications required by the adoption of the technology, and complexity in their application.	**8**
Calibration	The complexity of performing regular calibration activities on the device	**4**
Level of Personnel	Level of technical know-how and capabilities of personnel that should use the specific device	**6**
Design Specifications	Design specifications of the device: ergonomics, user interface, software consistency.	**4**
Performance Evaluation	Technical specifications of the device: useful life ratio, hazards history, efficiency, MTBF.	**7**
Manufacturers' Database	Degree of access to manufacturers' database and the possibility to use relative data for maintenance and monitoring purposes.	**8**

Table 23 "CT Laser Selection Criteria"

The definition of the above Table serves as a guideline for the creation of an AHP structure that allows the clinical engineer to critically evaluate different CT Laser alternatives based on their critical aspects. Of course, the choice of the factors, as mentioned before, is both qualitative and quantitative and may change according to the particular needs of a structure or department. Criteria definition must take into account a wide range of factors that Taxonomy already offers in a detailed version. It is in charge of the clinical engineer and management to select which ones to consider on a case-by-case basis. Also, the relative weights attributed to each factor may be modified on time when the specific context requires it. In this case, candidates decided to assign relative weight based on what emerged from their researches in Asset Management and Risk Management.

In the following Figure, it is provided the hierarchy of the AHP that takes into account the selection criteria mentioned above. The project and goal of the process, which is the first level of the hierarchy, is the selection of the best CT Laser among different alternatives. The selected criteria represent the first step of the analysis to compare various alternatives and to prioritize medical equipment. This latter is the second level of the hierarchy, composed of nine main criteria: Vendor Service, Cost of Adoption, Maintenance Requirements, Calibration, Level of Personnel, Design Specifications, Performance Evaluation, and Manufacturers' Database. Sub criteria, then, are presented for the Performance Evaluation criteria to clarify the element better. They are Useful Life Ratio, Mean Time Between Failures, Efficiency and Equipment History. This level is the third one, and the fourth level represents the different potential alternatives that must be evaluated in the choice of the medical device, in the specific case of a CT Laser.

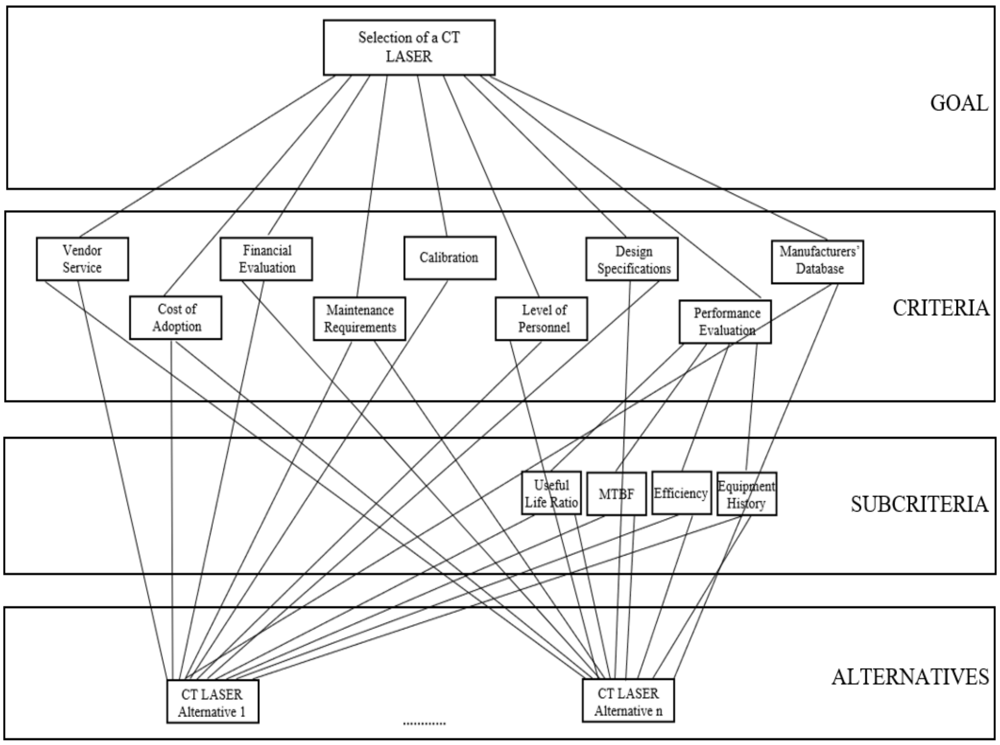

Figure 10 "AHP Hierarchy"

After having presented the levels of hierarchy for the AHP, there are shown the two pairwise matrixes. The first pairwise matrix is related to the comparison of the first level of the hierarchy, the criteria, and it is presented hereafter:

	Vendor Service	*Cost of Adoption*	*Financial Evaluation*	*Maintenance Requirements*	*Calibration*	*Level of Personnel*	*Design Specifications*	*Performance Evaluation*	*Manufacturers' Database*
Vendor Service	**1,00**	6,00	1,20	0,75	1,50	1,00	1,50	0,86	0,75
Cost of Adoption	0,17	**1,00**	0,20	0,13	0,25	0,17	0,25	0,14	0,13
Financial Evaluation	0,83	5,00	**1,00**	0,63	1,25	0,83	1,25	0,71	0,63
Maintenance Requirements	1,33	8,00	1,60	**1,00**	2,00	1,33	2,00	1,14	1,00
Calibration	0,67	4,00	0,80	0,50	**1,00**	0,67	1,00	0,57	0,50
Level of Personnel	1,00	6,00	1,20	0,75	1,50	**1,00**	1,50	0,86	0,75
Design Specifications	0,67	4,00	0,80	0,50	1,00	0,67	**1,00**	0,57	0,50
Performance Evaluation	1,17	7,00	1,40	0,88	1,75	1,17	1,75	**1,00**	0,88
Manufacturers' Database	1,33	8,00	1,60	1,00	2,00	1,33	2,00	1,14	**1,00**
Total	8,17	49,00	9,80	6,13	12,25	8,17	12,25	7,00	6,13

Table 24 "Criteria VS Criteria Matrix"

Each criterium has been compared with all the other criteria; in particular, the vendor service, for example, has been compared with the cost of adoption, the financial evaluation, etc., so column versus row. In each quadrant of the above part of the matrix, the ratio between relative weights has been placed. On the below section of the matrix, instead, the reciprocal of the respective number has been placed. Finally, the last row corresponds to the sum of the above columns. In this way, the first matrix has been computed and will serve as an input to create the normalized one from which the relative weights of the criteria will be calculated.

The second matrix is related to the comparison of the sub-criteria of the primary criterium Performance Evaluation, presented in *Table 5.10*. Instead, in *Table 5.9*, there are the relevance weights of each sub criterium, taken from the Taxonomy Table with the cumulated recurrence numbers (*Table 5.1*):

Selected Sub Criteria	***Relevance Weight***
Useful Life Ratio	**1**
MTBF	**8**
Efficiency	**2**
Equipment History	**13**

Table 25 "Performance Evaluation Sub Criteria"

	Useful Life ratio	*MTBF*	*Efficiency*	*Equipment History*
Useful Life ratio	**1,00**	0,13	0,50	0,08
MTBF	8,00	**1,00**	4,00	0,62
Efficiency	2,00	0,25	**1,00**	0,15
Equipment History	13,00	1,63	6,50	**1,00**
Total	24,00	3,00	12,00	1,85

Table 26 "Sub Criteria VS Sub Criteria Matrix"

Also, for this matrix, the same reasonings of the precedent one can be made. In this case, too, the results that will be obtained are the relative weights of the sub-criteria. The last step should be the creation of pairwise matrixes, where the alternatives are compared for each criterium and sub criterium, so, for: Vendor Service, Cost of Adoption, Maintenance Requirements, Calibration, Level of Personnel, Design Specifications, Manufacturers' Database, and Useful Life Ratio, Mean Time Between Failures, Efficiency and Equipment History. For a total of eleven tables, where on the row and the column, there are the possible alternative CT Laser machines.

