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A Study of Current Maintenance Strategies and the Reliability of Critical Medical Equipment in Hospitals in Relation to Patient Outcomes

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Abstract**—**This study investigates the relationship between the reliability of critical medical equipment (CME) and the effectiveness of CME maintenance management strategies in relation to patient outcomes in 84 public hospitals of a top 20 OECD country. The work has examined the effectiveness of CME maintenance management strategies used by the public hospital system of a large state run health organization. The conceptual framework was designed to examine the significance of the relationship between six variables: (1) types of maintenance management strategies, (2) maintenance services, (3) maintenance practice, (4) medical equipment reliability, (5) maintenance costs and (6) patient outcomes. The results provide interesting insights into the effectiveness of the maintenance strategies used. For example, there appears to be about a 1 in 10 000 probability of failure of anesthesia equipment, but these seem to be confined to specific maintenance situations. There are also some findings in relation to outsourcing of maintenance. For each of the variables listed, results are reported in relation to the various types of maintenance strategies and services. Decision-makers may use these results to evaluate more effective maintenance strategies for their CME and generate more effective patient outcomes.

Keywords**—**Critical medical equipment, maintenance strategy, patient outcomes, reliability.

I. Introduction

ENSURING the reliability and maintenance of critical medical equipment (CME) in hospitals is vital to patient outcomes and service availability. For these reasons, maintenance engineering is an important part of hospital management. Its aim is to develop an **optimal maintenance strategy that maximizes equipment availability and minimizes downtime**. This aim has become complicated by an increasingly complex array of technical medical equipment [1]. In hospitals, medical equipment can be classified according to mission criticality namely: critical, important or necessary, and the **risk equipment unavailability poses to patient outcomes as: high, medium or low** [1]-[3]. Further, the type of CME used in any hospital can be generally classified into: biomedical, laboratory, ward, service support, utilities and hospital furniture. **This study focuses on the maintenance strategies of six of the fourteen selected critical-high risk biomedical items of equipment specifically**: ***kidney dialysis, anesthesia, defibrillators, ventilators, infusion pumps and electrocardiograph (ECG) machines***. The contextual approach taken in this study, included *elements of Reliability Centered Maintenance (RCM)* [4], [5]. This is to analyze current maintenance strategies used on selected CMEs, and include both **quantitative and qualitative reliability analysis and reliability management** [6]. **Quantitative analysis** of reliability is established through evaluation of equipment availability, Mean Time Between Failure (MTBF), Mean Time To Repair (MTTR), and Failure Rate (FR) [7]. Various modes and causes of failure and unreliability are analyzed by **qualitative analysis** [6]. Improving maintenance performance leads to increasing productivity, quality, safety and environment in an organization [8]. Effectiveness and efficiency are significant elements to consider when evaluating the productivity of CME maintenance strategies [7]. Best practices developed for management of technical assets in other industries offers potential to improve services and patient outcomes and innovative proposals are discussed here.

II. Research Objective

The study aims to: determine representative **failure rates** and **mean time to repair statistics**, in relation to the CME in order to make correlations between the representative probabilities of *harm to patients* in the event of sudden unpredicted failure, to determine if there is a statistically significant relationship between the *availability* of CME and the effective and *efficient treatment of patients*, and to explore whether alternative ‘state of the art’ maintenance management strategies from other relevant industries have the potential *to improve the availability of CME and reduce risk to patients.*

III. Methodology

This study examined the **maintenance management strategies of CME** in a group of public hospitals. Of the 220 hospitals considered, 200 were invited to participate and **84 responded**. Reasons for non participation included: small size or type of hospital, i.e. without specific equipment maintenance responsibilities, lack of a maintenance management department, and/or non-availability of the critical

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medical devices selected for study. This study targets four different hospital departments: *biomedical engineering, surgical operations, cardiac catheterisation and dialysis*. The study also targets specific hospital staff, including the Directors of Bioengineering Departments, Directors and Managers of Nursing Units, and other users of CME including medicine and nursing staff.

