








RESEARCH ARTICLE

WILEY

Critical assessment of medical devices on reliability, replacement prioritization and maintenance strategy criterion: Case study of Malaysian hospitals

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Funding information

Ministry of Health Malaysia

Abstract

The Biomedical Engineering Maintenance Services (BEMS) is a comprehensive maintenance program that ensures the safety and reliability of medical devices. Significant and crucial devices are identified and prioritized for best practice prior to the equipment life cycle to mitigate functional problems, alarmed by the Fourth Industrial Revolution (4IR) underlying the modernization agenda. A model of multi-criteria decision-making (MCDM) to prioritize medical devices according to their criticality is presented in this paper, with the utilization of quality function deployment (QFD) and fuzzy logic in the development of the model through a quantitative survey of experts from all regions in Malaysia. As a result, a customized version of the Asset Criticality Assessment (ACA) is developed and is recommended for use in more than 144 Ministry of Health (MOH) hospitals. Subsequently, real data of four selected devices are pulled from the Asset and Services Information System (ASIS) to demonstrate a relevant and comparable end-result using the QFD and fuzzy logic. In essence, the key contribution of the customized ACA model is that it assesses a promising evaluation with a broader range on both the performance of medical devices and the appropriate asset replacement choices. This leads to an effective maintenance strategy for each device and the modernization of reliability computation metrics.

KEYWORDS

analytical hierarchy process (AHP), asset criticality assessment (ACA), fuzzy logic, quality function deployment (QFD)

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1 | INTRODUCTION

Maintenance refers to all acts that are necessary to keep an item, part or piece of equipment in, or restore it to, a proper state.¹ Thus, changes or replacements are necessary to keep the condition in line with the intended plan. Maintenance, according to Heizer and Reinder,² is defined as the efforts entailed in maintaining the equipment of a system in good functioning order, whereas Sehwarat and Narang³ define maintenance as work done in a logical order to maintain or enhance an existing system or piece of equipment to meet the standards in compliance with quality and functional requirements.

Preventive maintenance (PM), corrective maintenance (CM) and predictive maintenance (PdM) are examples of maintenance strategies.⁴ As a result, it is just as necessary to manage and control maintenance activities as it is to do maintenance. As the number of medical devices on the market grows, so does the size of maintenance activities, necessitating the need for advanced management and control.⁵ Medical devices and equipment have become increasingly complicated and sophisticated, and they are expected to work in harsh conditions. Hospitals must ensure that vital medical devices are safe, accurate and reliable and that they are performing at the needed level. Despite its importance, all inspection, maintenance and optimization models have only recently been applied to medical equipment.⁶ Due to the sheer growing quantity and complexity of medical devices, hospitals must set up medical device management in such a way that assures the critical medical equipment is safe and dependable enough to perform at the appropriate level. Decisions on medical equipment maintenance strategies must take into account not only manufacturer guidelines, but also a more efficient and cost-effective maintenance approach.⁷

High performance in medical device maintenance and use ensures maximum efficiency and increased availability of equipment at the lowest possible cost, while also ensuring quality, safety and environmental protection.⁸ Maintenance objectives, equipment properties, work processes, and work space all play a role in determining the best maintenance strategy.⁹ An effective maintenance strategy mix, according to Wang et al.,¹⁰ can increase plant and equipment availability and dependability while reducing unnecessary maintenance investment. To improve the efficiency and effectiveness of medical device maintenance, it is vital to consider the backbone of the maintenance plan to facilitate the best solution given the characteristics and flaws that these devices exhibit. Maintenance is no longer only a partner in medical services; it is now a necessity for providing high-quality medical care.¹¹ Its connection to an equipment performance is a matter of senior management's integrated strategy. As a result, the maintenance role falls under the purview of management.¹² An improper maintenance plan can have a substantial influence on performance and safety, as well as operating costs (OPEX). As a result, throughout the maintenance and management of the equipment life cycle, a critical assessment of the medical device state is an important operation to increase availability, performance and safety.

Due to this requirement, the Biomedical Engineering Maintenance Services (BEMS), under the supervision of the Ministry of Health (MOH) Malaysia is committed to proactive measures addressing equipment safety and clinical services through an excellent program on medical device replacement and performance monitoring, in addition to the scheduled tasks in a comprehensive maintenance routine. Significant and crucial devices were selected and prioritized for best practice and recommendation prior to the equipment life cycle, alarmed by the Forth Industrial Revolution (4IR) underlying the modernization agenda, to mitigate functional failures.

However, the visibility of the medical device's healthy and reliability in the current performance quantification is insufficient to consolidate a failure prediction indicator in conjunction with the 4IR niche vocabulary. Furthermore, the current parameters that have been referenced rely on limited resources such as equipment ageing (Life Expectancy Projection Guidelines), developed by the American Society for Healthcare Engineering (ASHE) and the American Hospitals Association (AHA), individual functionality, informal and non-holistic assessments to determine the appropriate justification for maintenance and replacement planning. Nevertheless, the conclusion of these approaches does not provide a precise and transparent measurement across a broad spectrum of equipment performance, resulting in erroneous equipment selection and, in turn, causing the wrong decision by the policy makers.

Previous research has shown that multiple strategies were used to construct a Critical Assessment model, with the first step defining the criteria and sub-criteria, followed by calculating the weight and intensities of each criterion. The criticality score of various devices may be determined and they can then be ordered depending on the score obtained from experts' opinions in a survey. Due to different levels of equipment usage, maintenance approaches and the nature of the Malaysian healthcare industry, the adaptation of these models for MOH application in terms of criteria, sub-criteria and weightage must be reinvented for BEMS accessibility in terms of criteria, sub-criteria and weightage.

In this paper, a model of multi-criteria decision-making (MCDM) to prioritize medical devices according to their criticality is presented, with Quality Function Deployment (QFD) and fuzzy logic used in the development of the model