From these tables, it will be possible to obtain the weights of the alternatives concerning each criterium and sub criterium, in such a way the final weight for each alternative can be calculated, and the final decision on the selection of the CT Laser can be taken. As already explained in Chapter 3, it has been decided to choose the AHP tool for its applicability when dealing with multiple criteria and, for its power in supporting the decision-making process in the choice, in the specific case, among critical medical devices.

5.4.3. Analysis Considerations

In conclusion, the Framework developed and presented by candidates, represents a reliable tool for healthcare providers and clinical engineers, or more in general for healthcare organizations' employees, for many reasons that are sum up below:

- It can be used as an input for both retrospective and prospective analysis. A combined application of prospective and retrospective investigation can be a reliable instrument for healthcare organizations. The retrospective method is used to analyze errors and to prevent their recurrence, while the prospective one to anticipate those errors;
- For what concerns the retrospective analysis, it can address the failure to the respective causes. Since it could be time-consuming and complex to trace all the potential sources of errors, with the proposed Framework, some sources of risk, that probably were not considered before, are provided;

- It can be used to verify if the factors considered in developing its Asset/Risk Management policies correspond to those presented in this study, since thanks to the Taxonomy developed, it is possible to search among a broad spectrum of factors;
- It is scalable and can be continuously updated;
- From a prospective point of view, the Taxonomy and the Framework can serve as anticipative tools to detect possible risks, in Asset Management functional areas or along the asset life cycle stages;
- It can be used as an input for the AHP methodology, and also for other prospective techniques of Risk Management such as the FMEA and the FMECA.

6. CONCLUSIONS AND FUTURE DEVELOPMENTS

The last chapter of this study aims at synthesizing the significant findings of the study. Results are articulated into three different sections. In the first one, findings related to literature analysis report an overview of the current state of the art regarding Asset Management and Risk Management main topics. Then, results coming from the proposed Framework of analysis are presented. Finally, qualitative findings emerged from a real-case application of the methodology. In the end, the last paragraph is added to propose possible future developments of the method and to stimulate discussion.

As mentioned above, the first conclusion, candidates reached, was the lack of an integrated contribute in healthcare literature able to consider potential risks for patient safety connected with medical equipment management. Such absence remains evident since researches were conducted from both Asset Management perspectives and Risk Management perspectives. If an integrated approach completely lacks, the contribution of both views independently is exhaustive. In particular, literature concentrates on the middle of the life of Medical Equipment for almost 73% of its overall contribution. The most significant majority of AM studies focus on maintenance and performance reliability analysis, while the implementation of Risk Management techniques represents the most significant area of interest for RM experts. Another miss to be evidenced regards an elaborated Taxonomy able to synthesize potential organizational and operational issues that may affect healthcare activities.

The implementation of the described methodology on a sample of 26 papers, equally distributed among Asset and Risk Management areas, allowed to evidence different criticalities and fields of interest in healthcare organizations.

The first finding refers to the main functional areas having a direct impact on the outcome of healthcare performances and their possible implications for patient safety. Operations Area has resulted in that with more significant influence. 33% of potential risks come from errors or misunderstandings directly in performing routine activities. The other areas that mostly resulted in representing a risk for healthcare organizations are Quality (19%), Safety & Security (15%), and HR (10%). Those having a lower impact are Logistics and External Stakeholders Influence, both with values below 5%. Still considering medical equipment management, the study revealed which lifecycle stage has the highest relevance for the implementation of an effective Asset Management policy. From findings, emerge how the Planning represents the phase that most influence the correct management of a medical device. Almost one-fourth of the overall decisions regarding ME management should be undertaken in this stage, as well as relative analysis. High relevance is also attributed to Maintenance and Acquisition stages, 17% and 12%, respectively.

In general, MOL is confirmed as the medical equipment moment that requires more considerable attention, verifying a trend already existent in literature. However, Beginning Of Life activities demonstrated to have a similar impact on the overall performance of ME.

From a Risk Management perspective, factors analysis allowed us to identify which steps of the Risk Management process require more considerable attention. The highest number of factors evidenced in literature are countermeasures applicable in the Implementation phase (37%). Significant influence is also attributed to factors belonging to the Risk Evaluation stage that counts for 27% of the total. Almost the same is the impact of the other three steps (Risk Identification, Risk Analysis, Monitoring, and Improvement), which is stable between 10% and 15% of the total.

The implementation of SHELL methodology allowed us to adopt a different approach, able to put human factors at the center of risk analysis and enabled evidence which area requires more considerable attention. Among the four presented, Liveware – Software interaction can reduce potential risks for healthcare organizations mostly. 43% of factors concentrate, in fact, in this area. 39% is instead related to L - H relationship, while lower interest is registered by L – L and L – E interacts (8% and 11% respectively).

Table Framework also evidences a more homogeneous distribution of decisional factors influencing patient safety compared to performance factors. In the first case, areas registering a medium-high interest from experts represent 36% of the total, while for performance elements, such value decreases to 22%. Major criticalities for decisional factors have been identified in the lack of interest for the risk identification phase, in particular regarding the maintenance, user training, and inventory lifecycle stages. Oppositely, for performance factors, Strategy and Cost represent functional areas requiring specific attention from experts.

Finally, the application of the proposed methodology in the real case for the Radiotherapy department offered other insights.

The retrospective application allowed the RT department to use Taxonomy developed to perform an in-depth root cause analysis, addressing responsibilities to different areas inside the healthcare organizations. Human Resources area resulted as the department major responsible for mistakes in RT with 35% weight: the absence of practical training sessions for personnel and lack of clinical experience are critical factors for this finding. Quality and Administrative issues also represent fundamental aspects of being managed. The Framework also allowed to rank potential risks for patient safety through an opposite criticality index. CT Laser out of alignment resulted as a significant source of uncertainty in radiotherapy activities.

On the other side, prospective application results in the development of a prioritization tool for CT Laser acquisition. The instrument structure follows an AHP approach, whose evaluation criteria have been qualitatively selected among those proposed in the Taxonomy. Manufacturers' database availability, maintenance requirements, and technical level of personnel resulted in being the most relevant variables to be considered.

Potential further applications of the methodology proposed may result in the adoption of a different perspective in assessing risks for patient safety. A new approach to include medical equipment management in risk evaluations. The proposed real case application in RT should be considered as a standpoint for further utilizations in other healthcare departments as an instrument for both retrospective and prospective evaluations. Each healthcare institution may decide to readapt or reallocate factors evidenced in order to suit its needs better. Excellent adaptability and the possibility for continuous updating are crucial elements that may guarantee future developments to the methodology.