A questionnaire survey was designed for this study, and each hospital was sent between 1 to 4 copies of this questionnaire depending on the number of relevant departments and the type of maintenance used. In total, 101 questionnaires were completed and submitted to the researcher. Ethics approval was necessarily obtained from the responsible authority for each hospital. This study focused on those CME whose failure or non-availability would pose a high level of risk to patients' lives. The criteria for judging the criticality of equipment included: the risk failure or breakdown poses to patients, the average usage time per patient, average number of patients who are serviced by these devices per month and year, the average operational life of CME and the availability of alternatives in case of failure of CME. This study is limited in its scope to the examination of 14 types of CME used in hospitals. A total of 5769 devices were examined using the questionnaire. However, for this paper only the six most significant CMEs are examined.

In a **pilot study** of *3 hospitals, five types of CMEs were examined, that had a non-availability high risk level*; kidney dialysis, anesthesia, defibrillators, diathermy and cardiac catheterization machines. In the process of collecting the data via the pilot questionnaire, the hospitals selected also suggested other types of CME that should be considered. These are shown in Table I below. However, only 14 CME were considered in this study. It is recommended that the comprehensive list is used in future research. This paper presents only the six most critical items.

The information from the pilot study was used to design the final questionnaire, which was divided into six key sections; (*1) maintenance management strategies (MMS) and maintenance service (MS), (2) reliability centered maintenance (RCM), and availability, (3) failures rate (FR), (4) patient risks, (5) maintenance cost and (6) maintenance practice*. These six sections were covered in 55 closed and open-ended questions. The questionnaire was designed according to research objectives and provides recommendations for best practice. The survey was available both online and as hard copy. Email, telephone, visits to hospitals, personal observations and meeting staff were also used in the data collection process and 11 hospitals were personally visited to enable the researcher to make observations of maintenance activities and gain further data.

TABLE I
OTHER CRITICAL MEDICAL EQUIPMENT TO BE CONSIDERED IN FUTURE RESEARCH

No	Equipment	No	Equipment
1	Surgical Laser	11	Bladder scanner
2	BIS Monitor	12	Reliance EPS
3	Insufflators	13	Olympus control unit
4	Respironics-light	14	Vision BIPAP
5	Trans illuminator	15	Respironics-Humidifier
6	PICCO machine	16	INR machine
7	Monitor	17	Respironics/Exsuffator
8	ABG Machine	18	Electronic Tourniquet
9	SCDS	19	Olympus Flushing
10	Autoclave	20	Respironics-Continuous positive Airway pressure units

IV. DATA ANALYSIS

The data analysis was carried out using the Monkey survey website, SPSS 19.0 for Windows and Microsoft Excel, which allowed the relationship and the degree of correlation between variables to be investigated [9], [10]. Each variable was given a standard unit measurement and the data was examined for validity and reliability. Three significant tests were performed; independent samples *t–test* of hypothesis for the Mean difference, compare means (One-Way ANOVA), and the chi-square test and descriptive statistics (means & frequencies) [11].

To investigate the research questions and hypotheses of this study, the conceptual frameworks proposing the five variables and associated factors that can affect patient outcome, are shown in Fig. 1. Where the data analysis was organized according to two variables: (1) independent: types of **maintenance management strategies (MMS)** and/ or **maintenance service (MS)**, and (2) dependent: these included **maintenance performance**, **maintenance practices**, **maintenance cost** and **patient outcomes**. The results enable the researcher to examine the relationship between the selected variables and the research hypotheses.

