Quality Improvement Study

ANNALS OF MEDICINE & SURGERY

OPEN

An operational maintenance approach for improving physiological monitor by HFMEA process: an empirical case study

Jen-Shu Chia, PhD[a,*], Ching Chang, PhD[b], Chen-Hsuan Yang, PhD[c], Ching-Hui Yang, PhD[d], Yung-Tai Chiang, PhD[e], Cheng-En Wu, PhD[a]

Background: This study explored the application of healthcare failure mode and effect analysis (HFMEA) to identify and evaluate risk-associated factors in the intensive care unit (ICU) through a clinical-based expert knowledge (decision) for the physiological monitor operational maintenance process.

Methods and intervention: A mixed qualitative and quantitative proactive approach to explore the HFMEA process by analyzing 20 units of physiological monitors in the ICU. An HFMEA expert team of six people was formed to perform a risk-based analysis and evaluate the potential hazard index, mitigating the hazard scores and risks.

Results: From the main processes and possible failure reasons, one high-risk hazard index greater than or equal to 8 of the standard score was found. This standard score indicates the signed manufacturer's contract for maintenance was the hazard index failure mode on the parts not regularly replaced according to the contract. This systematic hazard index failure mode shows the highest hazard scores in the possible failure reason category, established as a standard maintenance procedure. In addition, the HFMEA expert analysis of the 20 units of physiological monitors within 6 months of the original and remanufactured part maintenance results in operational availability from 90.9% for self-repair to 99.2% for contract manufacturer repair.

Conclusions: This study concludes a systematic reference in malpractices caused by maintenance negligence. The HFMEA expert team agrees that hazard failure scores greater than or equal to 8 are vital assessments and evaluations for decision-making, especially in maintaining healthcare intensive unit care physiological monitors.

Keywords: decision-based analysis, healthcare, HFMEA, hospital management, risk analysis

Introduction

For several decades, medical devices and instruments have significantly increased in all sectors, especially in the medical facilities' intensive care unit (ICU)[1,2]. Mitigating the risk-related issues is to proactively assess prior medical device and instrument failure to avoid high-risk medical care failure at the ICU. Several

HIGHLIGHTS

- Healthcare failure mode and effect analysis (HFMEA) is a novel approach used to identify and evaluate risk-associated factors in the intensive care unit through a clinical-based expert knowledge (decision) for the physiological monitor maintenance process.
- An HFMEA expert-based team of six personnel was formed to perform a risk analysis and evaluate the potential hazard index in mitigating the hazard scores and risks.
- Hazard risk priority was calculated as an indicator representing high-priority areas needing special attention and standard maintenance procedures such as cost efficiency and availability.
- An HFMEA expert team agrees and recommends hazard failure scores greater than or equal to 8 as vital assessments and evaluations for decision-making, especially in healthcare intensive unit care physiological monitors maintenance.
- An operational availability – a medical dispute between the hospital management and the manufacturer was also analyzed, recommending the manufacturer's responsibility and liability on standard operational availability upon not replacing the original parts due to failure.

[a]Program of Technology Management, [b]Department of Business Administration, College of Management, [c]Industry-University Education Center, Chung Hua University, Hsinchu, [d]General Education Center, Hungkuang University, Taichung and [e]Kinesiology, Health and Leisure, Chienkuo Technology University, Changhua, Taiwan, ROC

Study setting and selection: A mixed qualitative-based and quantitative-based cross-sectional study was employed in this study. The study setting was conducted at Jen-Ai Medical Foundation, Dali Jen-Ai Hospital intensive care units. An HFMEA professional team of six experts in their respective fields was formed after the ethical approval from the Jen-Ai Medical Foundation Dali Jen-Ai Hospital, Human Body Research Ethics Committee, approval number 110–96. The study was conducted between September 2021 and November 2021.

Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

*Corresponding author. Address: Program of Technology Management, College of Management, Chung Hua University, Hsinchu 30012, Taiwan, ROC. E-mail: d10803004@chu.edu.tw (J.-S. Chia).

Annals of Medicine & Surgery (2023) 85:3916–3924

Received 15 March 2023; Accepted 2 July 2023

Published online 7 July 2023

http://dx.doi.org/10.1097/MS9.0000000000001064

medical instruments, such as operating room monitors, defibrillators, surgical instruments, physiological monitors, and many others, are highly accessible by doctors, nurses, and medical professionals[3]. However, physiological monitors are one of the medical devices and primary care devices used in patients' health assessments[4,5]. It is one of the most common medical instruments which help monitor patients' vital signs and transmit the physiological data to an electronic medical record. Medical professionals relied on these devices as a focal patient assessment to keep abreast of various physiological data of patients at all times. Due to the nature of these machines in size and weight, their functions could lead to high degrees of complexity, which need full assessment and maintenance. Thus, the failure and risk assessment analysis of these physiological monitors is key to avoiding several failures, malfunctioning, and accidents.