APPENDIX

Appendix 1

Number	Paper	Asset / Risk	Paper focus	Factors Affecting Medical Equipment Management
1	*A Fuzzy Logic Model for Medical Equipment Risk Classification*	Risk	MOL - Maintenance	available budget, function, maintenance requirements, physical risk, operational conditions, equipment characteristics, criticality of equipment, management standards, prioritization, mission criticality, utilization rate, backup safety availability, MEMP
2	*Prioritization of medical equipment for maintenance decisions*	Asset	MOL - Maintenance	RCM, Prioritization (Function, Mission Criticality, Age, Risk, Hazard Recalls, MR, Utilization Rate, Availability, Failure Frequency, Detectability, Failure Consequence, Operational, Downtime, Non-Operational, Cost of Repair, Safety and Environment), Inspection, PM, Testing of medical equipment, classification of medical equipment, CMMS
3	*Failure Mode, Effects and Criticality Analysis (FMECA) for medical devices: Does standardization foster improvements in the practice?*	Asset	MOL - Maintenance	the multidisciplinary risk management team, hazard analysis, Severity, Occurrence, Detection, CA, risk analysis techniques, collecting and organizing information, design specifications, manufacturers database, regulatory agencies, guidance and standards, clinical experience, Company Quality system, database, similar tools analysis, complaints analysis
4	*Multicriteria decision making for Medical equipment maintenance: Insourcing, outsourcing and service contract*	Asset	MOL - Maintenance	maintenance planning, selection and monitoring of different contracts, making recommendations for the purchasing of new devices, contract monitoring, the cost of spare parts, quality control, visual inspection or basic performance check, the training of hospital personnel, training, equipment deterioration, availability of tools, complexity and frequency of failures, CM, PM, failure response time, maintenance strategy, prioritization (function, risk, level of importance of the mission, age, detectability, frequency of failures, downtime, utilization rate, availability of alternative devices), availability of resources, mean time between failures, degree of maintenance complexity
5	*Building Medical Devices Maintenance System through Quality Function Deployment*	Asset	MOL - Maintenance	maintenance period, failure response time, nature of maintenance system, safe medical device, MTBF, training of operators on installation, periodic training of operators, calibration of maintained device, do checkup after maintenance, spare parts availability, PM, existence of redundant device, presence of a medical engineering specialist, administrative procedures, enough staff, infrastructure and transportation within hospital, existence of work specialty, existence of suitable tools, enough budget, suppliers' contracts, device strength, meet standards, continuous education and training.

6	*Medical Equipment Management Strategies*	Asset	Life cycle	equipment failure, individual institution needs, inspection procedures, frequency of use, severity, MEMP, equipment inventory, PM, inclusion criteria, SPI, mission criticality, detectability, equipment hazards, reliability, failure patterns, availability of spares and backup, equipment replacement, maintenance strategy, equipment inventory, IPM program, CE service (eliminating scheduled maintenance, equipment planning and acquisition), education and training of staff, equipment downtime, cost of vendor services, time to obtain spare parts
7	*Medical Device Risk-Based Evaluation and Maintenance Using Fault Tree Analysis*	Risk	MOL	MEMP, scheduled maintenance, instructing clinical staff, training program, PM, IPM (tests and measurements, inspection data, PV activity, PP activity, SPIs), pre-acquisition evaluation, low involvement CE staff, CE experience, multidisciplinary team, mission risk, probability estimation of severity and occurrence (from history of similar devices, manufacturers records, in-house, government, private sector consultant experts), risk management records
8	*Maintenance and Repair of Medical Devices, Clinical Engineering Handbook, Chapter 37*	Asset	MOL	risk management techniques, calibration, standardization of devices, staff training, ownership ward, level of support and technical capabilities, safety and performance testing, usage or hours in service, reliability and failure analysis, routine testing, efficiency, maintenance procedures, maintenance costs, vendor service, medical device management databases, maintenance history, condition monitoring, inspection, maintenance requirements (planning phase), component information, manufacturer service information, test equipment, electrical static protection, parts availability and storage, reconditioned components, testing after repair, purchasing cost
9	*Medical Technology Management: From Planning to Application*	Asset	Life cycle	equipment-selection criteria, supervise installation, training users, monitor post procurement performance, cost accounting analysis, funds availability, prioritization of acquisition, upgrade, replacement of inventory, financial evaluation, resource allocation, vendor's negotiation, installation preparation, risk monitoring, criteria and standards identification, performance evaluation of criteria, cultural leadership, CE role, continuous quality improvement programme: financial review, follow-up study of operational costs, service problems, utilization indicators, replacement; equipment planning, capital equipment matrix
10	*Applying Risk Management Principles to Medical Devices Performance Assurance Program*	Risk	Life cycle	technology assessment, acquisition, inventory control, repair service, in-service education, performance assurance (PA), PA programme: preventive maintenance (PM), performance verification, and safety testing; PM: cleaning, lubricating, adjusting, and replacing; risk management: risk financing, risk control, risk management team; equipment design factors: inappropriate energy output, maintenance requirement, function degradation; equipment characteristics factors: high usage, use area requirement, regulatory factors; inclusion criteria (function risk, physical risk, maintenance requirement); risk control strategies: exposure avoidance, duplication, outsourcing; Inspection frequency: manufacturer recommendation, recalls/alerts, repair, history incidents, communication with stakeholders, personnel surveys

11	*Equipment control and Asset Management, Clinical Engineering Handbook, Chapter 35*	Asset	Life cycle	CMMS, inclusion criteria, scheduled maintenance (inventory, procedures, scheduling, monitoring), equipment function, physical risk with use, incident history, risk categories, regulatory control of marketing of MD, risk scores (required maintenance, function, required maintenance, mission criticality), MEMP, measuring performance, equipment lifecycle costs, preventive maintenance, applicable standards, manufacturers information, recognized guidelines (ECRI, ASHE; FDA)
12	*Medical devices Inspection and Maintenance*	Risk	MOL	maintenance costs, reliability engineering techniques, manufacturers' recommendations for Preventive Maintenance (PM), inspection, prioritization, outsourcing, MEIM. IPM (PM, SPI), safety of personnel, environment, . Maintenance strategies: CBM, RCM, RBM, RBI, RB life assessment. Maintenance history, age. MEMP: inspection, PM, inspection
13	*Influential factors on medical equipment maintenance management*	Asset	MOL - Maintenance	7 categories: Resources: physical resources (workspace, tools and equipment), human resources (trained and expert staff), financial resources (cost monitoring, budget management). Quality Control: Safety test (in design, manufacture, installation, use and maintenance), performance tests (clinical tests, functional tests, technical tests) adjustment and calibration. Documentation: process and activities doc, inventory database, Medical device ID (= for info as device specifications, warranty status, service installation, acceptance tests, calibration, etc), user manuals, work order records.Education: Technical and practical training. Service: repair/corrective maintenance, decommissioning, outsourcing, reform and improvement system, reporting adverse events and recall systems. Inspection and Preventive Maintenance: periodic, internal, case and practical inspection, guidelines, preventive maintenance. Designing and Implementation: process management (access level to me, development of policy, infrastructure management, bureaucratic processes, the codification of action plan), knowledge and attitude of managers, purchasing management (selection, procedure) local and global evidence/standards
14	*Healthcare Technology: A Strategic Approach to Medical Device Management*	Asset	Life cycle	preventive maintenance, repairs, incoming inspections, manufacturers recommendations, ECRI standards, policies, documentation, functional check, performance verification, risk-based planning, equipment history, CMMS (including hospital equipment ID, description, manufacturer, primary service provider, maintenance information, risk category, equipment status, vendor, costs, installation date), corrective work orders, staff training, outsourcing, temperature control, MEMP, alerts and recall plan, incident/failure reporting, incident response plan, equipment planning, total cost of ownership, level of standardization, RPMs