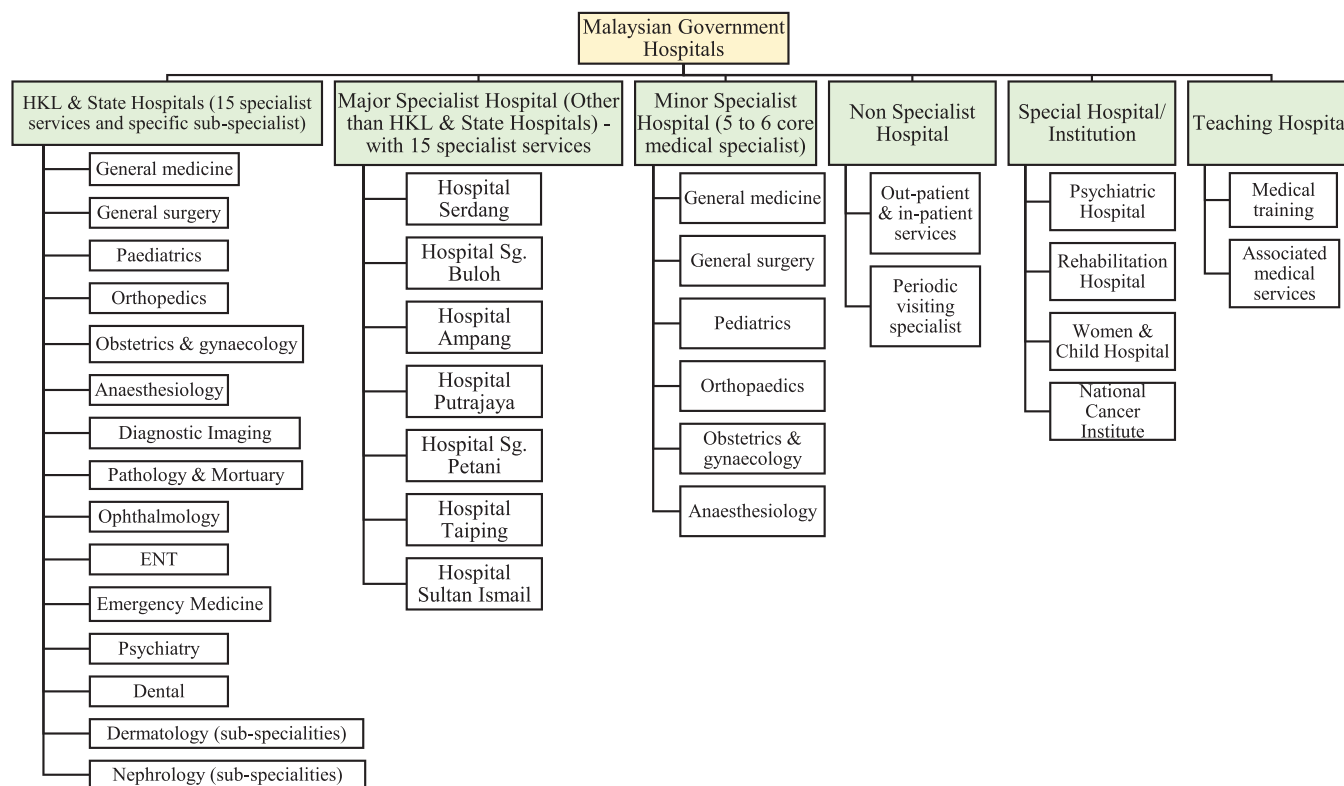


FIGURE 1 Types of government hospitals.

through a quantitative survey of experts from all regions of Malaysia. As a result, a customized version of the Asset Criticality Assessment (ACA) model is developed and proposed for practical use in more than 144 Malaysian hospitals. Real data from four different equipment type codes were collected from the Asset and Services Information System (ASIS)¹³ to show a relevant comparison end result using the QFD and fuzzy logic. This is significant because the new ACA model's primary contribution is to provide a more transparent evaluation and a broader spectrum on both medical device performance and the proper replacement selection, as well as to enable the proper maintenance strategy for each equipment type code, which includes modernizing maintenance metrics on reliability computation.

This is how the rest of the paper is structured: Section 2 includes a literature review that covers MOH hospitals and BEMS roles, as well as brief descriptions of critical evaluation via MCDM, QFD assessment review and reliability computation. In addition, the subsequent sub-section examines the research gap and the study's contribution. The proposed solution's approach and problem formulation are described in Section 3. Section 4 presents the results and discussions. The paper comes to a closing at Section 5.

2 | LITERATURE REVIEW

2.1 | MOH hospitals and BEMS responsibilities in the maintenance of medical devices

The national/state hospitals, major specialist hospitals, minor specialist hospitals, non-specialist hospitals, special hospitals/institutions, and teaching hospitals are the six types of Malaysian government hospitals¹⁴ as shown in Figure 1. Some of these hospitals are distinguished by Hazilah Abd. Manaf¹⁵ as follows: (i) national hospital—Hospital Kuala Lumpur (HKL)—provides an extensive array of tertiary medical services and serves as the National Referral Centre, (ii) state hospitals are built in each of the country's 13 state capitals which provide an extensive array of secondary services, and (iii) district-level hospitals provide basic inpatient care services and resident specialists provide some specialty services. Figure 1 summarises a more detailed explanation of the category of government hospitals. These hospitals can also be distinguished by the number of beds, size, capacity, and functionality of the hospital buildings, which are nearly uniformed in terms of building design, operational flow, installed equipment, energy trend, and maximum demand (MD) of energy usage at each of the aforementioned levels.¹⁶

More specifically, both the government and private parties have demonstrated a significant commitment to the readiness of MOH facilities and medical devices. In response to the lack of facilities and biomedical equipment, the Engineering Service Division (ESD), a government agency under MOH, is investing a special effort in administration and closely monitoring the implementation of a privatization project for the provision, operation and maintenance of hospital support services (HSS) for more than 144 MOH hospitals. The initiative was launched with the following aims in mind¹⁷:

- (i) Carry out the government's privatization strategy.
- (ii) Raise the standard of healthcare delivery and service quality in government hospitals.
- (iii) Improve efficiency and reliability of the provision, maintenance and management of HSS; and
- (iv) Promote, embed, and improve the culture of comprehensive planned preventive maintenance (PPM) in public assets and facilities.

The BEMS is supported by a defined method and key performance indicators (KPIs) that are guided by tight and timely monitoring by biomedical engineers (BME) from both the MOH and the company representatives to ensure the highest quality of services. The BME, according to the World Health Organisation (WHO),¹⁸ is a profession that has made significant contributions to the development and advancement of medical technology and clinical services. Contingent upon their preparation and part of employment, the duties of BME professionals can incorporate regulating the innovative work; research and development (R&D); design, structure, safety, and viability of medical devices/systems; selection and procurement; installation; integration with electronic medical records systems; daily operations monitoring; managing maintenance and repairs; training for safe use; and upgrading of medical devices to healthcare stakeholders.

2.2 | Maintenance strategy and the 4IR way forward

Since PM, CM and PdM are considered as the fundamentals of maintenance strategy,⁴ the remainder of the strategies are thought to be a mixture of these principles in order to construct a more organized and systematic idea and streamline routine maintenance in the industry.¹⁹ Traditional reactive maintenance, according to Magadán et al.,²⁰ only performs maintenance tasks once a failure is detected. Widespread PM refers to maintenance actions that are performed on a regular schedule based on previous failure experiences. PdM, on the other hand, has emerged as an excellent method for reducing costs and preventing equipment failure in the field. In general, part of the maintenance strategies for MOH hospitals is the adaptation of PM and CM which are structured into two groups, namely, schedule maintenance and unscheduled maintenance.