The recent development and applications of these physiological monitors without proper assessment and evaluation could lead to rapid failure and risk based on the hospital management and maintenance protocol settings. These physiological monitors have been popularized for monitoring and identifying disease states, tracking rehabilitation, and optimizing performance[6]. Several physiological monitors are mainly employed for heartbeat rate by measuring blood pressure, blood oxygen saturation concentration, or electrocardiogram. Nonetheless, several monitors are commonly used in a non-clinical setting, which includes non-invasive blood pressure, blood oxygen saturation concentration, heartbeat rate, electrocardiogram, temperature, respiration, and cardiac output. Thus, their measurement varies according to the different brands and applications and cannot be compared with those used in hospital settings.

Further, physiological monitors are one of the first-point assessments for patients' treatment. Therefore, a safe medical environment must be well-established and maintained per the medical institution's standard medical procedures. The joint commission on accreditation of healthcare organizations for improving the quality of care in healthcare settings based on certifications, standards, and patient-centeredness relied on six primary goals: (1) improving patient identification accuracy, (2) effective communication with medical providers, (3) improve the safety of high-risk drugs, (4) eliminate error occurrences in surgical positions and surgical procedures for surgical patients, (5) improve the safety of the infusion pump, and (6) improve the effectiveness of the clinical warning system[7,8].

The joint commission assessment on risk-related medical error avoidance and non-compliance in healthcare institutes evaluates other factors affecting patient safety and care. Such factors include but are not restricted to multitasking, interruptions, worker fatigue, communication issues, and many more[9,10]. Healthcare risk assessment is applied with suitable techniques to prevent unexpected failure scenarios. However, these healthcare risk management analyses are vital in improving performance. These risk system analyses are the healthcare failure mode and effect analysis (HFMEA)[11]. The HFMEA is a technical process used to evaluate healthcare-related risks and solve healthcare vulnerability in risk management. The first application of the failure mode and effect analysis (FMEA) model in the healthcare industry was in the 1990s, in drug production and medication error prevention in hospitals[12], by the American medical community for the Veterans Administration Hospital used under the Department of Medicine and Surgery. This system has been used for ages, and improving its application in healthcare is essential. Thus, its application in the healthcare sector is defined as a healthcare failure mode and effect analysis[8].

HFMEA identifies, rates, and prioritizes risks and hazards in the healthcare domain. It is a systematic process that identifies and prevents products and problems before occurrence. Further, it is used as a prospective assessment to identify and improve healthcare processes to ensure safe and clinically desirable outcomes. Though the HFMEA approach has been successfully utilized in the medical and healthcare environment to evaluate different clinical procedures, effectively identifying risk-prone conditions and reducing medical errors is of significant concern[13,14].

This study aimed to investigate critical issues pertaining to the operation of physiological monitors in clinical settings. These issues include equipment failures during startup or process and the inability to start the equipment. Such failures are of significant concern, mainly when the well-being of a patient is at stake. Therefore, the present study aimed to address these issues by employing the HFMEA process to identify gaps in the maintenance procedure. Further, the risk assessment involved the healthcare-specific definitions for severity, probability, and detectability, a systematic engineering-based approach used to identify system vulnerabilities and correct problems before they are realized[15]. Experts' judgment based on this risk criterion and failure mode versus risk criteria uses utilized as a key factor. An integrated risk index is introduced to compare the failure factor based on the failure's probability, detectability, and severity[16]. Thus, the current study employs a model structure that improves the accuracy of predicting and assessing the physiological monitor's maintenance needs. This approach also facilitates the development of a systematic management plan aimed at reducing unsafe design operations and negligence.

Methods and intervention

Study setting and selection

A mixed qualitative-based and quantitative-based cross-sectional study was employed in this study. The study setting was conducted at one of the major hospital ICUs. An HFMEA professional team of six experts in their respective fields was formed after the ethical approval. The study was conducted between September 2021 and November 2021. The manuscript has been reported in line with the SQUIRE 2.0 criteria[17].

Data collection and acquisition

After the formation of the professional expert team and followed by the review of the hospital assessment requirement, the expert team reviews their working process on the selection of the physiological monitors' process standard operating procedures (SOPs), as depicted in Figure 1 on the formulated study flowchart as adopted and modified from the National Center for Patient Safety (NCPS, 2001)[18] to suit in this study, highlighting the procedures to assess and validate risk-associated factors.

Creating the HFMEA team

This study creates an HFMEA team of six professional experts that includes two nurses in the ICU, one physician, one in-hospital maintenance staff, and two interdisciplinary professional technicians from the manufacturers responsible for maintenance.

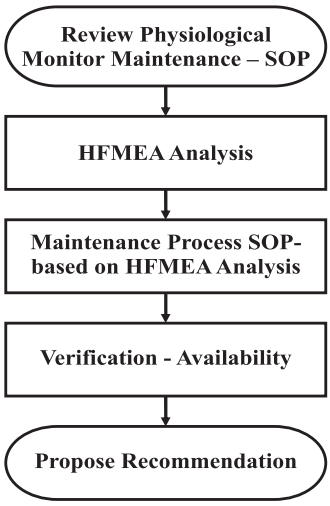

Figure 1. HFMEA study flowchart. HFMEA, healthcare failure mode and effect analysis; SOP, standard operating procedure.