15	*A Hybrid Decision-Making Model for Maintenance Prioritization in Health Care Systems*	Asset	MOL - Maintenance	DMs (=pool of clinical engineers: problem definition, variables identification, documentation), prioritization (probability scores, voting power, AHP process), maintenance policies: CM, PM, condition-based maintenance CBM. Inclusion criteria (function, recalls and hazards alerts, utilization rate, redundancy, age, technology obsolescence, maintenance requirements, risk), detectability, occurrence, consequences for patient safety, economic loss, environment
16	*Factors Affecting Medical Equipment Maintenance Management: A Systematic Review*	Risk	Life cycle	Equipment purchases, System design Organization and coordination Equipment control section, Parts management Vendor service management Service contract management Maintenance insurance Business/employee directories Prioritizing maintenance requests Planning of new Construction and major renovation, MEMP, RCM, Predictive maintenance PM, CM, SM, Acquisition planning, Work order management system Risk-based planning, Existence of work specialty, Enough staff, Existence of administrative person, Enough budget, CMMS, Prominent guidance, international Standards, Manufacturer data, Equipment history, Failure data, Hospital intranet system, Documentation, IT systems, Computer network and Database information Management, Internal and external Service records, Service contract and Purchasing information Reporting, Age equipment, replacement decision, Medical equipment DT, Repairs and replacement, Failure data Failure response time, High MTBF, contracts, equipment and stock parts inventory, Medical equipment condition, Operator check, Installation verification, Warranty inspection, Safety and performance inspection, Incoming inspections, Spare parts availability, Functional checks, Cost control, Existence of redundant Device, Administrative procedures, Infrastructure & Transportation within Hospital Existence of suitable tools, Training of operators on installation, Trained staff, Training programs, Level of technical know- How, Test equipment Acceptance test Technical inspection (safety, Operational and calibration checks) Risk support capabilities, Quality assurance program, Security, Risk management, SPI, Equipment quality control, Calibration and technical Analysis, Electrical safety checks, Do checkup after Maintenance, Alerts and hazards
17	*Planning Medical Technology Management in a Hospital*	Asset	Life cycle	system integration, facility preparation, staff planning, standards of care, operating costs, environmental impact, function, department requirements, skill level of personnel, supporting departments, cost of ownership and adoption, multidisciplinary team of users, user capability, compliance with regulations, repair time, failure rate, medical equipment upgrade, replacement, systematic protocol for replacement, strategy for identifying emerging technologies, multi-year planning for replacement, assessment methodology, clinical engineering knowledge, user interface, design, level of patient satisfaction

18	*Comprehensive Frameworks for decision.making support in medical equipment management*	Asset	Life cycle	function of equipment, physical risk, maintenance requirements, utilization level, area criticality, device criticality, failure rate, useful life ratio, device complexity, missed maintenance, downtime ratio, number of equipment, PM duration, efficiency, durability, quick response of technical team, back up availability, availability of operating instructions, existence of contact person, updating, spare parts, availability, type of service provider, standard compliance, mission criticality, age, labeling, electrical safety testing, regular inspections, complexity of devices, activities recording, equipped workshop, service manual availability.
19	*Failure mode and effects analysis applied to the maintenance and repair of anesthetic equipment in an austere medical environment*	Risk	MOL - Maintenance	access to spare parts, communication between biomedical engineers and clinical staff, resource availability, no proper training, lack of physical access to the machine, unavailability of the machine, absence of biomedical engineers' support, environmental conditions (e.g. heat, humidity and dust)
20	*Assessing Risk in the Kaiser Permanente Clinical Technology Program*	Risk	Life cycle	CMMS, regional variations in staffing levels, regional variations in policies and procedures, regional variations in scope of services, regional variations in operational issues, services provided, number of technologies provided, life cycle moment, role of clinical technology team, patient safety, staff safety, compliance with regulations, reputation, financial impact, severity, occurrence, decommissioning, equipment incident investigation, maintenance policy,
21	*An Integrated Nine-Step Approach to Managing Clinical Technology Risks*	Risk	Life cycle	strategic plan, variable staffing, lack of clinical tech career growth, inconsistent management of recalls, inconsistent decommissioning practices, multiple inventory systems, inability of quickly pull accurate inventory data, lack of comprehensive reporting, budget planning, negotiation at time of equipment purchase and after, leadership, contract management, clinical technology inventory costs, decommissioning costs, collaboration with stakeholders, process ownership, CMMS, IT systems, public relations, patient safety, regulations and policies, risk management units, communication, Joint Plan, governance, dashboards
22	*A comprehensive fuzzy risk-based maintenance framework for prioritization of medical devices*	Risk	MOL - Maintenance	age, equipment function, mission criticality, recalls, inspection, maintenance, evaluation, maintenance requirements, physical risks, hazard analysis (chance of no-detection), method of failure detection , ability of maintenance personnel, mean time between failures, repeatability, impact on patient safety, impact on the maintenance resources, economic loss, available identical machineries, usage-related hazards, utilization

23	*Human reliability assessment for medical devices based on failure mode*	Risk	Life cycle	design errors, design-inducing errors (use error of the technician), software: operation training, knowledge training, organizational rules, procedures; liveware: leadership, communication, cooperation, cognitive difference; environment: acoustic, luminous, environment, thermal; hardware: workspace, interface, occurrence, severity, detection,
24	*Risk-based maintenance—Techniques and applications*	Risk	MOL - Maintenance	quality risk analysis: preliminary hazard analysis, data and info, hazard analysis, risk estimation, frequency estimation, consequence estimation, function analysis, uncertainty, and sensitivity analysis, equipment deterioration, product quality, environmental impact, inspection, physical conditions, occurrence, hazard identification method
25	*A multicriteria decision making approach applied to improving maintenance policies in healthcare organizations*	Risk	MOL - Maintenance	purchasing costs, installation costs, direct labor costs, spare parts costs, degree of acceptance among personnel, quality of service derogated, impact on care cover, maintenance policy
26	*Elements of Risk Assessment in Medical Equipment*	Risk	Life cycle	CMMS, scheduled maintenance, repairs history, software upgrades, accident investigations, frequency of inspection, equipment function, physical risk, temperature, electrical safety, communication, education

Table 27 "Factors for Papers' Division"

Appendix 2

Legend	Factors from Asset Papers	Paper	Total count
1	*Availability*	2, 18	2
1	*Availability of tools*	4	1
1	*Redundancy*	15	1
2	*Availability of resources*	4	1
2	*Availability of budget*	5	1
2	*Availability of funds*	9	1
2	*Resource allocation*	9	1
2	*Budget management*	13	1
3	*Similar tools analysis*	3	1
3	*Availability of alternative devices*	4, 5	2
3	*Existence of suitable tools*	5	1
4	*Utilization rate*	2, 4, 15, 18	4
4	*Frequency of use*	6	1
4	*Usage of hours in service*	8	1
4	*Utilization indicators*	9	1
5	*Cost of spare parts*	4	1
5	*Availability of spare parts*	5, 6, 8, 18	4
5	*Time to obtain spare parts*	6	1
6	*Equipment deterioration*	4	1
6	*Durability*	18	1
7	*Maintenance planning*	4	1
7	*Maintenance period*	5	1
7	*Maintenance scheduled*	11	1
7	*Maintenance complexity*	4	1
7	*Missed maintenance*	18	1
8	*Level of support and technical capabilities*	8	1
8	*Level of personnel*	17	1
8	*User capability*	17	1
9	*Function*	2, 4, 11, 15, 17, 18	6
9	*Equipment function*	11	1
10	*Equipment hazards*	6	1
10	*Hazard recalls*	2, 6, 13, 15	4
10	*Hazard analysis*	3	1
11	*Equipment failure*	6	1
11	*Failure patterns*	6	1
11	*Equipment history*	14	1
11	*Failure consequence*	2	1
11	*Maintenance history*	8	1
11	*Incident history*	11	1