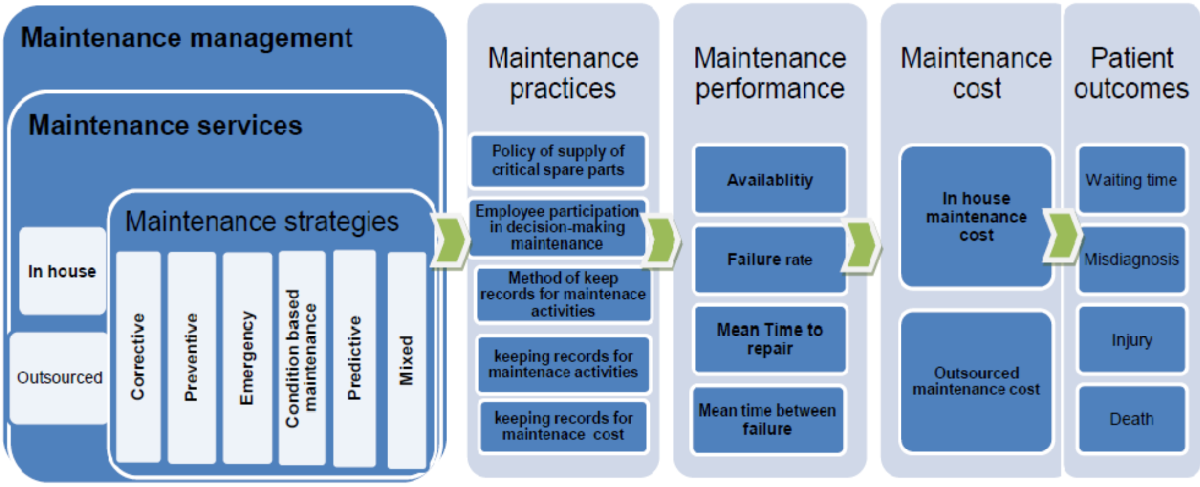

Fig. 1 Conceptual framework proposing of the variables that affect patient outcomes

V. Results

This study examined 14 types of CME; this was a total of **5769 devices**. From an average total number of CME; *8% were new, 57.6% had one to four years of use, and 39.6% had over five years of use*. In this study respondents indicated on average, *63% of particular items of CME had no alternatives or standby equipment* that could be substituted for the same work and provide the required health services to patients in the event of its **breakdown or unavailability**. The average frequency of usage per patient of CME was considered to be high per treatment. Operation times of CME investigated ranged from 1 to 48 hours. This meant that the patient remained in contact with the equipment during this period for healthcare service. The defibrillator and ECG equipment were deemed highly critical with potential high risks to patients, including *misdiagnosis, injury and death* [1].

In this study, an analysis of the results was used to examine the significance of the relationship between the six basic variables set out in the conceptual framework: *maintenance management strategy (MMS) and maintenance services (MS) of CME, maintenance practice (MP), maintenance costs (MC), medical equipment reliability and patient outcomes*. In this survey of 84 public hospitals located in 17 different local health districts, three types of maintenance services for CME were identified. *It was found that 72% used outsourced maintenance services, 16% used in-house and 12% used mixed maintenance services.*

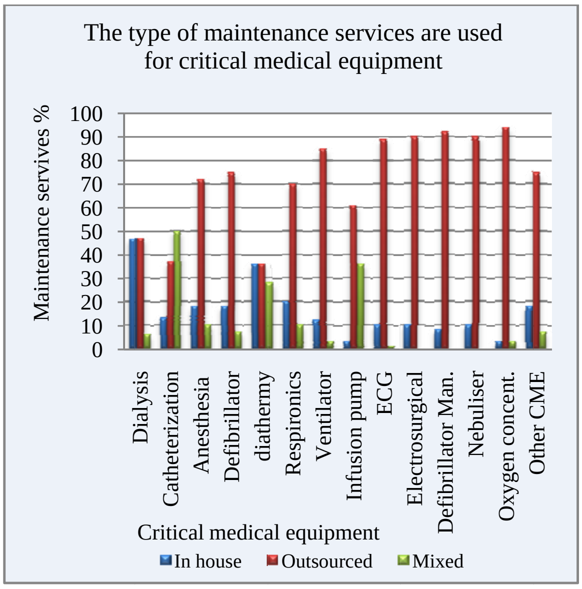

Fig. 2 The type of maintenance services used for critical medical equipment

The results sought to establish the relationship between **maintenance strategy**, **failure rate and availability** of **CME** and **improved of patient outcomes**. Using this analysis, it is proposed that alternative maintenance strategies for specific CME be used to increase their *availability and reliability*. The *total number* of CME usage was **107 171** and the reported *failure number FN* was 1534 per year, which as a generalized FN for the 84 hospitals appears to be low at **0.014% FR**.