All members of the HFMEA team were selected based on their experiences with the hospital/clinical management settings. They are senior team members who have worked for at least 10 years, with sound knowledge and expert decision-making of the highest standards. The identified techniques/processes, brainstorming approaches, SOPs, and flowcharts were explained thoroughly by the authors to the HFMEA expert team. The HFMEA expert team holds regular meetings once every 2 weeks for 3 months study period – identifying process steps involved, potential failure modes, assessing potential impact and identifying potential causes, and developing and prioritizing recommendations that are recommended to be implemented and monitored.

Potential failures and errors identification

The professional expert members identified and listed potential failure modes and errors in each physiological monitor. The assigned potential failure modes and error scores were collected by brainstorming and recorded on the HFMEA worksheet. These assigned scores are recorded based on the HFMEA hazard-score index matrix for the failure probability, as depicted in the hazard-score matrix in Table 1. These hazard scores determine the severity and probability/occurrence of any potential failure mode based on the hazard scoring matrix (Table 1). Thus, the severity score/index measures the possible effect of the failure mode, which could likely impact the physiological monitors if special measures are not taken and handled adequately.

Table 1

HFMEA hazard-scores index matrix.

Severity Occurrence	Catastrophic: (4)	Major: (3)	Moderate: (2)	Minor: (1)
Frequent: (4)	16	12	8	4
Occasional: (3)	12	9	6	3
Uncommon: (2)	8	6	4	2
Remote: (1)	4	3	2	1

Further, the severity categories include catastrophic (4), major (3), moderate (2), and minor (1), which are defined by specific operational definitions. Followed by the probability/occurrence ratings, which are determined by the frequent (4), occasional (3), uncommon (2), and remote (1). These potential effects for any severity and probability/occurrence for each failure mode and detecting failure were classified on a scale of occurrence – frequent (several times within 1 year), occasional (several times within 2 years), uncommon (sometimes in 2–5 years), and remote (5–30 years). Each failure mode's severity risk priority number was calculated based on the hazard-score index matrix. The calculated risk assessment scores for severity and occurrence (Table 1) are further assessed in the decision tree evaluation (Fig. 2). Furthermore, for each failure mode based on the risk assessment, the expert team has to determine these hazard risk scores, which are to be obtained in Table 2 on the maintenance analysis.

Maintenance procedure analysis and evaluation

The HFMEA expert team followed the HFMEA maintenance SOP, conducted by medical institutions using the daily machine start-up test by the unit users as the first level (Level 1) of operation. Later, the second level (Level 2) is conducted by the public works department, established within the hospital to carry out secondary maintenance according to the unit's time or needs. Lastly, the manufacturer contracts the third level (Level 3) maintenance to replace imported parts and perform deep cleaning and maintenance based on the contract agreement (Table 2).

Generally, the contracting committee maintenance approach is divided into three types according to the price of the inspection equipment and the complicated procedures: (1) Full-responsibility maintenance; (2) Maintenance of essential parts; and (3) Call repair maintenance. Therefore, according to the structure of the physiological monitor (Fig. 3), the second category is generally adopted: contract maintenance for essential parts.

Operational availability

Operational availability, also known as the goodness of service, is a function of reliability and maintainability. It defines a system's probability of performing under stipulated conditions of uptime and downtime[19]. In this study, 20 physiological monitor units are measured based on the degree the system is in an operational and committable state at the point in time when needed. Therefore, its active time ratio is proportional to the system lifecycle, which is the total amount of a system in a collection of its operational lifecycles and services[19]. The availability ratio of the system is equivalent to the total number of respective days the equipment was used, as described in the overall equipment usability. Therefore, this can be illustrated mathematically by defining operation availability (A_o) as shown in Equation (1):

$$A\,o = \frac{\text{Uptime}}{\text{Uptime} + \text{Downtime}}. \quad (1)$$

The system's operational availability in uptime and downtime can be disaggregated further to reveal the main contributing factors. Thus, the operational time (reliability) and maintainability can be shown as uptime and downtime, respectively. *Uptime* is when the machine or system is available for regular use, and