12	*Downtime*	2, 4, 6, 18	4
12	*Failure response time*	4, 5	2
12	*Repair time*	17	1
12	*Quick response of technical team*	18	1
13	*Safety and environment*	2	1
13	*Environment*	15	1
13	*Environmental impact*	17	1
14	*Electrical static protection*	8	1
14	*Electrical safety testing*	18	1
15	*Upgrade*	9	1
15	*Medical equipment upgrade*	17	1
15	*Updating*	18	1
16	*Availability of backup*	18	1
17	*Workspace, tools, and equipment*	13	1
17	*Equipped workshop*	18	1
17	*Area criticality*	18	1
18	*Mission criticality*	2, 4, 6, 11, 18	5
18	*Criticality analysis*	3	1
19	*Multidisciplinary risk management team*	3	1
19	*Multidisciplinary team of users*	17	1
20	*Equipment replacement*	6, 17	2
20	*Replacement of inventory*	9, 17	2
20	*Systematic protocol for replacement*	17	1
20	*Multi-year planning for replacement*	17	1
21	*Failure frequency*	2, 4, 17, 18	4
21	*MTBF*	4, 5	2
22	*Inspection procedures*	2, 6, 8, 13, 14, 18	6
22	*IPM programs*	6	1
23	*Strength of device*	5	1
23	*Complexity of device*	18	1
24	*Process management*	13	1
25	*Regulatory Agencies*	3	1
25	*Guidance and standards*	3	1
25	*Recognized guidelines (ECRI, ASHE, FDA)*	11	1
25	*Standards of care*	17	1
25	*ECRI standards*	14	1
26	*Standards/regulation compliance*	5, 17, 18	3
26	*Standards applicability*	11	1
26	*Use of local/global standards*	13	1
27	*Existence of a contact person*	18	1
28	*Selection and monitoring of different contracts*	4	1
28	*Contract monitoring*	4	1

28	*Suppliers contracts*	5	1
29	*User interface*	17	1
30	*Performance evaluation of criteria*	9	1
30	*Measuring performance*	11	1
30	*Performance test*	13	1
30	*Performance verification*	14	1
30	*Functional check*	14	1
31	*Testing of medical equipment*	2	1
31	*Visual inspection*	4	1
31	*Condition monitoring*	8	1
31	*Test equipment*	8	1
32	*Safe medical device*	5	1
32	*Safety and performance testing*	8	1
32	*SPI*	6	1
32	*Safety test*	13	1
33	*Supporting departments*	17	1
34	*Check up after maintenance*	5	1
34	*Testing after repair*	8	1
35	*Presence of a medical engineering specialist*	5	1
35	*Existence of work specialty*	5	1
35	*CE service (eliminate Scheduled maintenance, equipment planning and acquisition)*	6	1
35	*CE role*	9	1
36	*MEMP*	6, 11, 14	3
36	*Equipment planning*	9, 14	2
37	*Manufacturers database*	3, 11	2
37	*Purchasing recommendation*	4	1
37	*Manufacturers recommendation*	14	1
37	*DMs*	15	1
38	*Routine testing efficiency*	8	1
38	*Assessment methodology*	17	1
39	*Availability of staff*	5	1
39	*Staff planning*	17	1
40	*Company quality system*	3	1
40	*Quality control*	4	1
40	*Quality improvement program*	9	1
40	*Improvement system*	13	1
41	*Financial evaluation*	9	1
41	*Financial review*	9	1
41	*Economic loss*	15	1
42	*Collection and organization of info*	3	1
42	*Documentation of processes and activities*	13	1
42	*Work order records*	13, 14	2

42	*Failure reporting*	14	1
42	*Activities recording*	18	1
43	*Risk-based planning*	14	1
44	*MR*	2	1
44	*Maintenance requirements*	8, 11, 15, 18	4
45	*Classification of medical equipment*	2	1
45	*Database*	3	1
45	*Equipment inventory*	6	1
45	*Medical device management database/ID*	8, 13	2
45	*Equipment capital matrix*	9	1
45	*Inventory database*	13	1
46	*Temperature control*	14	1
47	*Training of personnel in hospital*	4, 5, 8, 9, 13, 14	6
47	*Education and training*	5, 6	2
48	*RCM*	2	1
48	*Reliability*	6	1
48	*Reliability and failure analysis*	8	1
48	*RPMs*	14	1
49	*Risk analysis and management techniques*	3, 8	2
49	*Risk categories*	11	1
50	*Cost accounting analysis*	9	1
50	*Equipment lifecycle cost*	11	1
50	*Cost monitoring*	13	1
51	*Cost of vendors service*	6	1
51	*Vendor service*	8	1
51	*Manufacturer service information*	8	1
51	*Service problems*	9	1
52	*Outsourcing*	13, 14	2
53	*Supervise installation*	9	1
53	*Installation preparation*	9	1
54	*Maintenance procedure*	8	1
55	*Physical risk*	11, 18	2
56	*Risk monitoring*	9	1
57	*Vendor negotiation*	9	1
58	*Maintenance cost*	8	1
59	*Infrastructure and transportation*	5	1
60	*Leadership*	9	1
61	*Calibration of maintained device*	5, 8, 13	3
62	*Training on installation*	5	1
63	*Maintenance strategy*	4, 6	2
64	*Decommissioning*	13	1
65	*System integration*	17	1

66	*Purchasing cost*	8	1
66	*Purchasing management*	13	1
67	*Frequency of repairs*	14	1
68	*Design specifications*	3, 17	2
69	*Administrative procedures*	5	1
70	*Prioritization*	2, 4, 11	3
71	*PM*	2, 4, 5, 6, 11, 13, 14, 15, 18	9
72	*CMMS*	2, 11, 14	3
73	*Age*	2, 3, 15, 18	4
74	*SOD-Severity Occurrence Detection*	2, 3, 4, 6, 15	5
75	*Clinical experience and Knowledge*	3, 17	2
75	*Knowledge and attitude of managers*	13	1
76	*CM*	4, 13, 15	3
77	*Number of equipment*	18	1
101	*Cost of repair*	2	1
102	*Maintenance system*	5	1
103	*Institution needs*	6	1
104	*Standardization of devices*	8, 14	2
105	*Component information*	8	1
106	*Reconditioned components*	8	1
107	*Prioritization of acquisition*	9	1
108	*Regulatory control of marketing*	11	1
109	*CBM*	15	1
110	*Technology obsolescence*	15	1
111	*Facility preparation*	17	1
112	*Department requirements*	17	1
113	*Strategy for identifying emerging tech*	17	1
114	*Labeling*	18	1
115	*Efficiency*	8, 18	2
116	*Useful life ratio*	18	1
117	*User manuals*	13	1
117	*Service manual availability*	18	1
117	*Availability of operating instructions*	18	1
118	*Complaints analysis*	17	1
118	*Level of patient satisfaction*	17	1
119	*Monitor post procurement performance*	9	1
119	*Follow-up study of operational costs*	9	1
119	*Operating costs*	17	1
120	*Incident response plan*	14	1
120	*Alerts and recalls plan*	14	1
121	*Inclusion criteria*	6, 11	2
121	*Equipment selection criteria*	9	1

