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RESEARCH ARTICLE - MANAGEMENT

Application the Risk-Based Maintenance for Optimizing the Overall Medical Devices Safety

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Abstract

The purpose of this study was to identify risks to patients as a result of sudden device failure during the delivery of medical treatment services. Which, can affect the reputation of hospitals following the exposure of patients' lives to various risks like death, injury, and misdiagnosis. Furthermore, a sudden failure will lead to increased economic losses as a result of increased maintenance costs. Of (20) medical devices, (6) high-risk devices were selected, such as a ventilator, diathermy, anesthesia, BiPAP, oxygen concentrator, and electrosurgical devices. A quantitative statistical analysis based on risk-based maintenance is used to evaluate the effectiveness of the reliability of the medical device and its risks to patient lives. The results show that the reliability of the chosen medical device has declined, with higher maintenance costs due to excessive maintenance or the type of maintenance policy used. Therefore, this study provides evidence that hospitals must adopt a risk-based maintenance approach to prevent sudden failure while in service. In addition, these medical devices have various complex parts that must adopt a combination of maintenance schedules. Based on Risk-Based Maintenance's experience in improving patient safety in public hospitals in the 20 most successful OECD countries.

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Keywords: Overall Medical Device; Risk-Based Maintenance; Patient Safety, Reliability; Ventilator.

1. Introduction

In the context of medical safety, most hospitals are required to adopt a continuous assessment of their critical devices that pose a high risk to patients' lives, to optimize their reliability and ensure provide a safe medication service. In addition, it must use effective maintenance programs that assist the device operators or users in repairing if it breaks down while providing health services. Which have been considered to have complex automation characteristics based on their design, and they need to provide accurate information about their operation and repair [1]. As a result, this assessment must address the economics of the life cycle of each medical device. For this reason, the EU Regulation has attempted to improve medical devices which present a high level of risk before their manufacture, after commercialization, obsolescence, and replacement [2]. Similarly, manufacturers are responsible for ensuring the safety of their medical products [3]. Therefore, hospitals may use an efficacy analysis method such as failure mode and effects analysis to measure the reliability of their medical device [4, 5]. Furthermore, it contributes to reducing the level of risk to which patients are exposed as a result of sudden failure of the medical device [6, 7]. Biomedical engineering may need to employ mixed maintenance strategies because of the different characteristics of medical devices or those suitable for the type of failure [8, 9].

Consequently, the objective of this study was to assess the risk-based maintenance used for certain medical devices in public hospitals. This study has become necessary across the world due to the increase in the spread of epidemics and diseases and the demand for services on selected medical devices during the Corona pandemic. Decision-makers could use the study to develop more effective maintenance programs for other medical devices. This will contribute to improving patient outcomes.

2. Methodology

A quantitative statistical analysis based on Risk-based Maintenance is used to evaluate the effectiveness of the reliability of the medical device and its risks to patient lives. This study targeted the different departments in the public hospitals in the top 20 OECD countries like biomedical engineering, hospital administration, surgical operations, and intensive care units. Out of (20) medical devices, (6) devices that have a high risk to patients' lives were selected Like a ventilator, diathermy, anesthesia, BiPAP, oxygen concentrator, and electrosurgical devices. The reason for selecting these devices is due to their increased sudden breakdown or non-availability for providing health services. Data were collected by using a survey form, personal observations, and statistical annual reports for the performance of selected hospitals. The correlation between variables was identified based on a statistical analysis by SPSS v.23. The results are adopted based on Chi-square analysis, Fisher's Exact Test, p-value, and T-Test analysis. Ethics approval was obtained. Accordingly, the name of the hospitals' responses has been coded. Each variable was given a standard unit measurement and the data was checked for validity and reliability.

3. Study Contribution

This study contributes to exploring whether the alternative state of maintenance programs from other relevant industries can improve the reliability of medical devices and can be reducing their risk to a patient's life. Also, explore whether this type of maintenance contributes to a more reliable medical device. Then, it reduces the risk to the life of the patient. Based on identifying the automatic compliance to electronic requirements that facilitate the concurrent or later production of electronic products and exploring the effective maintenance program that ensures hospitals can provide safe treatment services, especially after the spread of COVID-19 across the world.