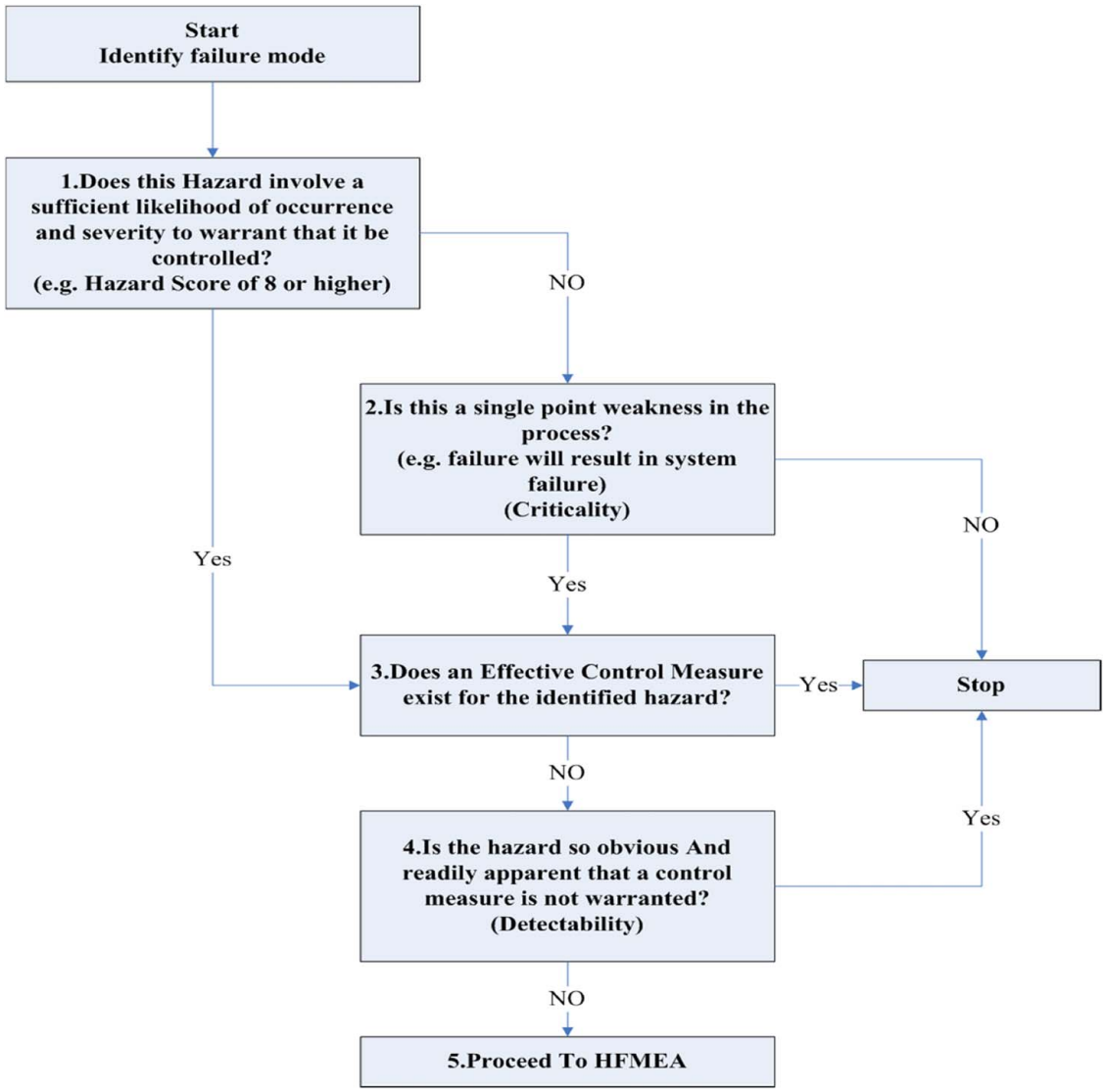

Figure 2. HFMEA decision tree evaluation. HFMEA, healthcare failure mode and effect analysis.

downtime is when the device or system is unavailable, including maintenance and logistic delay time.

Results

HFMEA hazard-score analysis

HFMEA hazard-score index matrix underlined the FOUR-point scale of occurrence, defined as Frequent (F), Occasional (O), Uncommon (U), Remote (R), and severity from Catastrophic (C), Major (MA), Moderate (MO), and Minor (MI). When the HFMEA expert team is asked to fill the FOUR-scale interval of failure modes risk, each expert has a different perception and opinion regarding the statement and ranking scales. These failure modes' risk ranking measurements were obtained and calculated (Table 3). The presented decision tree analysis (Table 3) shows three main processes, seven sub-processes with seven possible failure modes, and 18 possible failure reasons. After the HFMEA expert scores calculation, hazard, and decision tree analysis show one possible hazard index failure result greater than or equal to 8, showing that the 'parts not regularly replaced according to the contract, under the sign manufacturer's contract for maintenance'. This result translates to apparent discovery failure (Table 3), and about expert decision analysis, possible hazard index failure can be corrected.

Expert decision and recommendation

As depicted in Table 4, the HFMEA expert team analysis recommends or suggests system improvement after the professional team discussion. The proposed suggestions for improvement were also expected as significant feedback for more system application toward any physiological monitor in any clinical/

Table 2

Physiological monitor maintenance procedure.

Maintenance unit		Maintenance content
Level 1	Unit user to start the machine test daily	Before daily patient usage: 1: Machine appearance cleanup 2: Function light detection at machine startup
Level 2	Hospital maintenance department conducts maintenance according to SOP	1: Maintenance according to SOP 2: Manufacturer suggestion: functional test troubleshooting
Level 3	Sign manufacturer contract for maintenance	1: Regular maintenance according to contract 2: Functional test troubleshooting 3: Repair done

hospital setting. Therefore, its recommendation suggested an incremental improvement of the system or instrument. Thus, showing any hazard failure mode greater than or equal to 8 should be treated during the warranty period as a replacement in its specified time by the original manufacturer. In the event of failure/accident during the warranty period, the original manufacturer should bear the relevant costs.