Scheduled maintenance, which includes PPM, routine inspection (RI), scheduled corrective maintenance (SCM), calibration and warranty PPM, is a periodic prescribed inspection or servicing of medical devices performed on a calendar, hours or usage counters of operation basis. Unscheduled maintenance, on the other hand, is a technique for restoring malfunctioning biomedical equipment to a predetermined condition in terms of CM responsiveness.²¹

PPM is for a planned maintenance program and it outlines the frequency, tasks and activities that must be completed to guarantee that all equipment are operating properly and safely according to the manufacturer's design parameters. RI, on the contrary, is a user-area periodic inspection or rounds to examine the physical integrity, functionality and safety aspects of medical equipment, which may also include immediate correction for small errors. SCM, on the other hand, is a corrective maintenance procedure for medical devices that is necessary during the PPM or RI, and cannot be performed immediately after detection. Finally, CM is an action taken to return an object to its original state when it fails to work as intended by the maker. The general structure of the maintenance program is depicted in Figure 2.

Failures are predicted in the 4IR era based on real-time data from sensors in industrial equipment,^{23,24} as well as in the monitoring of currents, pressures, temperatures, and other variables in industrial plants.²⁰ With advancements in micro-electromechanical systems, a wide variety of low-cost sensors capable of sensing, calculating and wirelessly sharing information for environmental and equipment monitoring may be deployed.²³ Detection of operating anomalies is a type of PdM that can be done even if there is no data from earlier equipment failures.²⁵ Machine learning (ML) models based on binary classification are employed when available to predict breakdowns in the near future so that repairs or replacements can be planned.²⁶

Anomaly detection, also known as outlier identification, is the process of detection when something unexpected happens.²⁷ It is closely related to PdM since maintenance is required when anomalies in the device/machine occur or are going to occur. Unsupervised approaches, such as clustering-based ways to locate outliers, or supervised approaches,

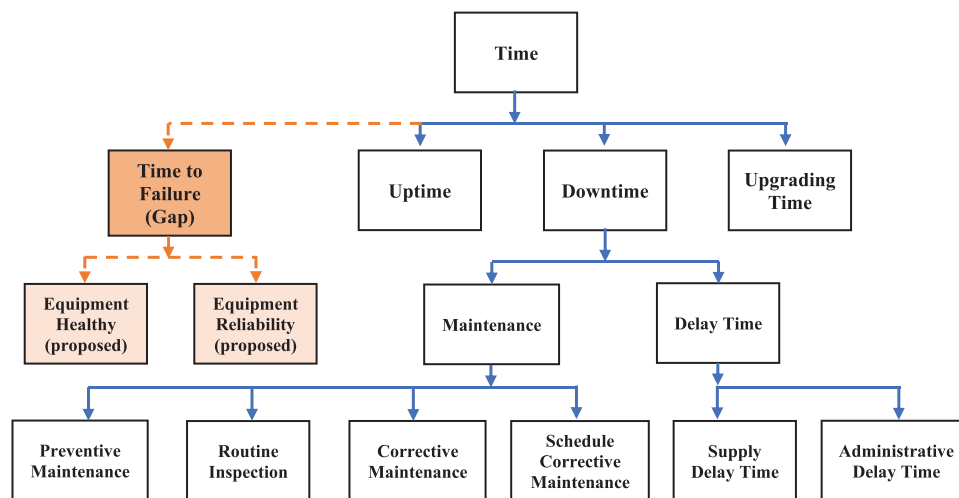


FIGURE 2 The current maintenance program structure for BEMS²² and the proposed solution for identified gap.

such as labeling data and learning classification models from labeled data, can be used to detect anomalies.²⁵ The prediction models are developed and validated on historically labeled data that includes information on previous equipment failures. Since the volume of historical data can be enormous, real-time cloud storage is a viable alternative, resulting in cloud-based PdM.²⁸

PdM is often referred to as condition-based maintenance (CBM)²⁹ or prognostics and health management (PHM),³⁰ is the process of estimating an equipment's current status and predicting when maintenance should be performed. Rather than performing PM regularly, PdM is cost-effective by performing maintenance at the right time. Two key tasks of PdM are prognostics and diagnostics. Diagnostics is related to finding anomalies in that it examines the state of one's health (SoH). Prognostics forecasts remaining useful life (RUL) in the same way that anomaly prediction does. Knowledge-based, physical model-based and data-driven PdM approaches are the three main types.²⁹ For data-driven prognostics and health management, a variety of health assessment and anomaly detection techniques have been described, including statistical hypothesis testing, regression and neural network-based methods.³¹ However, to the authors' knowledge, no studies on how to predict anomalies in a comprehensive and identifiable way have been published.

Although the definitions of CBM and PdM appear to be similar, CBM is a different support method that offers upkeep tasks (choices) based on data collected through the condition observation procedure. The lifetime (age) of hardware in CBM is determined by its operating state, which can be assessed based on various inspection criteria such as vibration, temperature, grease-up oil, pollutants, and clamor levels.³² CBM is an advanced support method and maintenance technique that relies on execution, parameter monitoring and the actions that follow.³³ The health of a piece of equipment or instrument is monitored using the CBM framework, which involves acquiring and analyzing assessment data such as vibration data, acoustic emanation data, oil investigation data, and temperature profiling. Future health status can also be predicted and optimal maintenance operations can be scheduled to avoid equipment breakdown and lower overall operating costs.³⁴ To implement this maintenance approach, CBM will require comprehensive support equipment or accessories. It is well-known that MOH has a large number of medical gadgets that are over 20 years old. As a result, more complex ways to optimize the government's OPEX are in great demand.

Based on the 4IR niche described above, there is a gap in the existing MOH hospital's maintenance strategy, as shown in Figure 2, where the PdM or CBM is not connected to a pipeline of real-time equipment fitness and deterioration information. To bridge this gap, a critical assessment engagement (both current contract and 4IR policy) is frequently significant as the entry point for enabling the correlation between the current maintenance structure and 4IR-forecast-driven approaches (referred to as time-to-failure portfolio) supported by equipment fitness and reliability measurement. As a result, PdM and CBM could lead to activities such as continuous or periodic monitoring and diagnostics of medical devices in order to forecast component degradations and undertake planned maintenance prior to failure.

2.3 | ACA – 4IR gateway via MCDM (QFD and fuzzy logic)

Asset criticality is a function of the operational impact on the organization's mission due to the loss, damage, or destruction of an asset.³⁵ Dekker et al.,³⁶ define equipment criticality as a function of the use of equipment, rather than of the

equipment itself, and explain how a certain device may be in one case critical and in another, auxiliary.³⁷ A machine and device criticality evaluation, according to Jasiulewicz-Kaczmarek et al.,³⁸ is an organized series of tasks that enables the identification of machines and devices whose failures have the largest potential influence on the company's business goals. As a result of conducting a critical assessment, the reliability technical team can focus their attention and resources on the most vital assets. Nevertheless, a huge percentage of empirical evidence overlooks the uncertainties that coincide with expert opinions³⁹; for instance, the replacement prioritization criteria in MS2058:2018⁴⁰ does not show evidence of holistic opinion from the experts in establishing the criteria and scoring. Moreover, some of the criteria are seen as redundant between certain parameters in the replacement factor (e.g., asset condition and asset status), as well as undeclared of certain parameters (e.g., an undetermined hour of usage in asset usage parameter) and unjustified pattern of weightage scoring. Thus, the justified ACA module through appropriate methodologies (i.e., MCDM, Analytical Hierarchy Process (AHP), QFD, fuzzy logic, etc.) is in high demand for a more transparent output that takes into consideration various dimensions of input criteria, rather than assuming that all medical equipment is critical.