4. Maintenance

4.1. Risk-Based Maintenance

Gharahasanlou et al., (2017) study identified risk-based maintenance as an effective qualitative analysis of the flow of historical decomposition [10]. So far, the majority of hospital managers need to choose an appropriate maintenance program to minimize the risk to patients' lives [11]. Based on an understanding of the risk to patients' lives of breaking the medical device and tracking the historical evolution of its medical devices. As, traditional maintenance is indicated as no longer sufficient to ensure the medical device receives optimal maintenance [12, 11]. This program remained to perform cleaning, auditing, repair, replacement, and maintenance planning activities. As a result, no medical device is 100% safe in the absence of resources available to hospitals [12, 9].
For this reason, it must adopt risk-based maintenance to assess the failure caused rather than meet optimal maintenance requirements [9]. On this basis, the assessment of the hazards associated with the devices is based on their reliability and safety. Choose an efficient maintenance program that reduces the likelihood of equipment failures and determines the consequences, which can add value to capital investment [13].

4.2. Risk-Based Medical Device Breakdown

In general, failure of the medical device during its functioning in medical treatment leads to harm to the patient's life. The increase in the impact of medical device failure on patients' lives is due to the following reasons:

- Usually, the medical devices are connected directly or indirectly to a patient's body to provide a clinical treatment (Electrocardiography, monitor, and ventilator), surgical (anesthesia, and surgical endoscopic device), and biological signals (diathermy, X-ray), and clinical laboratory tests [14].
- The rise in medical device errors is caused by a lack of information about its operation or maintenance. For example, in US hospitals, there are (1:200) patients who die due to medical errors [15].
- Human and organizational errors lead to 80 percent of medical accidents as proven by Lardner and Fleming's (1999) study [16].
- Technical errors are estimated at 20-30 percent of medical accidents as proven by Turner (1994), and Lardner and Fleming (1999) studies [16].
- A lack of maintenance activities or operation errors leads to a rising failure rate of the medical device during its operation [17, 18].
- A lack of occupational safety procedures. In 1971 before safety measures were applied across the world, the electrical device was considered quite an alarming risk to patients. There were (3 patients per day: 1200 patients yearly) who had accidentally electrocuted just in United States hospitals [14].

Accordingly, medical device errors have serious consequences in diagnosis, treatment, and monitoring (analysis of graphs, curves, or data). Based on this, it may cause harm through direct contact with the patient's body due to the leakage of electric current, overdoses of accelerated electrons, especially in the case of treatment like X-rays in unacceptable doses, and under-or over-dosage of drugs through direct infusion. Also, it caused indirect harm through misdiagnosis caused by erroneous readings of the device like blood cell count, blood pressure, body size, magnitudes of neoplastic structures, and size of gestational. Harm is also through errors in estimating the required treatment time such as miscalculation of doses of accelerated electrons [14].

5. Patients Safety

5.1. Safe Medical Services

Globally, hospitals have an increased need to provide health services characterized by high quality and safety while providing health treatment services to patients. Especially after the spread of COVID-19 across the wide world. Thus, most hospitals need to apply an effective maintenance program for their medical device. That reduces the risk to a patient's life includes; death, injury, and misdiagnosis [19, 20]. Therefore, biomedical engineering must be verified for calibration, safety, and reliability for all medical devices especially those that are used in life-or-death situations. Also, medical device errors become a source of serious harm to the patient [14, 9, 11]. Medical device has different levels of risk. For example, a critical-care monitoring device requires needs maintenance programs to ensure its continued operation while providing health service and reducing its risks. Whereas, X-ray film processors have a lower risk to patient lives. So, it's scheduled or preventative maintenance [9].

5.2. Levels of Risk to Patients' Lives

Medical devices can be classified according to their level of performance into three types: critical, important, and essential. Each type contains a level of risk that may harm the patient's life, ranging from high to low risk [19-21, 9].