Operational availability validation

Prior to the HFMEA expert team submitting the recommendations to the hospital based on the HFMEA analysis results, the expert team carefully reviewed the maintenance SOPs. The physiological monitor machines were carefully reviewed based on the maintenance qualification from 2021/1 and 2022/1 for 6 months, respectively. An inspection date from 2021/1 to 2022/6, maintenance cost, and parts comparison of 6 months is shown in Table 5. The same manufacturer brand of the physiological monitors used for 3 years was purchased because they were out of warranty. Thus, the contract cost of each machine is 10% of the purchase cost of New Taiwan Dollar (NT$) 140,000, which is NT$ 14,000, and the total amount of the 20 units is NT$ 280,000.

Operational availability outcome

After evaluating the 20 units of the physiological monitors based on the operational availability of uptime and downtime, the HFMEA expert team calculated the run-down system usage from its last maintenance, repair, and completion date for each physiological monitor unit from 2021/1 to 2021/6. The 6 months of parts maintenance (original and remanufactured) by the public works department resulted in an uptime (usage days) of 2741 days and a downtime (maintenance) of 275 days, which equates to the following operational availability of the maintenance records of the

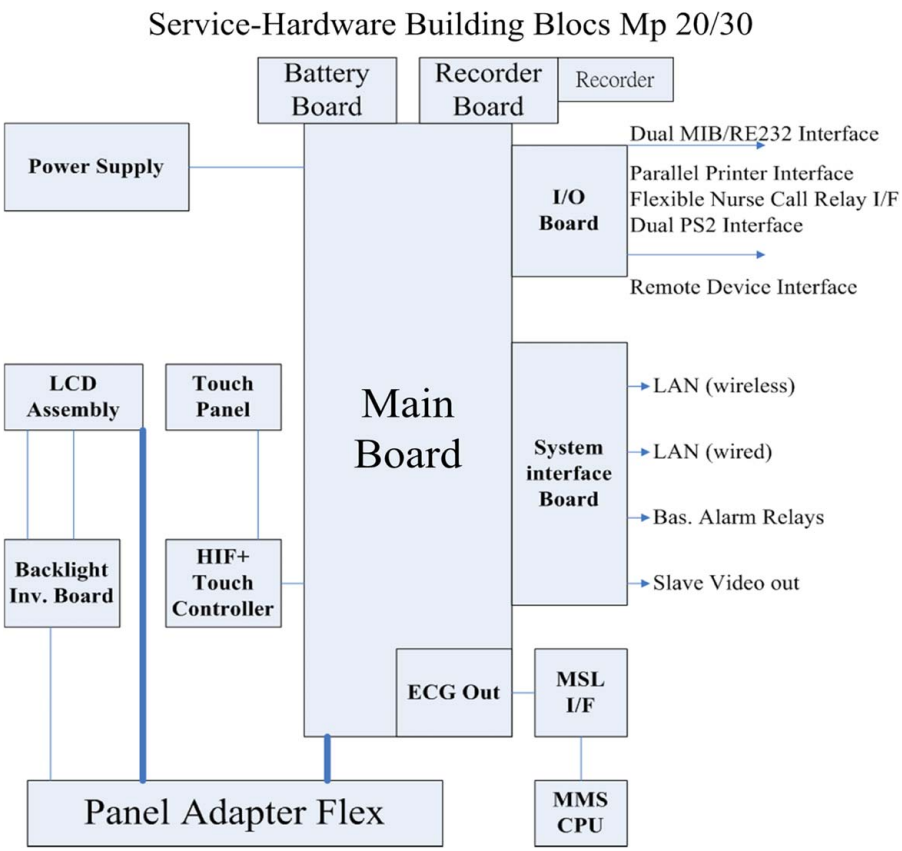

Figure 3. Physiological monitor construction diagram.

Table 3

Decision tree analysis.

				Hazard matrix analysis			Decision tree analysis		
Main process	**Sub-process**	**Possible failure modes**	**Possible failure reasons**	**Severity**	**Occurrence**	**Index**	**Control measure**	**Detectability**	**Proceed?**
1: Unit user to start machine test daily	1.1: Machine appearance cleanup	1.1.1: Not actually implemented appearance cleanup	1.1.1.1: Bad attitude of staff, poor cooperation	3	2	6	—	—	Stop
			1.1.1.2: Staff busy work not performing appearance cleaning	2	2	4	—	—	Stop
	1.2: Function light detection at machine startup	1.2.1: Not actually implemented machine self-test	1.2.1.1: Bad attitude of staff, poor cooperation	3	2	6	—	—	Stop
			1.2.1.2: Staff busy work not performing machine self-test	2	2	4	—	—	Stop
2: Hospital maintenance department conducts maintenance according to SOP	2.1: Maintenance according to SOP	2.1.1: Maintenance not performed according to SOP	2.1.1.1: Bad attitude of staff, poor cooperation	3	2	6	—	—	Stop
			2.1.1.2: Staff busy work not performing appearance cleaning	2	2	4	—	—	Stop
			2.1.1.3: Patient in use, cannot be stopped	1	1	1	—	—	Stop
			2.1.1.4: Machine failure, unable to boot	3	2	6	—	—	Stop
	2.2: Manufacturer suggestion: functional test troubleshooting	2.2.1: Not actually implemented check	2.2.1.1: Maintenance staff did not perform due to their busyness	3	2	6	—	—	Stop
			2.2.1.2: Patient in use, cannot be stopped	1	1	1	—	—	Stop
			2.2.1.3: Machine failure, unable to boot	3	2	6	—	—	Stop
3: Sign Manufacturer contract for maintenance	3.1: Regular maintenance according to contract	3.1.1: Not actually implemented check	3.1.1.1: Patient in use, cannot be stopped	1	1	1	—	—	Stop
			3.1.1.2: Machine failure, unable to boot	3	2	6	—	—	Stop
	3.2: Functional test troubleshooting	3.2.1: Not actually implemented check	3.2.1.1: Parts discontinuation, cannot be performed	3	2	6	—	—	Stop
			3.2.1.2: Stock parts zero inventory	3	2	6	—	—	Stop
			3.2.1.3: Parts not regularly replaced according to the contract	4	4	16	NO	NO	YES
	3.3: Repair done	3.3.1: Not actually implemented check	3.3.1.1: Bad attitude of staff, poor cooperation did not perform post-maintenance tests	3	2	6	—	—	Stop
			3.3.1.2: Maintenance staff did not perform post-maintenance tests due to busy work	3	2	6	—	—	Stop