121	*Criteria and standards identification*	9	1
122	*Ownership ward*	8	1
122	*Total cost of ownership*	14, 17	2
123	*Cost of adoption (personal training)*	17	1

Table 28 "Initial Factors' Table for Asset Papers"

Legend	Aggregated Asset Factors	Recurrence
1	*Availability of tools*	4
2	*Budget management*	5
3	*Similar tools analysis*	4
4	*Utilization rate*	7
5	*Management of spare parts*	6
6	*Equipment deterioration*	3
7	*Maintenance planning*	5
8	*Level of personnel*	3
9	*Function*	7
10	*Hazard analysis*	5
11	*Equipment history*	6
12	*Downtime*	8
13	*Environment*	3
14	*Electrical safety testing and protection*	2
15	*Medical equipment upgrade*	2
16	*Availability of backup*	1
17	*Workspace analysis*	4
18	*Mission criticality*	6
19	*Multidisciplinary risk management team*	2
20	*Equipment replacement*	6
21	*MTBF*	6
22	*Inspection procedures*	7
23	*Equipment characteristics*	2
24	*Process management*	1
25	*Recognized guidelines and standards (ECRI, ASHE, FDA)*	5
26	*Standards/regulation compliance*	5
27	*Administrative person*	1
28	*Selection and monitoring of different contracts*	3
29	*User interface*	1
30	*Performance evaluation*	5
31	*Testing of medical equipment*	4
32	*Safety testing*	4
33	*Supporting departments*	1
34	*Testing after repair*	2
35	*CE service and presence*	4
36	*Equipment planning*	5
37	*Manufacturers database*	5
38	*Assessment methodology*	2
39	*Availability of staff*	2
40	*Company quality system*	4
41	*Financial evaluation*	3

42	*Recording of processes and activities*	6
43	*Risk-based planning*	1
44	*Maintenance requirements*	5
45	*Medical device management database/ID*	7
46	*Temperature control*	1
47	*Training of personnel in hospital*	8
48	*Reliability and failure analysis*	4
49	*Risk analysis and management techniques*	3
50	*Equipment lifecycle cost*	3
51	*Vendor service*	4
52	*Outsourcing*	2
53	*Supervise installation*	2
54	*Maintenance policy*	1
55	*Physical risk*	2
56	*Risk monitoring*	1
57	*Vendor negotiation*	1
58	*Maintenance cost*	1
59	*Infrastructure and transportation*	1
60	*Leadership*	1
61	*Calibration*	3
62	*Training on installation*	1
63	*Maintenance strategy*	2
64	*Decommissioning*	1
65	*System integration*	1
66	*Purchasing management*	2
67	*Frequency of repairs*	1
68	*Design specifications*	2
69	*Administrative procedures*	1
70	*Prioritization*	3
71	*PM*	9
72	*CMMS*	3
73	*Age*	4
74	*SOD-Severity Occurrence Detection*	5
75	*Clinical experience and knowledge*	3
76	*CM*	3
77	*Number of equipment*	1
101	*Cost of repair*	1
102	*Maintenance system*	1
103	*Institution needs*	1
104	*Standardization of devices*	2
105	*Component information*	1
106	*Reconditioned components*	1

107	*Prioritization of acquisition*	1
108	*Regulatory control of marketing*	1
110	*CBM*	1
111	*Technology obsolescence*	1
112	*Facility preparation*	1
113	*Department requirements*	1
114	*Strategy for identifying emerging tech*	1
115	*Labeling*	1
116	*Efficiency*	2
117	*Useful life ratio*	1
118	*Availability of operating instructions*	3
119	*Level of patient satisfaction*	2
120	*Monitor post procurement performance and operating costs*	3
121	*Incident response plan*	2
122	*Equipment selection criteria*	4
123	*Total cost of ownership*	3
124	*Cost of adoption (personal training)*	1

Table 29 "Aggregated Factors' Table for Asset Papers"

Legend	Factors from Risk Papers	Papers	Total count
1	*Duplication*	10	1
1	*Repeatability*	22	1
1	*Availability identical machines*	22	1
1	*Lack of physical access to machines*	19	1
1	*Availability of machines*	19	1
1	*Existence of redundant device*	16	1
2	*Availability of budget*	1, 16	2
2	*Budget planning*	21	1
2	*Availability of resources*	19	1
3	*Existence of suitable tool*	16	1
4	*Utilization rate*	1, 22	2
4	*Equipment use factors*	10	1
4	*Usage related hazard*	22	1
5	*Spare parts cost*	25	1
5	*Availability of spare parts*	16, 19	2
5	*Management of parts*	16	1
5	*Equipment and stock parts inventory*	16	1
6	*Function degradation*	10	1
6	*Equipment deterioration*	24	1
6	*Physical condition*	24	1
7	*Scheduled maintenance*	7, 26	2
7	*Impact on maintenance resources*	22	1
7	*SM*	16	1
7	*Maintenance insurance*	16	1
8	*Cognitive difference*	23	1
8	*Ability of maintenance personnel*	22	1
8	*Level of technical know-how*	16	1
9	*Function*	1, 10, 22, 24, 26	5
10	*Hazard analysis*	24, 16, 22	3
10	*Method of failure detection*	22	1
10	*Management of recalls*	21	1
11	*Repairs history*	26	1
11	*Frequency of recalls*	10, 22	2
11	*History of incidents*	10	1
11	*Maintenance history*	12	1
11	*Equipment history*	16	1
11	*Failure data*	16	1
12	*Repair service*	10	1
12	*Failure response time*	16	1
13	*Environment*	12, 19, 24	3

14	*Electrical safety*	16, 26	2
14	*Inappropriate energy output*	10	1
15	*Software upgrades*	26	1
16	*Availability of backup*	1	1
17	*Acoustic environment*	23	1
17	*Luminous environment*	23	1
17	*Thermal environment*	23	1
17	*Workspace*	23	1
17	*Operational conditions*	1	1
18	*Criticality of equipment*	1	1
18	*Mission criticality*	1, 7, 22	3
19	*Multidisciplinary team*	7	1
19	*Risk management team*	10	1
20	*Replacement decisions*	16	1
21	*MTBF*	16, 22	2
22	*IPM*	7	1
22	*Inspection frequency*	10, 26	2
22	*Inspection program*	12, 16, 22, 24	4
22	*Equipment quality control*	16	1
22	*Check of operator*	16	1
22	*Inspection of technicality*	16	1
23	*Equipment characteristics*	1, 10	2
24	*Process ownership*	21	1
25	*Regulations FDA, ECRI*	7	1
25	*Regulations and policies*	21	1
25	*International standards*	16	1
26	*Standards management*	1	1
26	*Compliance with regulations*	20	1
27	*Existence of administrative person*	16	1
28	*Contract management*	21	1
28	*Service contract management*	16	1
29	*User Interface*	23	1
30	*PA program*	10	1
30	*Performance verification*	10	1
31	*Inventory control*	10	1
31	*Equipment control*	16	1
31	*Condition Monitoring*	16	1
31	*Functional checks*	16	1
31	*Equipment test*	16	1