- A high level of risk to the patient's life resulting from the breakdowns of the medical device or its misuse by the user, which may cause death to the patient or serious injuries, such as key resuscitation devices, life support, anesthesia, ventilator, and radiotherapy

- A medium level of risk to patient lives, devices, and diagnostic instruments has a significant impact on patient care but would be unlikely to cause direct serious injury. Due to its misuse, breakdown, or device being out of service with unavailable alternatives. Examples, are MRI, CT scanner, Catha lab, auto-timer, and analysis-level risk upon patient lives due to device failure or misuse. But, it's unlikely to result in an injury like an electron microscope.

5.3. Medical Devices Errors

Medical device errors can be occurred due to; policies and guidelines factors dealing with patients (7.7% and 17.9%), staff accomplishment and communication factors (21.4%), and organizational issues (86.5% and 25.0%). Based on medical device breakdowns and unavailability issues [22]. In England and Wales, critical care units had informed the accident cases for patients influenced from 2004 to 2014 were categorized as 'highly risky' (77%) or 'death' (23%). It indicates that (89%) of these incidents can be potentially avoidable [25]. In Australia, the most common patient accidents had exposed indicated due to medical devices are breakage or failure (46%). Unavailability of medical devices for providing health treatment in time (14.0%). For example, the accidents reported by the ventilator device were (2.5), the anesthetic device (2.0), the Dialysis device (2.0), and the Infusion device (19.5) according to Mitchell et al., (2015) study.

The American Society of Anaesthesiologists' Closed Claims Project database report indicated that between the 1970s to the 2000s, patients had injuries by the anesthesia gas delivery device. This risky injury leads to the patient's death or permanent brain damage. That influenced the patients' lives after supplemental oxygen supply, after completing the surgical process, after ventilator mishaps, and intensive care room. The majority (85%) of accidents involved medical provider error with or without medical device failure. Where (54%) of these accidents can be preventable by adopting a periodic inspection procedure and preventative maintenance for anesthesia devices [23]. Most of the accidents were due to the anaesthesiologists' situational awareness errors. Which leads to death or brain damage (74%). About three-quarters were informed due to modern anesthesia malpractice [24]. Moreover, during the expansion of the COVID-19 Pandemic across the world, The National Health Commission and the Chinese Society of Anaesthesiology had given recommendations to avoid anesthesia influence. Based on taking health, safety procedures, and infection precautions in trauma and acute care cases [25].

6. Results

A quantitative statistical analysis was used to determine the level of efficiency of the maintenance services in reducing the risk of medical device failures in patients' lives. It has proven that some of the selected hospitals still use traditional maintenance to service their medical devices such as corrective, preventive, and emergency maintenance. Besides, it's relying heavily on long-term contracts with medical device manufacturers. Consequently, this type of maintenance service doesn't contribute to reducing the downtime of the medical device while providing treatment service to patients as proven in the following results. This section provides the results obtained from the Chi-square analysis, Fisher's Exact Test, p-value, and T-Test analysis performed.

6.1. Maintenance Issues

In this study, maintenance issues at select hospitals were identified as follows:

- Unavailability of alternative medical devices that can perform the same work and provide the required health services to patients in case these devices are stops working. Where the percentage of non-availability of alternatives to these devices was as follows: 0.71 for the oxygen concentrator, 0.62 for the diathermy, 0.59 for the Electrosurgical, 0.54 for the anesthesia, 0.49 for the Ventilator, and 0.45 for the BiPAP devices.
- Occasionally, when emergency maintenance is required the medical devices become unavailable for treatment services. The maintenance is carried out externally. That may take up to several days for repair.
- A lack of budget that requests to replace medical devices with new ones when it starts having issues with their performance. Also, its maintenance becomes costly due to increased medical device failure rates.
- It's required to increase funding for routine and emergency maintenance and replacement of obsolete equipment.
- The unavailability of spare parts that need to replace the broken-down parts in case of these medical device breakdowns while the provided treatment to the patients.
- Difficulty in getting the necessary information required to service medical devices, access to any specialized tools, and medical maintenance software.
- Large medical devices are not easily replaceable when they need to be removed from the department to be serviced.