Table 4

Suggested system improvement.

Main process	Sub-process	Possible failure mode	Possible failure reasons	Suggested actions to reduce failure mode
3: Sign Manufacturer contract of maintenance	3.2: Functional test troubleshooting	3.2.1: Not actually implemented check	3.2.1.3: Parts are not regularly replaced according to the contract	During the warranty period, it is recommended to replace at a specified time by the original manufacturer. In the event of failure/accident during the warranty period, the original manufacturer should bear the relevant costs.

general work department by availability:

$$A\,o = \frac{\text{Uptime}}{\text{Uptime} + \text{Downtime}} = \frac{2760}{2760 + 275} = 90.\,9\%.$$

Furthermore, after the HFMEA expert team analysis of the 20 units of the physiological monitors from 2022/1 to 2022/6 with an uptime of 3064 days and a downtime of 24 days, the signed manufacturer's contract for maintenance was increased to 99.2% based on the operational availability of the manufacturer as follows:

$$A\,o = \frac{\text{Uptime}}{\text{Uptime} + \text{Downtime}} = \frac{3064}{3064 + \quad 24} = 99.\,2\%.$$

With little difference in the overall maintenance cost (Table 5), medical institutions can save downtime and parts acquisition time. Most importantly, maintenance engineers will no longer have to purchase parts, allowing them more time for machine testing. Thus, this will allow a fair and safer medical environment for patients and healthcare professionals.

Discussion

Based on the HFMEA hazard analysis results, the failure modes whose risk assessment is greater than or equal to 8 points and cannot be controlled by the decision tree analysis are recalculated. The hazard risk matrix score of 'Effect analysis' in Level 3. 'Sign manufacturer contract for maintenance @3.2: Functional test troubleshooting @3.2.1 Not actually implemented check @3.2.1.3 Parts not regularly replaced according to the contract' as one of the highest failure hazard factors. Therefore, with the consensus of all participants in the project, priority should be given to improving the contents and plans to prevent the occurrence of potential hazards so that the physiological monitor can significantly be operated in a safer environment (Table 3). At the same time, other issues are reviewed for processing and formulate countermeasures systematically. As highlighted in Table 5, if any parts fail to work simultaneously, the results will be compared with Table 6, which the signed manufacturer's contract for maintenance will consider if the total cost of purchasing the remanufactured parts is only NT$ 12 500 and the waiting time for parts purchased is 7–70 days to be fixed/replaced.

Nonetheless, from January to June 2021, medical institutions' maintenance or operational availability rate is 90.9%. From January to June 2022, the operational availability rate thus increased to 99.2% after the HFMEA hazard analysis through the signed manufacturer's contract for maintenance using original parts. In this situation, the total amount, perhaps the initial expenditure, is more significant than the maintenance of subcontracted parts. However, there are considerable savings in each machine part in the acquisition purchase money, time, and standby time (Table 6). The in-hospital maintenance engineer can

Table 5

Inspection results of the item parts and maintenance cost.

Items	Parts	Parts cost (NT$)	Repair duration	Replacement (time)	Repair (time)	Warranty length
Main board	Original	4000	4 h	2 h	3 h	1 year
	Remanufacture	2500	5–10 days	2 h	3 h	6 months
Power supply	Original	2500	4 h	2 h	3 h	1 year
	Remanufacture	1500	5–10 days	2 h	3 h	3 months
LCD assembly	Original	5000	4 h	2 h	3 h	1 year
	Remanufacture	3500	5–10 days	2 h	3 h	3 months
Touch panel	Original	2000	4 h	2 h	3 h	1 year
	Remanufacture	1000	5–10 days	2 h	3 h	3 months
I/O board	Original	2000	4 h	2 h	3 h	1 year
	Remanufacture	1500	5–10 days	2 h	3 h	3 months
System interface board	Original	2500	4 h	2 h	3 h	1 year
	Remanufacture	1500	5–10 days	2 h	3 h	3 months
Battery board	Original	1500	4 h	2 h	3 h	1 year
	Remanufacture	1000	5–10 days	2 h	3 h	3 months

Note: New Taiwan Dollar (NT$): (US$ 1.00 = NT$ 30.58).