TABLE II-A
RESULTS OF T-TEST EXAMINING THE RELATIONSHIP BETWEEN THE TYPES OF MAINTENANCE SERVICES USED FOR CME AND FN

Equipment	T- test					Results
	P-value	In-house		Outsourced		
		M	*SD*	*M*	*SD*	
Defibrillator	**0.001**	1.33	0.49	1.05	0.23	Sig.
Anesthesia	0.108	1.50	0.55	1.21	0.42	Not. Sig.
Ventilator	0.476	1.00	0.00	1.03	0.18	Not. Sig.
Infusion p.	**0.001**	2.00	0.00	1.39	0.49	Sig.
ECG	**0.052**	1.40	0.55	0.15	1.15	Sig.
dialysis	0.351	1.57	0.53	1.71	1.71	Not. Sig.

TABLE II-B
RESULTS OF T-TEST EXAMINING THE RELATIONSHIP BETWEEN THE TYPES OF MAINTENANCE SERVICES USED FOR CME AND FN

Equipment	T- test				
	N	Unit	*F*	*DF*	*T*
Defibrillator	67	487	29.278	65	3.007
Anesthesia	34	91	2.739	32	1.441
Ventilator	36	268	0.520	34	-0.349
Infusion pump	46	3051	35.123	44	1.74
ECG machine	59	267	3.948	57	1.437
Kidney dialysis	14	151	0.941	12	-0.522

The reasons for the failure of this equipment were classified in the survey into three types from this survey: *technical causes 43.67%, human error 52.73% and over-use 3.6%*. Noteworthy, among the results were the highest percentages of FN attributed to the three classifications these were; *technical causes 90% FN with the defibrillator, human error 76% FN with the infusion pump, and over-use 12.5% FN with the cardiac catheterization machine*.

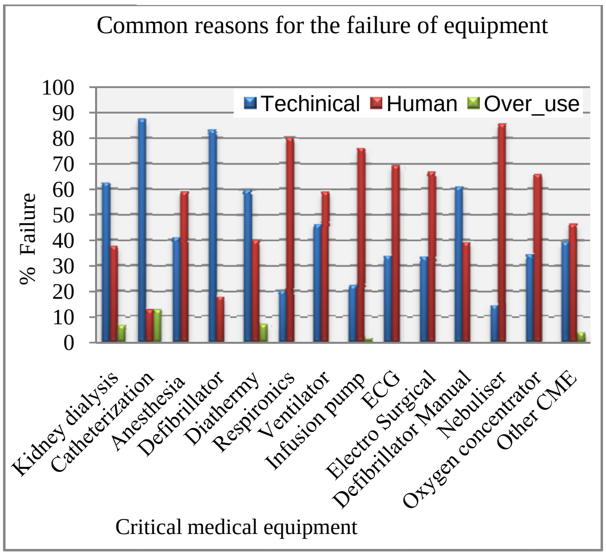

Fig. 3 The common reasons for the failure of the critical medical equipment

Participants claimed that in the last five years (2007-2011) only 660 failures occurred, yet this current study (2012) has generated a 20% increase in FN as 1534 failures while in service were reported in this study. These results however, are inconclusive, because they are not statistically reliable as the survey requested opinions, and accurate quantitative statistics were not available or access within the scope of this research. The failure number FN was analyzed for each individual piece of equipment, to find the failure rate FR in 2012, for CME.

Of the 101 respondents, a very few indicated that they used reliability and availability data to evaluate the performance of CME. Only 2.82% indicated they had no data to evaluate the performance of CME, such as the kidney dialysis, anesthesia and defibrillator machines. Similarly, only 12.83% indicated they used failure rate data to evaluate the performance of most of the equipment surveyed, and of this 1.4% indicated they used mean time to failure, and 3.7% indicated they used mean time between failures, for evaluation purposes.