6.2. Medical Devises Reliability

The reliability of the medical devices had evaluated to identify whether the maintenance services used were effective in reducing FR and increasing their MTBF. Internal and external maintenance services had adopted widely in maintaining the hospital's devices. The results of significant tests are shown in Tables 1 and 2.

As appear in Table 1 the comparisons between maintenance services used for the hospitals' medical devices and their failure rates. The contingency analysis found no significant relationship between these two variables of more than 0.05 for all medical devices. The average failure rate for the medical device serviced by internal maintenance was: FR>Median= 65% and FR<=M=37% per device. But it was FR>M=63% and FR<=M=44% per device serviced by external maintenance. This shows that the internal maintenance service is effective in supporting ventilator and Electrosurgical devices but not at a significant level higher than the external maintenance service for BiPAP devices.

Whereas the following Table 2 shows the contingency analysis found there is a significant relationship between these two variables of less than 0.01 for the diathermy and BiPAP devices. On average MTBF of the internal maintenance service was: MTBF<=Median=75%, and MTBF<Median=53% per machine. Whereas the average MTBF of the external maintenance service was: MTBF<=Median=25% and MTBF<Median=47% per machine. This shows that internal maintenance service is effective in supporting diathermy devices but at significance, levels are higher than for BiPAP devices.

Table 1. Measuring the Failures Rate of the selected Medical Devices

Medical Devices	Chi-square analysis				FR	Maintenance	
	N	χ^2	P-value	Fisher's Exact Test		Internal	External
Diathermy	48	.739 [a]	.487	.487	FR<= .01042 FR> .01042	40 55.3	60 44.7
Anesthesia	25	2.564 [a]	.160	.160	FR<=.00104 FR>=.00104	20 60	80 40
Ventilator	25	4.167 [a]	.121	.121	FR<=.00035 FR>.00035	20 70	80 30
BiPAP	57	2.109 [a]	.189	.189	FR<=.00069 FR>.00069	57.1 37.9	42.9 62.1
Electrosurgical	25	2.241 [a]	.286	.286	FR<=.00017 FR>.00017	25 63.4	75 36.6
Oxygen concentrator	9	.090 [a]	1.000	1.000	FR<=.00167 FR>.00167	60 50	40 50

Table 2. Measuring the Mean Time between Failures for the Selected Medical Devices

Medical Devices	Chi-square analysis				MTBF	Maintenance	
	N	χ^2	P-value	Fisher's Exact Test		*Internal*	*External*
Diathermy	48	6.533[a]	.013	.013	MTBF<=48 MTBF >48	90 44.7	10 55.3
Anesthesia	25	.694[a]	.621	.621	MTBF<=1400 MTBF>= 1400	80 60	20 40
Ventilator	25	3.516[a]	.123	.123	MTBF<=2880 MTBF>2880	100 55	0 45
BiPAP	57	6.224[a]	.017	.017	MTBF<=1440 MTB>=1440	63 30	37 70
Electrosurgical	25	.672[a]	.617	.617	MTBF<=6000 MTBF>6000	75 53.7	25 46.3
Oxygen concentrator	9	1.102[a]	.524	.524	MTBF<=600 MTBF<=600	40 75	60 25

In conclusion, the results obtained from the chi-square significance tests displayed above indicated that the maintenance services used in hospitals can be improved to reduce FR and increase the MTBF of their medical devices. Furthermore, predictive maintenance such as risk-based maintenance can be applied for continuous improvement of their maintenance services.

6.3. Evaluating Failures Reasons

A comparison between failure reasons of the medical devices based on the type of maintenance services had given in Table 3. The contingency analysis found no significant relationship between these two variables in more than 0.05 of all medical devices selected in this study. The higher average of failure reasons was due to human error: 57% per device when maintenance services were external with the manufacturer companies, compared with 54% per device when its services were applied internally and maintained by biomedical engineering. The higher failure rate was due to human error with BiPAPs and electrosurgical devices for both types of maintenance services. Whereas, the reasons for failures due to human errors displayed higher rates when external maintenance services, rather than internal for anesthesia devices. These a proven that maintenance services used for BiPAPs and electrosurgical devices were ineffective when supporting these machines at significant levels. But the external maintenance services were displayed as ineffectiveness in supported anesthesia devices due to a rise in failure rates due to human error.