32	*Safety testing*	10	1
32	*SPI*	12	1
32	*Inspection of warranty*	16	1
32	*Inspection of safety and performance*	16	1
32	*SPI Safety and Performance Inspection*	16	1
33	*Risk support capabilities (supporting departments)*	16	1
34	*Checkup after maintenance*	16	1
35	*CE staff involvement*	7	1
35	*CE experience*	7	1
35	*Role of clinical technology team*	20	1
35	*Absence of biomedical engineers support*	19	1
35	*Existence of work specialty*	16	1
36	*MEMP*	1, 7, 12, 16	4
37	*Manufacturer recommendations*	10, 12	2
37	*Manufacturer data*	16	1
38	*Technology assessment*	10	1
39	*Variable staffing*	21	1
39	*Availability of staff*	16	1
40	*Quality risk analysis*	24	1
40	*Quality assurance program*	16	1
41	*Economic loss*	22	1
41	*Financial impact*	20	1
42	*Data and info*	7, 16, 24	3
42	*Ability of quickly full accurate inventory data*	21	1
42	*Lack of comprehensive reporting*	21	1
42	*Work order management system*	16	1
42	*Computer network and database info management*	16	1
42	*Internal and external service records*	16	1
43	*Risk-based planning*	16	1
44	*Maintenance requirements*	1, 10, 22	3
45	*MEIM*	12	1
45	*Multiple inventory systems*	21	1
45	*Medical equipment DT*	16	1
46	*Temperature control*	26	1
47	*Training of clinical staff*	7, 16, 19	3
47	*Education*	25	1
47	*In-service education*	10	1
47	*Training of operations and knowledge*	23	1
48	*Reliable engineering technique*	12	1

48	*RCM*	16	1
49	*Risk management*	7, 10, 16	3
49	*Preliminary risk analysis*	24	1
49	*Risk estimation*	24	1
49	*Risk management unit*	21	1
50	*Cost control*	16	1
51	*Service provided*	20	1
51	*Vendor service management*	16	1
52	*Outsourcing*	10, 12	2
53	*Installation verification*	16	1
54	*Maintenance policy*	20, 25	2
55	*Physical risks*	1, 10, 22, 26	4
56	*Risk control strategies*	10	1
57	*Negotiation*	21	1
58	*Maintenance cost*	12	1
59	*Infrastructure and transportation*	16	1
60	*Leadership*	21, 23	2
60	*Prominent guidance (Leadership)*	16	1
61	*Calibration*	16	1
62	*Traning on installation*	16	1
63	*Maintenance strategy*	12	1
64	*Decommissioning*	20, 21	2
64	*Decommissioning cost*	21	1
65	*Cooperation*	23	1
65	*Coordination*	16	1
65	*Design system (system Integration)*	16	1
66	*Acquisition planning (purchasing management)*	10, 16	2
66	*Equipment purchase (purchaising management)*	16	1
66	*Purchasing cost*	25	1
67	*Frequency of repairs*	16	1
68	*Design errors (Design Specifications)*	23	1
68	*Design inducing errors (Design Specifications)*	23	1
69	*Organizational rules (administrative procedures)*	23	1
69	*Administrative procedures*	16	1
70	*Prioritization*	1, 12	2
71	*PM*	7, 10, 12, 16	4
72	*CMMS*	16, 20, 21, 26	4
73	*Age*	12, 16, 22	3
74	*SOD-Severity Occurrence Detection*	7, 20, 23, 24	4

75	*Lack of clinical tech career growth (clinical experience)*	21	1
76	*CM*	16	1
77	*Number of equipment*	20	1
201	*Training program*	7, 16	2
202	*Pre-acquisition evaluation*	7	1
203	*Communication*	10, 19, 21, 23, 26	5
204	*Installation cost*	25	1
205	*Direct labor cost*	25	1
206	*Degree of acceptance among personnel*	25	1
207	*Risk financing*	10	1
208	*Uncertainty and sensitivity analysis*	24	1
209	*Strategic plan*	21	1
210	*Clinical technology inventory costs*	21	1
211	*Stakeholder collaboration*	21	1
212	*Public relations*	21	1
213	*Dashboards*	21	1
214	*Joint plan*	21	1
215	*Life cycle moment*	20	1
216	*Reputation*	20	1
217	*Acceptance test*	16	1
218	*Planning of new construction and major renovation*	16	1
219	*Quality of service erogated*	25	1
219	*Impact on care cover*	25	1
219	*Product quality*	24	1
220	*Exposure avoidance*	10	1
221	*Governance*	21	1
221	*Business/employee directories*	16	1
222	*Equipment incident investigation*	20	1
222	*Accident investigations*	26	1
223	*Safety of personnel*	12	1
223	*Staff safety*	20	1
223	*Security*	16	1
224	*Regional variations in staffing level*	20	1
224	*Regional variations in policies and procedures*	20	1
224	*Regional variations in scope of service*	20	1
224	*Regional variations in operational issues*	20	1
225	*Impact on patient safety*	22	1
225	*Patient safety*	20, 21	2
226	*IT systems*	16, 21	2

226	*Hospital intranet system*	16	1
227	*Personnel survey*	10	1

Table 30 "Initial Factors' Table for Risk Papers"

Legend	Aggregated Risk Factors	Recurrence
1	*Availability of tools*	6
2	*Budget management*	4
3	*Similar tools analysis*	1
4	*Utilization rate*	4
5	*Management of spare parts*	6
6	*Equipment deterioration*	3
7	*Maintenance planning*	5
8	*Level of personnel*	3
9	*Function*	5
10	*Hazard analysis*	5
11	*Equipment history*	7
12	*Downtime*	2
13	*Environment*	3
14	*Electrical safety testing and protection*	3
15	*Medical equipment upgrade*	1
16	*Availability of backup*	1
17	*Workspace analysis*	5
18	*Mission criticality*	4
19	*Multidisciplinary risk management team*	2
20	*Equipment replacement*	1
21	*MTBF*	2
22	*Inspection procedures*	10
23	*Equipment characteristics*	2
24	*Process management*	1
25	*Recognized guidelines and standards (ECRI, ASHE, FDA)*	3
26	*Standards/regulation compliance*	2
27	*Existance of administrative person*	1
28	*Selection and monitoring of different contracts*	2
29	*User Interface*	1
30	*Performance evaluation*	2
31	*Testing of medical equipment*	5
32	*Safety testing*	5
33	*Supporting departments*	1
34	*Testing after repair*	1
35	*CE service and presence*	5
36	*Equipment planning*	4
37	*Manufacturers database*	3
38	*Assessment methodology*	1
39	*Availability of staff*	2
40	*Company quality system*	2
41	*Financial evaluation*	2