The model of MCDM has been widely used to prioritize medical devices and provide criteria for determining the best maintenance strategy^{7,41–43} within the same page on prioritizing medical devices through critical assessment. It is a type of decision making that is classified into two categories, namely, multiple objectives and MCDM. MCDM is also possible by determining preferred judgements based on various qualities, such as evaluation, prioritization/scoring and alternative selection.⁷

More sensibly, MCDM is a multi-stage process that includes identifying objectives, selecting criteria to measure the objectives, outlining alternatives, giving weights to the criteria, and rating alternatives using the proper mathematical method. Therefore, MCDM provides the unbiased integration of current planning objectives, as well as the independent identification and evaluation of the best planning solutions.⁴¹

Meanwhile, failure mode and effects analysis (FMEA), according to Tang et al.,⁴⁴ employs the risk priority number (RPN) model to assess and rank the project's failure modes, which is a common method for risk assessment and prevention. The value of RPN may be impacted by the three risk categories in the FMEA, occurrence (O), severity (S), and detection (D). These three risk factors are evaluated subjectively by the experts on the FMEA team based on their expertise and professional experience. They represent the likelihood that the failure mode will occur, the severity of the consequences following the failure mode occurrence, and the likelihood that the failure mode can be detected after it has occurred, respectively.

Besides, Deng entropy is used to measure uncertainty in negation evidence and is developed by Tang et al.⁴⁵ The suggested measure is based on the basic probability assignment's (BPA's) negation function and it can quantify the uncertainty of the negation evidence. It is also suggested to use a new measure to quantify uncertainty in the negation evidence when combining information from many sources. The proposed method's efficacy and logic in measuring and fusing ambiguous information are confirmed by experimental findings on a numerical example and a defect diagnosis scenario.

Various methodologies, such as QFD, AHP and fuzzy logic, have been used in the development of a critical assessment model in previous studies. The suggested model's first step is to identify the criteria and sub-criteria, after which the weights and intensities of each criterion are determined. The criticality score of these gadgets may be determined and they can then be sorted according to the score obtained from the survey.

PM management has been studied in the past. PM is a basic role of clinical engineering, with the goals of ensuring continued safety and performance of the medical devices, as well as preserving the equipment's investment through increased longevity.⁴⁶ The number of maintenance activities grows in lockstep with the variety of medical equipment, necessitating greater administration and control which utilized QFD as an indication of one of these tactics in PM prioritizing.⁵ To prioritize PM for the list of medical equipment, the model was constructed using three domains, namely, the requirement domain, function domain, and concept domain. The AHP is used to prioritize the PMs based on a model that is split into three tiers.³⁷ The initial level in an application is the aim, which in this case is the prioritization of medical devices. The criteria and sub-criteria are on the second level, while the options are on the third.

Similarly for the suggested model, after the criteria and sub-criteria are identified, followed by determining the weights and intensities of each criterion, the next stage is to assess the options in terms of the criterion. The criticality score of these devices may then be calculated and they can be ranked according to that score.

QFD is one of the quantitative tools and approaches in overall quality management that may be used to translate customer requirements and specifications into technical or service requirements.⁴⁷ Yoji Akao created QFD in Japan around the end of the 1960s. Mizuno used QFD for the first time in 1972 at Mitsubishi's Kobe shipyard site.⁴⁸ Competitive performance, customer requirements, goal values, design requirements, and competitive performance are all linked together in one chart by QFD.⁴⁷ Therefore, QFD is regarded as a quantitative technique for evaluating customer happiness. A QFD

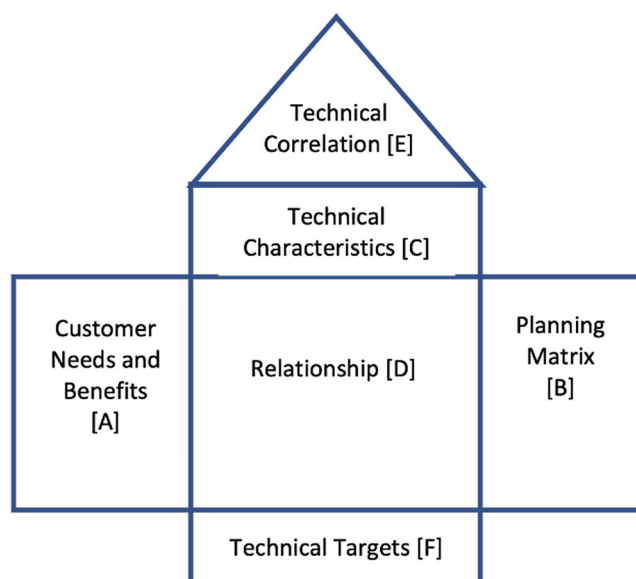


FIGURE 3 Function deployment for HOQ.

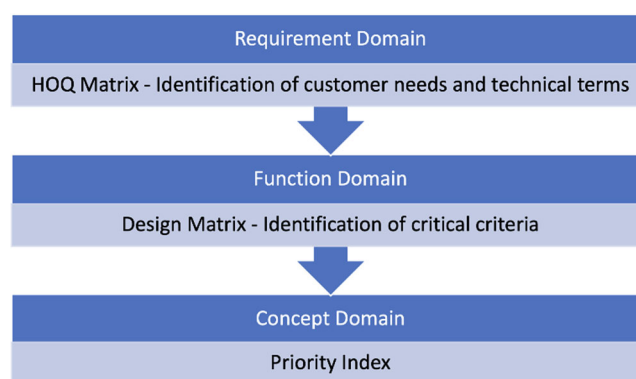


FIGURE 4 Framework of proposed three-domain.

system is often split down into four interconnected steps to fully deploy customer needs phase by phase.⁴⁹ The house of quality (HOQ) matrix, process planning matrix, design matrix, and production matrix are all part of the four-phase model.^{49,50} The HOQ is one of the most often utilized matrices in a variety of applications. The HOQ matrix contrasts WHATs (voice of customers) and HOWs (technical needs and voice of engineers).^{46–50} The essential sections of the HOQ matrix are depicted in Figure 3.⁴⁶ Normally, the process is carried out in the order specified by the letters “A” to “F”. List of customer needs is represented by Room “A”, each of which is compared to rivals, and the findings, which are absolute and relative weights for prioritization of customer wishes, are then reported in Room “B”. Meanwhile, consumer expectations are transformed into technical characteristics in Room “C”, and the correlation between each customer need and technological response is recorded in Room “D”. Moreover, Room “E” that is on the roof, evaluates how well the technological responses complement one another. On the other hand, technical target weights, competitive information, and priority of technical features will all be in “F”.⁵¹ Figure 4 shows a three-domain framework for PM priority which was developed using the requirement domain, function domain and concept domain.