Table 3. Failure Reasons Based on Maintenance

Medical Devices	Chi-square analysis				Internal		External	
	N	χ^2	P-value	Fisher's Exact Test	Technical %	Human error %	Technical %	Human error %
Diathermy	47	.296a	1.000	1.000	100	0	97.4	2.6
Anesthesia	25	.050a	1.000	1.000	37.5	62.5	41.7	58.3
Ventilator	25	.877a	.562	.562	40	60	20	80
BiPAP	57	.323	.323	.323	11	89	15	85
Electrosurgical	45	.298a	1.000	.505	25	75	14.6	85.4
Oxygen concentrator	9	1.440	1.000	1.000	60	40	66.7	33.3

A comparison providing Failure reasons for selected medical devices is given in Table 4. The contingency analysis found no significant relationship between these two variables in more than 0.05 of all medical devices selected in this study. The higher average reason for failure was due to technical issues were displayed as 58% per device with FR<= Median. Where the failure due to “Human errors” was 55% per device with FR> Median. The higher rate of failure was due to technical reasons of the diathermy, electrosurgical, and oxygen concentrator devices. Whereas, the higher rate of failures was due to human error related to the anesthesia, BiPAPs, and oxygen concentrator devices. This shows maintenance services used for BiPAPs, and electrosurgical machines were ineffective in supporting these devices at significant levels. But external maintenance services were more ineffective in supporting anesthesia machines than internal maintenance services due to a rise in human errors.

Table 4. The Reasons for the Medical devices Failure

Medical Devices	Chi-square analysis				FR	Reasons	
	N	χ^2	P-value	Fisher's Exact Test		Technical %	Human error %
Diathermy	48	.979[a]	1.000	1.000	FR<=.01042	95.8	4.2
					FR>.01042	100	0
Anesthesia	25	.050[a]	.823	1.000	FR<=.00104	37.5	62.5
					FR>=.00104	41.7	58.3
Ventilator	25	.329[a]	.653	.653	FR<=.00035	20	80
					FR>.00035	30	70
BiPAP	57	.495[a]	.670	.670	FR<=.00069	9.5	90.5
					FR>.00069	17.7	83.3
Electrosurgical	25	.084[a]	1.000	1.000	FR<=.00017	65.4	34.6
					FR>.00017	61.1	38.9
Oxygen concentrator	9	2.880 [a]	.196	.196	FR<=.00167	40	60
					FR<=.00167	100	0

6.4. Safe Medical Devices

A quantitative analysis is to prove whether the selected hospitals have encountered problems in maintaining their medical devices. Clarify the impact of these problems on patient outcomes. The results indicated there are several issues based on the type of maintenance services used for medical devices. It includes that these hospitals were significantly dependent widely on contractual maintenance for long terms to maintain their medical devices. Based on a lack of biomedical engineering departments in these hospitals. For this reason, patient outcomes had been affected by the maintenance problems. A summary of the results of this effect by type of maintenance services is shown in Tables 5 and 6.

Table 5. The Result of a T-Test Comparison between the Internal Maintenance Services Used for Medical Devices and The case of Accident That Influence Patient Outcomes

Medical Devices	T-Test analysis for Internal maintenance						
	F	P-value	M	SD	DF	t	Result
Diathermy	18.826	0.000	1.63	1.15	92	-2.379	Sig.
Anesthesia	1.516	0.227	2.71	1.25	32	-3.182	Not. Sig.
Ventilator	0.389	0.537	3.00	1.22	37	-3.771	Not. Sig.
BiPAP	13.767	0.001	2.25	1.39	50	3.08	Sig.
Electrosurgical	15.330	0.000	1.22	1.39	60	-3.289	Sig.
Oxygen concentrator	0.073	0.792	2.00	1.29	12	1.216	Not. Sig.