TABLE III
FAILURE RATE OF CRITICAL MEDICAL EQUIPMENT

No	Equipment	RN	Usage time	FR%
1	Defibrillator	144	464	31
2	Defibrillator manual	16	104	15
3	Diathermy	136	1,340	10
4	Dialysis	366	4,937	7.4
5	Infusion pump	331	20,187	1.6
6	Oxygen concentrator	47	3,335	1.4
7	Anesthesia	132	13,549	0.1
8	Respironics	21	2,346	0.9
7	OCME	39	4,486	0.9
9	ECG	154	2,654	0.6
10	Ventilator	48	8,109	0.6
11	Electrosurgical	44	9,390	0.5
12	Nebuliser	39	0,810	0.4
13	Catheterisation	16	1,570	0.3

Respondents confirmed that the reasons for the **unavailability** of CME in this study for providing healthcare to patients was due to either, the CME being *limited in number* (according to 33.28% of respondents), or *the device was out of service* (according to the remaining 66.72% of respondents). The *unavailability of the surveyed equipment ranged between 96 to 360 hours per month*. The defibrillator and infusion pump had the highest instance of unavailability at 360 hours per month, followed by the diathermy and ECG machines at 336 hours per month, and the kidney dialysis machine at 240 hours per month. Overall, the average **availability** of these machines per year ranged between 96% for the anesthesia and ventilator, 94% for the ECG, 91%for the nebulizer 91%. The lowest availability rate of these machines per year was for the defibrillator at 89% and the infusion pump at 61%.

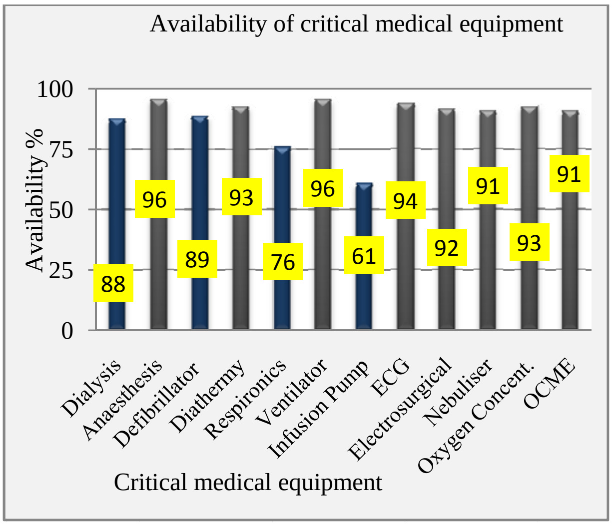

Fig. 4 Overall average of availability of critical medical equipment in 2011-2012

As can be seen in Fig. 4 above, the average availability of CME ranged from 61% to 96% in the year 2011-2012. It can be seen, however, that the availability of all the surveyed CME was well below this standard, particularly, in the case of the defibrillator, kidney dialysis, respironics and infusion pump machines. *This lack of availability may be due to the maintenance services used.*

In this study, 44% of respondents suggested there are problems in keeping each of the CME properly maintained and available. On average, 19.17% of respondents reported that this maintenance problem often affects patients outcomes, 56.64% reported that this happened sometimes and 24.26% reported it had never happened see Fig. 5. No significant difference was found between in-house and outsourced maintenance services in relation to effects on patient outcomes.

This study's examination of whether the breakdown of CME caused accidents where patient outcomes were affected, such as misdiagnosis, injury or death found that: 8% were aware of "patient death", 19% were aware of "patient injury" and 73% of answered "not at all". Additionally, respondents were asked to identify the level of risk to patients' lives posed by the failure of Review Stage CME during operation. In this survey, the level of risk was divided into four: high, middle, low and very low, for each of these cases of, death, injury and misdiagnosis. The most significant results of CME was 'a perceived higher level of risk of death' from: the defibrillator manual 100% of respondent, defibrillator 94.4%, oxygen concentrator 76.9%, the ventilator 67.5% and anesthesia 65.8% machines as shows in Table IV-A and Table IV-B.