Table 6

Cost and maintenance comparison.

Item	Original parts	Remanufactured parts
Total cost of single part	NT$ 19 500	NT$ 12 500
Contract costs	NT$ 14 000	—
No. of days to repair	4–28 days	7–70 days
Replacement duration	2–14 h	2–14 h
No. of hours for repair	3–2 h	3–21 h
Warranty length	1 year	3–6 months

Note: New Taiwan Dollar (NT$): (US$ 1.00 = NT$ 30.58).

have more time to schedule more machine inspections, which can serve similar functionality and usability to keep patient safety.

Furthermore, it is significant for hospital settings to implement HFMEA hazard analysis in building preventive systems, understand risk factors in advance, establish preventive measures, and improve high-risk procedures to avoid patient injury due to accidents. The risk assessment principle of HFMEA as expert decision-making could be applied to risk and failure mode in understanding the usage status of the hospital's physiological monitor and discussing the maintenance operation process in depth.

The objectives and implementations of healthcare and medical technologies are frequently based on prices, compatibility, recognition with the seller, and past acquired knowledge[20]. A proactive risk evaluation reflects an impartial analysis that considers these intrinsic limitations of new technology and its pertinence for a specific environment of use within the clinical care unit. We absorbed this aspect by employing various electronic medical record systems in different health systems. The systematic application and settings of the latest technologies can pose unforeseen challenges to care delivery. Therefore, it is imperative to be vigilant in designing implementation strategies for any monitoring system.

Limitations

A few limitations were highlighted in terms of the different ways of maintenance in each medical institution, and the annual maintenance budget (expenses) might vary depending on the type and size of the machine. Thus, the benefit of HFMEA analysis cannot be over-emphasized based on the only maintenance approach of the case hospitals and cannot be used as a general approach to analyzing any clinical setting. Further, among several limitations, one may consider HFMEA expert analysis as a subject to naturally subjective differences based on personal opinions between evaluators regarding where it is applied. This can result in inconsistencies in the interpretation of data and the identification of potential failure modes. Additionally, the expertise and experience of the evaluators can also impact the analysis and the resulting recommendations. Also, in the clinical application, the application of HFMEA recommendations may be challenging, as there may be practical barriers to implementation. For instance, the cost of implementing certain recommendations or the need for additional staff training may be prohibitive. In conclusion, HFMEA may not capture all potential failure modes or factors that may contribute to errors, as it is based on a specific set of assumptions and data inputs.

Additionally, HFMEA clinical application might vary based on the level of each medical facility in the staffing level, budget acquisition, and vendor maintenance. In larger medical institutions, maintenance departments are typically responsible for ensuring the upkeep of medical equipment. Their maintenance contracts are available for medical equipment costing approximately over NT$ 10 000 000. However, once the warranty expires, the equipment/machines valued at hundreds of thousands of NT$ are typically subjected to basic troubleshooting by maintenance staff and repairs by contract. It is important to note that the scope of maintenance is limited based on the age of the machine, the budget obtained in a given year, and the machine's benefit analysis, which varies yearly. As a result, based on some expert decisions, the use of HFMEA to analyze medical device maintenance is recommended for large medical institutions with maintenance departments. Furthermore, this also may not be applied to all levels of medical institutions in a general application.

Conclusions

This study presents a standard maintenance process, presenting an HFMEA analysis that did not reach the 8 points level of the risk matrix score. However, these hazard failures can be improved. Based on the findings, this study concludes based on the HFMEA expert team recommendation on the cleaning operation of the cleaning staff's SOP, the check items of 'machine wipe', and the staff's SOP 'daily power on' should be added. The essential principle for ensuring that the machine works appropriately, is through daily shift inspection. For the important parts with the highest hazard scores, the original manufacturer's recommendations should be monitored: it is best not to use the service life of each part beyond the recommended replacement time. In addition to the possible chain damage of various parts, the machine shuts down abnormally during use, which could result in subsequent medical system disputes. This study could serve as a vital assessment point for HFMEA analysis in failure/mistakes in clinical/hospital settings for better physiological monitor devices. Finally, due to the operating costs of medical institutions, attached factory parts or remanufactured parts are generally used. Due to the high price, only between half or two-thirds of the original parts, the warranty is between 3 and 6 months, far less than the original manufacturer's 1–2 years warranty. Suppose the parts can be replaced immediately within a reasonable period according to the original manufacturer's recommendations. In that case, the use of the machine will not be affected by the damage to the parts. When follow-up medical disputes arise from the maintenance of the parts, the maintenance time of the parts, and the machine failure caused by the replacement, the company can be requested a certain degree of compensation from the original. In summary, large medical institutions may utilize HFMEA to review various types of medical equipment maintenance SOPs to secure the best maintenance contracts with manufacturers, ultimately improving the rate of medical equipment performance and enhancing patient safety. Additionally, the use of HFMEA provides maintenance personnel with sufficient time to evaluate the service life of each machine part, reducing the likelihood of preventable failures in patient use that may result in significant medical incidents.