The far more significant sections of HOQ are “B” and “F”, respectively; see⁵¹ for further information. The derivation of planning matrix “B” is obtained from a comparison of a hospital’s anticipated service with those of other hospitals. The relevance of client requirements is assessed in this matrix and genuine customer requirements assessments are assigned. The improvement ratio is derived from dividing the objectives by the evaluation of the planned requirements, with the goal being the expected value for each requirement. The absolute weight is determined by multiplying the goal by the importance ratio, whereas the relative weight is determined by normalizing the absolute weight. The relative weight of

technical goals, Room “F”, is determined by calculating the absolute weight of HOWs and then normalizing it to determine the relative weight.^{5,52} The goal is to use QFD as a new strategy in medical device management to handle the problem of medical device PM priority based on a set of influencing factors.

Saleh et al.⁵ used the QFD to build new modeling for medical equipment PM priority based on a three-domain framework of functions, requirements and concepts, with the requirements domain being the HOQ matrix or planning matrix. The top 11 technical terms have been chosen for the second matrix's inputs based on their relevance and weights (WHATs). Among the factors are standards compliance, service provider type, function, age, maintenance requirements, functional verifications, mission criticality, device complexity, team certification, regular inspection, and physical risk. They separated the critical criteria into three categories for the HOWs of the second matrix: risk-based criteria such as physical risk, function, and maintenance requirements; mission-based criteria besides area criticality, utilization level, and device criticality; and maintenance-based criteria such as device complexity, failure rate, number of missed maintenances, useful life ratio, and downtime ratio. The findings of this study demonstrated that risk-based parameters have substantial impact on PM prioritisation decisions, in addition to the age and criticality of medical equipment.

Taghipour et al.³⁷ presented a MCDM model and AHP for determining the criticality of medical equipment. In a maintenance management programme, devices with lower criticality scores can be given a lesser priority. Those with higher scores, on the other hand, should be thoroughly explored to determine the causes for their increased criticality, and necessary steps, such as “PM”, “user training”, “device redesign”, and so on, should be done. They also explain how the individual score values are acquired for each criterion that can be utilized to develop guidance for proper maintenance techniques for various types of devices in this study. To demonstrate the use of the suggested methodology, data from 26 distinct medical devices were retrieved from a hospital's maintenance management system.

Saleh et al.⁴⁶ applied QFD which shows its validity in the prioritization process, and it is also considered as a planning tool for ensuring quality in any process. They also invented fuzzy logic, an AI tool, for assisting with prioritization. By adopting the human style of thinking, fuzzy logic provides a genuine foundation for human reasoning.⁵³

Houria et al.⁵⁴ combined the AHP, the technique for order preference by similarity to ideal solution (TOPSIS), and mathematical optimization (particularly mixed integer problems (MILP)) to deliver the maintenance department's decision maker a full solution to the problem at hand. These three strategies are used to: (1) perform a multi-criteria analysis to determine the criticality of medical equipment, (2) rank different maintenance plans based on their (benefits) worth to the hospital, and (3) select the best maintenance approach for each item while staying within a budget.

Shamayleh et al.⁵⁵ advised using a customized reliability-centered maintenance (RCM) strategy for the selection of maintenance operations for medical equipment. Concentrating on lowering the criticality level, the authors define criticality as the severity and frequency of failures. The suggested method uses reliability growth analysis to identify opportunities, then a complete failure mode and effect analysis (FMEA) to explore main failure modes and recommend strategies to lower criticality. The study emphasizes the difficulty of typical time-driven PM to prevent failures on its own. As a result, a criticality-focused RCM approach is more useful and time and cost-efficient than standard time-driven preventative maintenance techniques.

Osman et al.⁵⁶ employed MCDM and provided AHP. A set of criteria is used to determine a criticality score for each piece of equipment, based on a literature assessment and expert comments. As a result, a list of equipment is evaluated according to its scores and an optimal threshold is chosen to distinguish between maintenance and replacement needs.

Hutagalung and Hasibuan⁷ developed priorities for medical equipment maintenance based on medical device criticality scores. The AHP approach is used to calculate criticality scores based on the evaluation of criteria, sub-criteria, and ratings (AHP). Devices that have a higher critical weight receive higher maintenance priority than devices with a lower critical weight. The approach was used to define how to prioritize the maintenance of 20 medical devices at the Jakarta Eye Hospital's Outpatient Department.

Jamshidi et al.³⁹ proposed a novel risk-based prioritizing methodology for determining the most effective maintenance strategy. In the first stage, numerous risk assessment criteria are considered as part of a fuzzy-FMEA (FFMEA). In the second stage, seven different dimensions are used to examine all aspects of hazards and risks when prioritizing medical equipment, such as use-related hazards, age and usage. Finally, in the third phase, a simple approach is introduced to determine the best maintenance strategy for each device based on the results of the previous steps.

Tawfik et al.⁵³ advocated for the maintenance of medical devices to be prioritized according to their risk level. Provided that current risk categorization methods communicate risk in terms of physical risk, equipment function and maintenance requirements, other important factors such as equipment operational situations should be considered. Seeing that fuzzy logic is more human-like than traditional logic, it is intended to improve the way devices are prioritized. Within four hospitals, the proposed approach was tested on 136 distinct medical equipment. The findings revealed that

depending on the operational conditions within the hospital, the same piece of equipment can have varying risk scores. Hernández-López et al.,⁵⁷ developed an MCDM model using these variables and the result is interpreted as an index of equipment maintenance priority. The numerical output of the index was classified into three categories: high, medium, and low priority.

ASHE in 1996 presented a categorization scheme based on five criteria for evaluating medical equipment, namely, clinical application (*A*), equipment function (*E*), probability of failure (*F*), PM requirements (*P*), and environmental use (*U*).^{53,58} The following equation is used to obtain a total score (*T*) for each component. This method divides medical devices into five categories based on their total score: priority I, priority II, priority III, hazard surveillance, and management program elimination.

$$T = E + A + \left(\frac{P + F + U}{3} \right) \quad (2.1)$$

In addition, ASHE has also outlined factors that affect the life expectancy of medical devices, such as the repair parts availability, equipment that no longer meets manufacturer or government safety standards, availability of new technology, maximum maintenance expenditure limits, obsolescence that inhibits or prohibits modern medical policy, and equipment reliability.