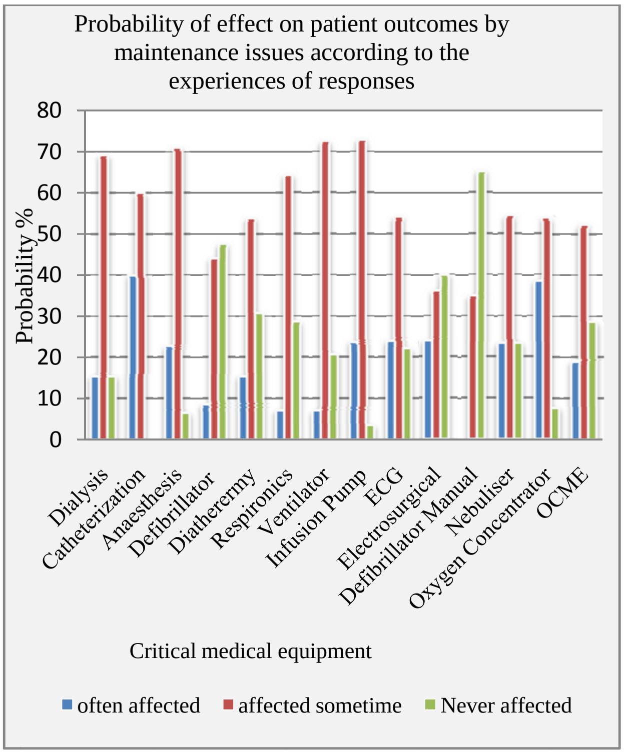

Fig. 5 Probability of effect on patient outcomes by maintenance issues according to the experiences of responses

TABLE IV-A
A HIGH RANGE OF LEVEL OF PERCEIVED RISK THAT EQUIPMENT FAILURE POSES TO PATIENTS ACCORDING TO DEATH, INJURY AND MISDIAGNOSIS

No	Equipment	% Death	% Injure	% Misdiagnosis
1	Defibrillator, Manual	100	0	0
2	Defibrillator	94	64	44
3	Oxygen concentrator	77	0	0
4	Ventilator	68	0	0
5	Anesthesia	66	50	0
6	Catheterization	50	75	100
7	Diathermy	44	50	25
8	Infusion pump	17	25	0
9	Electrosurgical	11	0	0
11	Nebuliser	31	0	0
12	Dialysis	18	44	33
13	Respironics	11	25	0
14	ECG	5	0	46
	OCME	9	17	61

VI. Discussion

Previous study has argued that in the context of hospitals, advancing medical technology means that traditional maintenance is no longer efficient to ensure that medical equipment is receiving the best possible maintenance [1]. Clinical engineering professionals need to continually review and improve their management strategies in order to keep up with equipment technology development, as well as with rising demands of health care organizations. This requires the development of risk-focused maintenance management plans [12].

However, it is not efficient to focus on risks caused by individual pieces of equipment to individual patients. Emphasis should also be on the impact of equipment failure on patients, particularly, to provide timely and accurate diagnoses for immediate therapeutic decisions or surgical interventions [12]. For this reason, healthcare organizations are responsible for ensuring that their medical equipment is available and can be used safely and efficiently, while also complying with the related health and safety standards [4].

TABLE IV-B
A MID- RANGE OF LEVEL OF PERCEIVED RISK THAT EQUIPMENT FAILURE POSES TO PATIENTS ACCORDING TO DEATH, INJURY AND MISDIAGNOSIS

No	EQUIPMENT	% DEATH	% INJURE	% MISDIAGNOSIS
1	Defibrillator, Manual	0	0	0
2	Defibrillator	4	0	0
3	Oxygen concentrator	15	0	0
4	Ventilator	3	50	0
5	Anesthesia	5	30	0
6	Catheterization	50	25	0
7	Diathermy	0	25	0
8	Infusion pump	68	25	60
9	Electrosurgical	68	100	0
11	Nebuliser	50	0	0
12	Dialysis	0	33	0
13	Respironics	33	50	100
14	ECG	0	0	50
	OCME	18	17	17

In this study, it is suggested that the current maintenance strategies used need to be improved, CME in hospitals, have adopted the recommendation the Joint Commission on Accreditation of Healthcare Organisation (JCAHO) be used for different strategies for different parts as appropriate. For example, different strategies can be employed for defibrillators used in emergency departments and intensive care units than those used in general patient care areas or clinics [2], [12].