42	*Recording of processes and activities*	8
43	*Risk based planning*	1
44	*Maintenance requirements*	3
45	*Medical device management database/ID*	3
46	*Temperature control*	1
47	*Training of personnel in hospital*	6
48	*Reliability and failure analysis*	2
49	*Risk analysis and management techniques*	6
50	*Equipment lifecycle cost*	1
51	*Vendor service*	2
52	*Outsourcing*	2
53	*Supervise installation*	1
54	*Maintenance policy*	2
55	*Physical risks*	4
56	*Risk monitoring*	1
57	*Vendor Negotiation*	1
58	*Maintenance cost*	1
59	*Infrastructure and transportation*	1
60	*Leadership*	3
61	*Calibration*	1
62	*Traning on installation*	1
63	*Maintenance strategy*	1
64	*Decommisioning*	3
65	*System integration*	3
66	*Purchasing management*	4
67	*Frequency of repairs*	1
68	*Design specifications*	2
69	*Administrative procedures*	2
70	*Prioritization*	2
71	*PM*	4
72	*CMMS*	4
73	*Age*	3
74	*SOD-Severity Occurrence Detection*	4
75	*Clinical experience and Knowledge*	1
76	*CM*	1
77	*Number of equipment*	1
201	*Training program*	2
202	*Pre acquisition evaluation*	1
203	*Communication*	5
204	*Installation cost*	1
205	*Direct labour cost*	1
206	*Degree of acceptance among personnel*	1

207	*Risk financing*	1
208	*Uncertainty and sensitivity analysis*	1
209	*Startegic plan*	1
210	*Clinical technology inventory costs*	1
211	*Stakeholder collaboration*	1
212	*Public relations*	1
213	*Dashboards*	1
214	*Joint plan*	1
215	*Life cycle moment*	1
216	*Reputation*	1
217	*Acceptance test*	1
218	*Planning of new construction and major renovation*	1
219	*Quality of service*	3
220	*Exposure avoidance*	1
221	*Governance*	2
222	*Accident Investigation*	2
223	*Staff safety*	3
224	*Regional variations*	4
225	*Patient safety*	3
226	*IT systems*	3
227	*Personnel survey*	1

Table 31 "Aggregated Factors' Table for Risk Papers"

Legend	Factors	Asset Recurrence	Risk Recurrence	Total Recurrence
1	*Availability of tools*	4	6	10
2	*Budget management*	5	4	9
3	*Similar tools analysis*	4	1	5
4	*Utilization rate*	7	4	11
5	*Management of spare parts*	6	6	12
6	*Equipment deterioration*	3	3	6
7	*Maintenance planning*	5	5	10
8	*Level of personnel*	3	3	6
9	*Function*	7	5	12
10	*Hazard analysis*	5	5	10
11	*Equipment history*	6	7	13
12	*Downtime*	8	2	10
13	*Environment*	3	3	6
14	*Electrical safety testing and protection*	2	3	5
15	***Medical equipment upgrade*** [1]	2	1	3
16	*Availability of backup*	1	1	2
17	*Workspace analysis*	4	5	9
18	*Mission criticality*	6	4	10
19	*Multidisciplinary risk management team*	2	2	4
20	*Equipment replacement*	6	1	7
21	*MTBF*	6	2	8
22	*Inspection procedures*	7	10	17
23	*Equipment characteristics*	2	2	4
24	*Process management*	1	1	2
25	*Recognized guidelines and standards (ECRI, ASHE, FDA)*	5	3	8
26	*Standards/regulation compliance*	5	2	7
27	*Administrative person*	1	1	2
28	*Selection and monitoring of different contracts*	3	2	5
29	*User interface*	1	1	2
30	*Performance evaluation*	5	2	7
31	*Testing of medical equipment*	4	5	9
32	*Safety testing*	4	5	9
33	***Supporting departments***[1]	1	1	2
34	***Testing after repair***[1]	2	1	3
35	***CE service and presence***[1]	4	5	9
36	*Equipment planning*	5	4	9
37	*Manufacturers database*	5	3	8
38	*Assessment methodology*	2	1	3
39	*Availability of staff*	2	2	4
40	*Company quality system*	4	2	6

41	*Financial evaluation*	3	2	5
42	*Recording of processes and activities*	6	8	14
43	*Risk-based planning*	1	1	2
44	*Maintenance requirements*	5	3	8
45	*Medical device management database/ID*	7	3	10
46	*Temperature control*	1	1	2
47	*Training of personnel in hospital*	8	6	14
48	*Reliability and failure analysis*	4	2	6
49	*Risk analysis and management techniques*	3	6	9
50	*Equipment lifecycle cost*	3	1	4
51	*Vendor service*	4	2	6
52	*Outsourcing*	2	2	4
53	*Supervise installation*	2	1	3
54	*Maintenance policy*	1	2	3
55	*Physical risk*	2	4	6
56	*Risk monitoring*	1	1	2
57	*Vendor negotiation*	1	1	2
58	*Maintenance cost*	1	1	2
59	*Infrastructure and transportation*	1	1	2
60	*Leadership*	1	3	4
61	*Calibration*	3	1	4
62	*Training on installation*	1	1	2
63	*Maintenance strategy*	2	1	3
64	*Decommissioning*	1	3	4
65	*System integration*	1	3	4
66	*Purchasing management*	2	4	6
67	*Frequency of repairs*	1	1	2
68	*Design specifications*	2	2	4
69	*Administrative procedures*	1	2	3
70	*Prioritization*	3	2	5
71	*PM*	9	4	13
72	*CMMS*	3	4	7
73	*Age*	4	3	7
74	*SOD-Severity Occurrence Detection*	5	4	9
75	*Clinical experience and knowledge*	3	1	4
76	*CM*	3	1	4
77	*Number of equipment*	1	1	2
101	*Cost of repair*	1		1
102	*Maintenance system*	1		1
103	*Institution needs*	1		1
104	*Standardization of devices*	2		2
105	*Component information*	1		1

106	*Reconditioned components*	1		1
107	*Prioritization of acquisition*	1		1
108	*Regulatory control of marketing*	1		1
110	*CBM*	1		1
111	*Technology obsolescence*	1		1
112	*Facility preparation*	1		1
113	*Department requirements*	1		1
114	*Strategy for identifying emerging tech*	1		1
115	*Labeling*	1		1
116	*Efficiency*	2		2
117	*Useful life ratio*	1		1
118	*Availability of operating instructions*	3		3
119	*Level of patient satisfaction*	2		2
120	*Monitor post procurement performance and operating costs*	3		3
121	*Incident response plan*	2		2
122	*Equipment selection criteria*	4		4
123	*Total cost of ownership*	3		3
124	*Cost of adoption (personal training)*	1		1
201	*Training program*		2	2
202	*Pre-acquisition evaluation*		1	1
203	*Communication*		5	5
204	*Installation cost*		1	1
205	*Direct labor cost*		1	1
206	*Degree of acceptance among personnel*		1	1
207	*Risk financing*		1	1
208	*Uncertainty and sensitivity analysis*		1	1
209	***Strategic plan*** [1]		1	1
210	*Clinical technology inventory cost*		1	1
211	*Stakeholder collaboration*		1	1
212	*Public relations*		1	1
213	*Dashboards*		1	1
214	*Joint plan*		1	1
215	*Life cycle moment*		1	1
216	*Reputation*		1	1
217	*Acceptance test*		1	1
218	***Planning of new construction and major renovation*** [1]		1	1
219	*Quality of service*		3	3
220	*Exposure avoidance*		1	1
221	*Governance*		2	2
222	***Accident Investigation***[1]		2	2
223	*Staff safety*		3	3

224	*Regional variations*		4	4
225	*Patient safety*		3	3
226	*IT systems*		3	3
227	*Personnel survey*		1	1

Table 32 "Final Legend"

[1] **Bold** factors are those factors that have been put in both decisional and performance *Tables 4, 5, 6* and *7*.

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