Reda and Dvivedi⁵⁹ recommended Fuzzy QFD and FMEA to prioritize the essential resources on the stated wastes and ascertain the risk connected to each failure mode's sub-element for lean application. A creative strategy for selecting the best lean tools to leverage these crucial resources by taking the Value Stream Mapping and plant architecture into account. Due to its narrow emphasis on the most crucial resources, it saves time by assessing just those that are necessary for a successful lean implementation. An Ethiopian shoe manufacturing company is used as a case study to show how applicable the proposed approach is. Future state plant structure and value stream map helps cut overall cycle time by 56.3%, lead time by 69.7%, distance traveled for materials and transportation-related operations by more than 75% and the number of employees needed by 200 instead of 202.

Jasiulewicz-Kaczmarek et al.³⁸ introduced fuzzy logic and the creation of the Machine Criticality Index (MCI) to create a two-level hierarchical classification for the machine criticality assessment criterion. By considering both potential interactions between the machine criticality assessment criteria as well as their relevance, the model expands on the currently used techniques for determining how critical a machine is. The Shapley value and interaction index of various criteria and sub-criteria were defined based on the fuzzy measure's importance index. The evaluation of Shapley values and interaction indices shows that the proposed fuzzy machine criticality assessment is capable of giving maintenance managers a better comprehension of the importance of individual criteria and sub-criteria in the evaluation of the machine criticality and their effect on the final value of the MCI index. They can create better plans for machine maintenance programs and resource allocation by considering the MCI index's final value. The authors come to the conclusion that not all evaluation factors are equally crucial. As a result, it is important to weigh each criterion according to the various stakeholder needs for the machine criticality process.

Hossain and Thakur⁶⁰ suggested the fuzzy AHP and fuzzy-decision-making trial and evaluation laboratory (DEMATEL) as hybrid MCDM tools. The implementation of Industry 4.0 in the smart healthcare supply chain (HCSC) was prioritized using fuzzy-AHP, and fuzzy-DEMATEL was used to investigate the cause-and-effect correlations between the components. According to the study's findings, the most important aspect of implementing Industry 4.0 in HCSC is healthcare logistics management (HCLM), which is followed by integrated HCSC, sustainable HCSC practices, HCSC innovation and technological aspects, HCSC institutional perspectives, HCSC competitiveness, social aspects, and HCSC economic factors. The integrated HCSC, HCLM, HCSC competitiveness, and HCSC social elements were emphasized as the cause group components in the cause-effect analysis, and they are the crucial success criteria for adopting Industry 4.0 in the HCSC.

Clemente-Suárez et al.⁶¹ reviewed the literature through both primary and secondary sources, including databases, online pages, and sources including scientific journals. To do this, the databases Embase, PubMed, SciELO, Web of Science, and Science Direct Scopus were utilized. Search terms such as COVID-19, coronavirus 2019, SARS-CoV-2, 2019-nCoV, fuzzy MCDA, multi-criteria decision analysis, MCDM + COVID-19, and fuzzy MCDM + COVID-19 were used. Although some earlier research was employed, they used papers from 10 January 2020 to 25 March 2021 to investigate the fundamental concepts of the multi-criteria decision analysis technique in general. The findings of this study demonstrate that crucial the fuzzy multi-criteria decision analysis method is a helpful tool for healthcare experts and first responders' emergency professionals to deal with this pandemic as well as to control the ambiguity caused and its associated dangers.

Tortorella et al.⁶² suggested a problem-oriented methodology to prioritize the adaptation of 4IR technologies in hospitals using the algebraic operations suggested in the QFD's HOQ. This method enables them to contribute to both the significance of healthcare value chain problems and the current level of 4IR technology acceptance. The suggested model integrates various approaches to determine an organization's maturity in relation to a particular issue and highlights areas for development. Two case studies conducted in a sizable public hospital in Brazil and a private hospital in India provide for a comparative analysis in which the authors identified similarities and differences in the improvement goals in each institution. Results show that the suggested strategy facilitates the systematic integration of 4IR technologies into healthcare organizations, regardless of hospital ownership, as digital applications are assessed according to their potential to tackle the problems recognized by managers from both case studies.

Haber et al.⁶³ presented a systematic approach to the development of Product-Service Systems (PSSs). With this end in mind, the Kano model was added to the Quality Function Deployment for Product Service Systems (QFD for PSS) approach to filter the customer's requirements and turn the desirable ones into Receiver State Parameters (RSPs), which serve as the foundation of QFD for PSS. The Fuzzy Analytical Hierarchy Process (FAHP) method was then included in the process to correctly evaluate these factors and their built-in uncertainty.

Neira-Rodado et al.⁶⁴ suggested a novel integration of fuzzy Kano, QFD, AHP, and DEMATEL to translate customer needs into product characteristics and prioritize design alternatives taking interdependence and vagueness into account. The first step was to determine the needs of the customer. Second, the fuzzy KANO was used to determine the effect of each demand, which was frequently ambiguous, on customer satisfaction. Third, design alternatives were specified, and AHP was used to determine the weights of the requirements. DEMATEL was then used to assess the interdependence between options.

Haber and Fargnoli⁶⁵ suggested a PSS methodology to tailor solutions to various patterns of usage while attaining higher environmental performance than a stand-alone product. The strategy is based on integrating the tools from the QFD for PSS and the Screening Life Cycle Modeling (SLCM) groups. The FAHP is added to QFD for PSS to eliminate service-related ambiguities and uncertainties and to better describe the product and service features of the solution. The environmental impact is calculated and compared to the manufacturer's present solution as part of the SLCM's evaluation of potential outcomes. An example from a case study at a supplier of medical diagnostic tools demonstrates the application of the strategy and the possibility that could result: The PSS approach can be adjusted to accommodate both clients who use the product heavily and those who use it more moderately. This provides flexibility and a life cycle that is optimized through simpler upkeep, updates, and end-of-life plans.

These are some of the most evidently cited publications in the literature that explore a variety of critical assessment modeling methodologies, including MCDM, AHP, QFD, fuzzy logic, and the ASHE references, where the fundamental body of criteria and sub-criteria can be segregated as shown in Table 1. As a result, the proposed ACA's assessment criteria would be based on the adaptation recognized (indicated in Table 1 using orange color) as the most strongly supported by previous research and guidelines, as well as the maintenance staff's ability to get input data from the ground. However, due to the obvious wide range of equipment usage, maintenance capacity, and the nature of the healthcare industry, adapting these models for MOH hospitals necessitates a complete rethinking of the core framework for BEMS accessibility. In addition, the establishment of sub-criteria (e.g., asset availability through the mean time between failure (MTBF) information) may assess a promising evaluation with a broader range on both performance of medical devices and the appropriate asset replacement choices. This also leads to the modernization of reliability computation metrics⁶⁶ and effective maintenance strategy for each medical device.