Preventive maintenance (PM) often does not increase reliability and actually may introduce failure, a notion well documented in industrial maintenance [12]. However, as medical equipment becomes more complex, it is argued that PM activities become less relevant. This is because PM is only concerned with inspection and scheduled maintenance activities, which do not take into consideration age-related failure [13]. In contrast to preventative and corrective maintenance strategies, predictive maintenance actively utilizes diagnostic methods in order to avoid the risk of breakdown Endrenyi et al. [14]. When applying predictive maintenance to medical equipment, it is important to be flexible in the planning and scheduling of maintenance activities. This is because it is often difficult to perform planned maintenance activities at a suitable time due to their use on patients and outside control factors. For this reason, Wang et al., [12] suggest the use of a grace period (or slippage) for determining when an item of medical equipment must be considered overdue for a planning inspection or maintenance occurrence.

It is argued that predictive maintenance (Pr.M) is more advanced than other maintenance strategies because it focuses on inspection, condition and risk-based techniques [13]. CBM as part of Pr.M strategy, reduces incidences of sudden random failures to achieve a “zero-failure” strategy, as the condition control helps to discover failure causes, potential failures and mechanisms of failure ahead of usage [15]. The main advantage of CBM is that it promotes cost-effective production because it can be performed without stopping equipment or processes [16]. Ghasemi et al., [17] found that CBM can assist in finding the optimal observation interval of an operation process based on the total long-run average cost as well as the corresponding replacement policy that optimizes the total long-run average cost of the replacement and observations. Reliability Centered Maintenance (RCM) however, does play an important role in measuring the availability and reliability of medical equipment in healthcare organizations [4]. An effective maintenance strategy can increase the availability and reliability of medical equipment, increase healthcare service productivity and reduce the failure rate and life cycle cost [18]. Despite the development of medical equipment, according to Khalaf et al., [1], no medical device is one hundred percent safe and resources are never unlimited. Vanier [19] argues that while the Computerized Maintenance Management Software CMMS is excellent for storing data it was not used in the hospitals surveyed in this study.

VII. LIMITATIONS OF THIS STUDY

The limitations of this study relate to the difficulties in accessing relevant and reliable data. This is because: (1) many hospitals do not have a biomedical engineering department and a central database of maintenance activity because they tend to outsource these activities. Of the 220 hospitals, only 13 hospitals or (5%) had a biomedical engineering department. These hospitals tended to be large urban hospitals. (2) Each hospital uses different methods of keeping records of maintenance activities; for example, one local health district uses a database (46%), computer (43%), and paper (11%). Of 101 survey respondents, 6% said they often kept records of maintenance cost, 1% occasionally kept records of maintenance cost and 2% seldom kept records of maintenance cost. The lack of accessible data means that some hypotheses and research questions could not be answered.

VIII. CONCLUSION AND RECOMMENDATIONS

A proposed model (Fig. 6) for improving MMS used for CME was designed based on the results, discussion and recommended in this paper to improve patient outcomes.

Model design steps are:

1. Identify the problem
2. Identify the current maintenance strategies

3. Proposed the kind of maintenance management strategies that could be used to increase CME availability and decrease the cost of ownership while achieving the desired level of patient outcomes including: (a) Condition-Based Maintenance CBM (b) Total Productive Maintenance TPM and (c) Predictive maintenance Pr. M.
4. Computerized maintenance management software (CMMS)
5. Continuous improvement process into maintenance management strategies.