Table 6. The Result of a T-Test Comparison between the External Maintenance Services Used for Medical Devices and the case of Accident That Influence Patient Outcomes

Medical Devices	**T-Test analysis for External maintenance**						
	F	***P-value***	***M***	***SD***	***DF***	***t***	***Result***
Diathermy	18.826	0.000	1.15	0.60	92	-2.379	Sig.
Anesthesia	1.516	0.227	1.37	0.93	32	-3.182	Not. Sig.
Ventilator	0.389	0.537	1.35	0.8	37	-3.771	Not. Sig.
BiPAP	13.767	0.001	1.23	0.74	50	3.08	Sig.
Electrosurgical	15.330	0.000	1.22	0.72	60	-3.289	Sig.
Oxygen concentrator	0.073	0.792	2.85	1.35	12	1.216	Not. Sig.

6.4 Evaluating the Risk-Base Maintenance Services

An investigation had conducted to establish whether there was a significant relationship between the types of maintenance services used for selected medical devices and the level of risk to patients' lives if these devices breakdowns while providing treatment services in this study. The ordinary comparisons for an independent-samples t-test analysis had performed. Significant levels are resulting from Levene's test for equality of variances that were less than 0.05. That means that the assumption of equal variance has been proved for the diathermy, anesthesia, and ventilator devices. The mean of 'high level of risk to patients' lives' by breakdown medical devices due to the types of maintenance services used is given, as shown in Tables 7 and 8.

The results show there is a statistically significant difference between the level of the risk upon patient outcomes due to types of maintenance services for these variables for the diathermy, anesthesia, and ventilator devices. While it was displayed as not significant for the oxygen concentrator device, it was not performing for each BiPAP and electrosurgical device. These results show there is a statistically significant difference between the level of the risk upon patient outcomes due to types of maintenance services for these variables for the diathermy, anesthesia, and ventilator devices. While it was displayed as not significant for the oxygen concentrator device, it was not performing for each BiPAP and electrosurgical device.

Table 7. Results of An Independent Samples T-Test between Internal Maintenance with Medical Devices that have a High Level of Risk to Patient Life

Medical Devices	T-Test analysis for Internal maintenance						
	F	***P-value***	***M***	***SD***	***DF***	***t***	***Result***
Anesthesia	12.99	0.001	2.69	0.6	92	12.99	Sig.
Diathermy	11.44	0.002	2.71	0.49	24	1.68	Sig.
Ventilator	17.56	0.000	3	0	37	-1.56	Sig.
Oxygen concentrator	1.333	0.271	2.00	0.82	12	0.00	Not. Sig.

Table 8. Results of An Independent Samples T-Test between External Maintenance with Medical Devices that have a High Level of Risk to Patient Life

Medical Devices	T-Test analysis for External maintenance						
	F	***P-value***	***M***	***SD***	***DF***	***t***	***Result***
Anesthesia	12.99	0.001	2.92	0.35	92	12.99	Sig.
Diathermy	11.44	0.002	2.95	0.23	24	1.68	Sig.
Ventilator	17.56	0.000	2.47	0.75	37	-1.56	Sig.
Oxygen concentrator	1.333	0.271	2.00	1.00	12	0.00	Not. Sig.

The mean of internal maintenance services used for these devices, except the oxygen concentrator device, was found to display significantly lower ratings of 'high level of risk to patients' life' than did external maintenance services. While it shows no significant equal ratings of 'high level of risk to patients' lives' for oxygen concentrator devices. For this reason, hospitals need to adopt an effective maintenance service that assists in reducing the level of risk to patient lives.

6.4. Evaluation of the Level Risks on Patients' Life

Comparison rates for a 'high level of risk upon patients' live' caused by a breakdown of the selected medical equipment based on the types of maintenance services used are given in Table 9. The result displayed an insignificant relationship between 'high levels of risk for patient lives' based on maintenance services for all medical devices mentioned in this table, except for the diathermy device. The results show a high percentage of the influence of incidents on patient outcomes by these devices in both types of maintenance services currently used in selected hospitals. The maintenance services remain in need of continuous improvement to reduce the rate of incidents that affect patients' life although there was an insignificant relationship between these variables.