2.4 | The focus on reliability, failure rate, and redundancy computation in advancing BEMS

A machine's reliability, according to Afsharnia,⁶⁸ is the likelihood of fulfilling its functions within a set of time frame under specific conditions. Seeing as reliability is a proportionate measure of a machine's functional availability, it can be measured by the amount of time it can operate before breaking down. To put it another way, quality consistency through time is referred to as reliability.⁶⁹ Equipment reliability is affected by the frequency of failures, which is assessed by MTBF.⁶⁶

The intensity of failure denoted as $\lambda(t)$ is the predicted number of times an item will fail in a given period, assuming it is fresh and new at time zero and is operating at time t .⁶⁸ Failure rates are used to predict reliability. If a big quantity of a

TABLE 1 The main body of critical assessment criteria and sub-criteria from various methodologies.

Author (year)	Critical assessment criteria																	
	(a) Functionality/condition/quality	(b) Equipment age/useful life ratio	(c) Physical risk	(d) Maintenance requirement	(e) Utilization level	(f) Area/mission criticality	(g) Clinical application	(h) Device criticality	(i) Failure rate/frequency of breakdown/MTBF/availability/reliability	(j) Importance/maintenance complexity	(k) Missed maintenance	(l) Downtime ratio	(m) Recall and hazard alert	(n) Availability of alternatives devices	(o) Repair/maintenance cost ratio	(p) Safety & environment	(q) Detectability	(r) Class of equipment (Class I, II & III)
Saleh et al. ⁵ and Saleh et al. ⁴⁶	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓						
Taghipour et al. ³⁷	✓			✓	✓	✓			✓			✓	✓	✓	✓	✓		
Houria et al. ⁵⁴	✓	✓	✓			✓	✓		✓		✓	✓	✓	✓			✓	✓
Shamayleh et al. ⁵⁵	✓			✓	✓			✓	✓									
Osman et al. ⁵⁶		✓				✓	✓	✓	✓			✓		✓	✓			
Hutagalung and Hasibuan ⁷	✓	✓	✓			✓			✓	✓		✓	✓	✓	✓	✓	✓	✓
Jamshidi et al. ³⁹	✓	✓				✓	✓						✓	✓	✓			
Tawfik et al. ⁵³	✓			✓	✓	✓	✓							✓				
ASHE ^{53,58,67}	✓	✓	✓	✓				✓	✓				✓	✓	✓	✓	✓	
Jasiulewicz-Kaczmarek et al. ³⁸	✓	✓	✓					✓	✓			✓	✓			✓	✓	
Haber et al. ⁶³	✓	✓			✓	✓	✓	✓	✓	✓				✓	✓	✓	✓	
Neira-Rodado et al. ⁶⁴	✓			✓	✓								✓				✓	
Haber and Fargnoli ⁶⁵	✓	✓			✓	✓	✓		✓	✓		✓	✓	✓	✓	✓	✓	
Clemente-Suárez et al. ⁶¹			✓	✓	✓	✓			✓			✓		✓			✓	

particular product to test throughout time can be achieved, then the product's reliability at time t is provided as below⁷⁰:

$$R(t) = \frac{\text{Number of products that have NOT failed by time } t}{\text{Total number of products being tested at time } t = 0} \quad (2.2)$$

The probability of a device failure at time t is defined as the failure rate of a device at time t and denoted by $F(t)$.

$$F(t) = \frac{\text{Number of products failure between } t \text{ and } t + \Delta t}{(\text{Number of products that have NOT failed by time } t) \times \Delta t} = \frac{N_F}{N_S \times \Delta t} \quad (2.3)$$

Where N_F represents several products that failed during the time of interval, $t + \Delta t$ and N_S represent a number of products that have NOT failed by time t . The failure rate at time t can be computed if Δt is small and the failure rate does not change during this time interval.

The reliability graph is a straight horizontal line when the failure rate is constant, and it reflects the intermediate phase of the bathtub curve in Figure 5. A constant failure rate can successfully anticipate the reliability of a product to a specific time when there is little break-in failure (early failure).

If the failure rate $F(t)$ is a constant (i.e., independent of t so then we can set $F(t) = F$), then the reliability $R(t)$ at time t is given by;

$$R(t) = e^{-Ft} \text{ where } F \text{ constant failure rate} \quad (2.4)$$

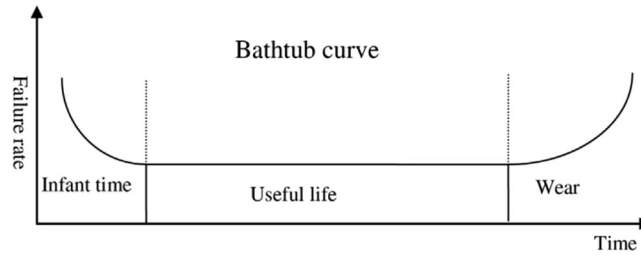


FIGURE 5 Bathtub curve represented by infant mortality, useful/operation, and wear-out phases.⁷¹

Subsequently, the mean time to failure (MTTF) is the average time an item should function before failing, and it only pertains to non-repairable items. MTTF is just the average of all failure times.

$$MTTF = \frac{\text{Total time of operation, } T}{\text{Total number of failures during time } T} \quad (2.5)$$

For repairable devices, the MTBF is used. As it refers to the average time between failures, it is represented as:

$$MTBF = \frac{\sum (\text{Time of operation, } T)}{\text{Total number of failures during time } T = \sum T_i} \quad (2.6)$$

Moreover, the mean time to repair (MTTR) is the total time to repair the failures, which is also known as “downtime” for unplanned outages. Availability A_o , on the contrary, is the portion of this total time that the system is actually in working order and available to do its job, and is given by⁷²;

$$A_o = \frac{MTBF}{(MTBF + MTTR)} \quad (2.7)$$

The relationship between the failure rate, MTBF and MTTF can be well derived as below:

$$F(t) = \lambda(t) = F = \frac{1}{MTBF} = \frac{1}{MTTF} \quad (2.8)$$

Thus,

$$MTBF = \frac{1}{\lambda} \quad (2.9)$$

For variable failure rate, the density function of the Weibull distribution can be applied using⁷¹:

$$f(t) = \frac{\beta}{\eta} \left(\frac{t-\gamma}{\eta} \right)^{\beta-1} \exp \left[- \left(\frac{t-\gamma}{\eta} \right)^{\beta} \right] \quad (2.10)$$

The Weibull failure distribution function is:

$$F(t) = \int_{\gamma}^t \frac{\beta}{\eta} \left(\frac{t-\gamma}{\eta} \right)^{\beta-1} \exp \left[- \left(\frac{t-\gamma}{\eta} \right)^{\beta} \right] .dt \quad (2.11)$$

$$= 1 - e^{-\left(\frac{t-\gamma}{\eta} \right)^{\beta}} \quad (2.12)$$

The reliability function would be:

$$R(t) = 1 - F(t) \quad (2.13)$$

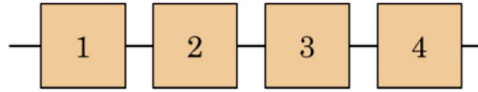


FIGURE 6 The reliability block diagram (RBD) of a four-in-series system components.