In conclusion, this study has chosen hospitals that do not rely on predictive maintenance for CME. It also recognizes the lack of a biomedical engineering department and the consequently high reliability on contracts with maintenance companies. The evaluation of performance of CME was carried out by using qualitative and quantitative measures in order to examine the failure rate and it is affect the analysis. Major factors to perform measurements are the CME's availability and failure rate. As the final results of this study it is proposed that maintenance management strategies could increase CME of availability and decrease the cost of ownership while achieving the desired level of patient outcomes. This study provides several proposals; (1) Computerized Maintenance Management Software CMMS based on Condition-Based Maintenance CBM. (2) Using Total Productive Maintenance (TPM) which have potential to improve quality of perform CME.

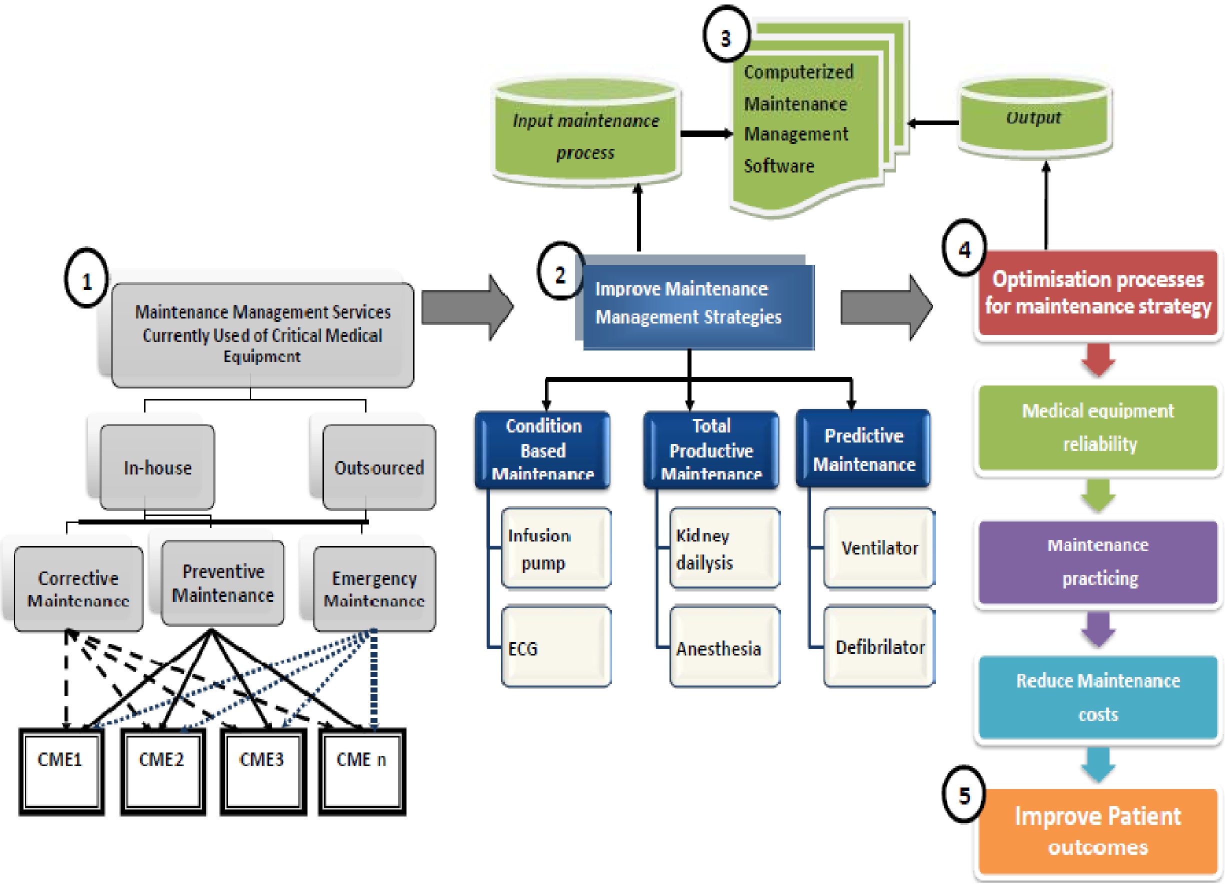

Fig. 6 Formulation of a model for improving maintenance management strategies used of critical medical equipment designed by the researcher Mkalaf (2013)

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