Ethical approval

The study was conducted according to the guidelines of the Declaration of Helsinki and was approved by the local Institutional Review Board (Jen-Ai Hospital 110-86).

Consent

All authors have read and agreed to the published version of the manuscript.

Sources of funding

Not applicable.

Author contribution

C.C. and C.-H.Y.: conceptualization and methodology; J.-S.C.: software, validation, investigation, resources, data curation, and writing – original draft preparation; J.-S.C., C.C., C.-H.Y., and C.-E.W.: formal analysis; J.-S.C. and C.-E.W.: writing – review and editing; C.C. and Y.-T.C.: supervision.

Conflicts of interest disclosure

The authors declare that there are no conflicts of interest.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Acknowledgements

The authors extend their appreciation to those involved in this study in part or whole, such as the expert team and English editing personnel, for their valuable comments and suggestions to improve the readability and quality of this paper.

References

[1] Fortune Business Insights. Infographics - Intensive Care Unit (ICU) Equipment Market Size. 2021:245. The global intensive care unit (ICU) equipment market. FBI103058. https://www.fortunebusinessinsights.com/infographics/intensive-care-unit-icu-equipment-market-103058

[2] Michard F, Bellomo R, Taenzer A. The rise of ward monitoring: opportunities and challenges for critical care specialists. Intensive Care Med 2019;45:671–3.

[3] Liu M, Lin Y, Xiao K, *et al*. Review of physiological parameters monitoring technology in the ICU. Zhongguo Yi Liao Qi Xie Za Zhi 2021;45:662–9.

[4] Diao JA, Marwaha JS, Kvedar JC. Video-based Physiologic Monitoring: Promising Applications for the ICU and Beyond. Nature Publishing Group; 2022:1–2.

[5] Mann JK, Kaffashi F, Vandendriessche B, *et al*. Data collection and analysis in the ICU. In: De Georgia M, Loparo K (eds). Neurocritical Care Informatics Informatics. Springer, Berlin, Heidelberg. 2020:111–134.

[6] Sawka MN, Friedl KE. Emerging wearable physiological monitoring technologies and decision aids for health and performance. Am Physiol Soc 2018;124:430–1.

[7] Leatherman S, Berwick DM. Accelerating global improvements in health care quality. JAMA 2020;324:2479–80.

[8] Wang B, Tabshouri B. The Joint Commission vs Joint Commission International: Part II–comparing the survey practices for medical equipment management and maintenance. J Clin Eng 2018;43:75–82.

[9] Sherman JD, Hopf HW. Balancing infection control and environmental protection as a matter of patient safety: the case of laryngoscope handles. Anesth Analg 2018;127:576–9.

[10] Wilson M, Riedy SM, Himmel M, *et al*. Sleep quality, sleepiness and the influence of workplace breaks: a cross-sectional survey of health-care workers in two US hospitals. Chronobiol Int 2018;35:849–52.

[11] Simsekler MCE, Kaya GK, Ward JR, *et al*. Evaluating inputs of failure modes and effects analysis in identifying patient safety risks. Int J Health Care Qual Assur 2019;32:191–207.

[12] Homauni A, Zargar Balaye Jame S, Hazrati E, *et al*. Intensive care unit risk assessment: a systematic review. Iran J Public Health 2020;49:1422–31.

[13] Liu H-C, You X-Y, Tsung F, *et al*. An improved approach for failure mode and effect analysis involving large group of experts: an application to the healthcare field. Qual Eng 2018;30:762–75.

[14] Rodziewicz TL, Houseman B, Hipskind JE. Medical Error Reduction and Prevention. *StatPearls*. StatPearls Publishing; 2022.

[15] Liu H-C. Improved FMEA Methods for Proactive Healthcare Risk Analysis. Springer; 2019.

[16] Leoni L, De Carlo F, Paltrinieri N, *et al*. On risk-based maintenance: a comprehensive review of three approaches to track the impact of consequence modelling for predicting maintenance actions. J Loss Prev Process Ind 2021;72:104555.

[17] Ogrinc G, Mooney SE, Estrada C, *et al*. The SQUIRE (Standards for QUality Improvement Reporting Excellence) guidelines for quality improvement reporting: explanation and elaboration. Qual Saf Health Care 2008;17(Suppl 1):i13–32.

[18] DeRosier J, Stalhandske E, Bagian JP, *et al*. Using health care failure mode and effect analysis: the VA National Center for Patient Safety's prospective risk analysis system. Jt Comm J Qual Improv 2002;28:248–67; 209.

[19] Diatte K, O'Halloran B, Van Bossuyt DL. The integration of reliability, availability, and maintainability into model-based systems engineering. Systems 2022;10:101.

[20] Luca L, Paul O. Price Setting and Price Regulation in Health Care Lessons for Advancing Universal Health Coverage: Lessons for Advancing Universal Health Coverage. OECD Publishing; 2019.