Furthermore, comparison ratios of the accident cases that had influenced patient lives like injury or death due to the breakdown of medical devices while providing medical treatment are given in Table 10. A contingency Table analysis found a significant relationship between these variables for all medical devices mentioned in Table 10, except for the diathermy and oxygen concentrator devices. The mean of the accident cases that had influenced patient lives by a breakdown of the medical devices displayed a higher rating for medical devices that its service was internal maintenance, more than did external maintenance services, except for the oxygen concentrator device. In summary, all results obtained from these significant tests had performed above. The maintenance services used need to be improved to avoid risk-based maintenance due to the sudden breakdown of these medical devices in patients' lives.

Table 9. Compared Results for Chi-Square that display the Level of Risks in Patients' Lives according to Types of Maintenance Services

Medical Devices	Chi-square						
	DF	***N***	***χ^2***	***P-value***	***Maintenance Services***	***Death***	***Injury***
Anesthesia	4	99	18.767^a	0.001	Internal	0.75	0.19
					External	0.95	0.03
Diathermy	2	28	3.164^a	0.206	Internal	100%	0%
					External	0.95	0.05
Ventilator	4	40	3.399^a	0.493	Internal	100%	0%
					External	0.62	0.24
Oxygen concentrator	4	15	3.429^a	0.489	Internal	0.43	0.29
					External	0.14	0.43

Table 10. Evaluated the Causes of Accidents That Influenced the Patients' Lives Due to the Breakdown of Medical Device

Medical Devices	Chi-square						
	DF	N	χ^2	P-value	Maintenance Services	Death	Injury
Diathermy	4	99	6.244^a	.182	Internal	0.13	0.13
					External	0.03	0.04
Anesthesia	4	39	11.913^a	.018	Internal	0.29	0.43
					External	0.07	0.07
Ventilator	4	40	11.159^a	.025	Internal	0.40	0.40
					External	0.06	0.09
BiPAP	4	74	12.847^a	.012	Internal	0.25	0.25

					External	0.05	0.05
Electrosurgical	4	63	9.815[a]	.044	Internal	0.25	0.25
					External	0.04	0.06
Oxygen concentrator	4	15	3.929[a]	.416	Internal	0.14	0.29
					External	0.43	0.29

7. Conclusion

The final results of this study agreed with the suggestion of the "Joint Commission on Accreditation of Healthcare Organizations". That indicates the majority of hospitals need to improve the maintenance services used for their medical devices. Which recommends the use of different maintenance programs that suit the structure of each medical device, and the type of potential failure, and contribute to reducing the risk to patients. For example, different maintenance services may be employed for diathermy used in emergency departments and intensive care units, as opposed to devices operating in general patient care areas or clinics [21, 9]. At this time, medical devices become more complex. So, preventive maintenance activities become less relevant. Whereas predictive maintenance actively utilizes diagnostic methods such as CBM to avoid the risk of the breakdown of medical devices [26, 27]. Total Productive Maintenance is effective for maintaining anesthesia devices due to their classification as critical device. Based on this, it has a higher level of risk to the patient's life [5].

So, it is important to be flexible in the planning and scheduling of maintenance activities because it is often difficult to perform planned maintenance activities at a suitable time due to the equipment being in use as well as external factors beyond the operator's control. Also, there is a need to use a grace period (or slippage) for determining when an item of medical equipment must be considered overdue for planned inspection or maintenance [28].

Furthermore, healthcare organizations can be achieved economic advantages and social. Also, increasing its market value, which will contribute to maintaining its organizational reputation. For this reason, this study suggests adopting suitable maintenance-based risks to (1) ensure the delivery of a safe medical service, (2) reduce sudden failures of medical equipment while it delivers medical treatment, and (3) manage maintenance costs.

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