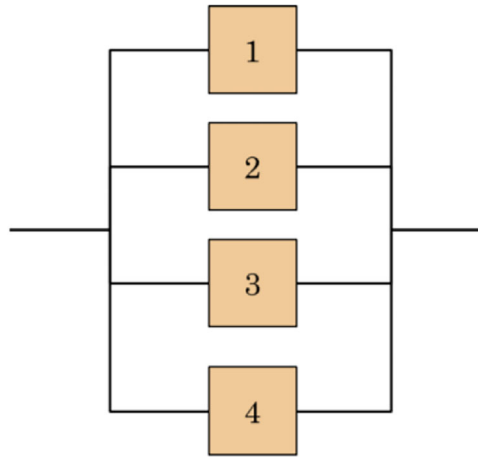


FIGURE 7 Four elements RBD (1,2,3,4) arranged in a reliability parallel configuration.

$$= e^{-\left(\frac{t-\gamma}{\eta}\right)^{\beta}} \quad (2.14)$$

The equipment functionality and failure rate criteria from Table 1 may enable a broader means of reliability in the BEMS program, as these criteria may facilitate the measurement and computation of failure rate, reliability rate and time to failure, such as the MTBF and MTTF, as deduced above. All these can be achieved with the understanding and application of Equations (2.2)–(2.14). The requirement of reliability also outlined by ASHE and the effort in computing this value will aid to modernise the present contract, as described by the proposed gateway (both the current contract and the 4IR policy) in Figure 2.

As a consequence, enhancing system configurations visually depicted using reliability block diagrams (RBDs), where each component is represented by a block and the connections between them express the system configuration, as shown in Figure 6, is a potential approach for improving reliability.⁷³ The system's operation is contingent on being able to cross the diagram from left to right only by transiting through the operational elements, as shown in Figure 6 as well.

The system reliability, R_s , for this configuration is given by^{68,74,75}:

$$R_s = R_1 \times R_2 \times R_3 \times R_4 \dots R_n \quad (2.15)$$

Where for the n components, the reliability values are represented by R_1, R_2, \dots, R_n . Subsequently, redundancy, as well as the way forward to improve reliability, can be depicted as a parallel interconnection; for example, an RBD for a system-of-four components in a parallel arrangement as shown in Figure 7⁷³:

Therefore, the parallel n components of system reliability are given by^{68,74,75}:

$$R_s = 1 - (1 - R_c)^n \quad (2.16)$$

Where, R_c is the reliability of each component and n is the identical constant failure rate components.

2.5 | Research gap and contribution of the study

Following the literature review as a whole and the 4IR niche as outlined, there is a gap in the present maintenance strategy for MOH hospitals, as indicated in Figure 2, where the PdM or CBM is not linked to a pipeline of real-time data on equipment fitness and deterioration. To bridge this gap, a critical assessment engagement (both current contract and

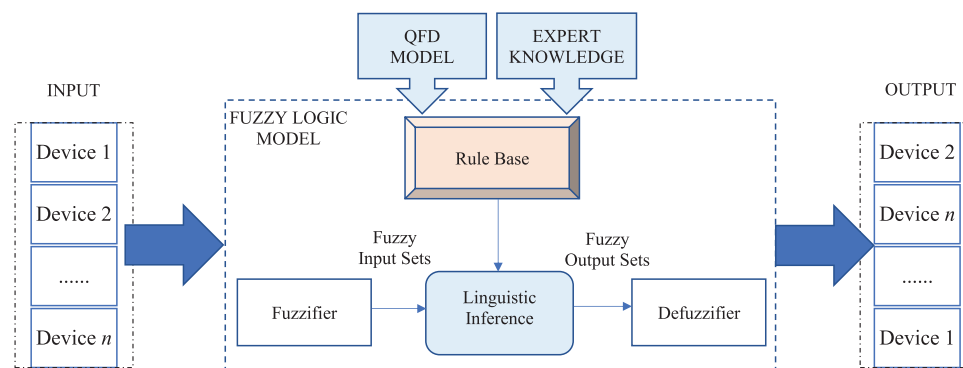


FIGURE 8 The proposed framework for rule base and expert knowledge priority.

4IR policy) is frequently significant as the entry point for enabling the correlation between the current maintenance structure and 4IR-forecasted-driven approaches (referred to as time-to-failure portfolio) supported by equipment fitness and reliability measurement.

The effort in constructing a customized ACA model using QFD and fuzzy logic, fitted with the input of Malaysian experts and the equipment profiling of the Malaysian healthcare-based industry offers a potential evaluation with a broader scope on both the performance of medical devices and the appropriate asset replacement option. Subsequently, a coherent body of knowledge on the modernization of PdM and CBM offers a new contribution thereafter. This new contribution could lead to activities such as continuous or periodic monitoring and diagnostics of medical devices to foresee component degradations and carry out planned maintenance prior to the actual failure.

This will also inspire developers, building owners, and users to get charged in obtaining possible financial and scientifically based system reliability enhancement benefits, as demonstrated by Section 2.4. The following is a summary of the contributions made by this paper:

- Introduce and emphasize transparency in modeling an intangible evaluation concerning the few inputs that are currently available, such as safety, level of usage, useful life, reliability, technology, maintenance cost ratio, and condition of medical devices in MOH hospitals, which has also demonstrated its potential in tracking the equipment life cycle profile.
- Highlights enhanced performance metrics resulting in significant broader measures in the medical device industries.
- More specifically, this paper justifies a customized seven-input parameter of the ACA assessment and the weightage toward obtaining the PS scoring, which apparently enables the extensiveness of the most appropriate maintenance strategy to be conducted while being guided by the classified scoring and significantly provides a more justified method for making a selection of replacement equipment.

Furthermore, this model can bridge the gap between the need for additional technical examination related to reliability and the current provision in the HSS agreement between the MOH and the company for more advantageous engineering means. Prior until now, this was not conceivable because the needs were incompatible with the legality of the existing agreement. As described in Section 2.4, this also leads to the appropriate maintenance approach for each device and the modernization of maintenance metrics to encompass a wider variety of performance computation techniques (reliability computation). Through the use of Equations (2.15) and (2.16) the top management's choice on the adjustment of the dependability methods may be effectively carried through.

3 | METHODOLOGY

Figure 8 depicts the suggested PM priority framework, in which the cascaded models consist of two. In practise, any model will almost always comprise several separate implementation techniques. The framework takes a list of PM-required medical equipment as input and the output is a list of medical devices with prioritized ranking. The Fuzzy Logic Model combines the QFD model's output with the knowledge-base of the expert.

A QFD system is commonly divided into four interrelated phases, each of which is utilized to fulfill a single customer need. Figure 3 shows the four-phase model, which includes a HOQ and process planning matrix, production matrix and

TABLE 2 Customer requirements and technical characteristics of HOQ.

Criteria	Requirements	Attributes
1. Customer requirement (WHATs) a. Patients b. Clinical staff	Basic requirements	(i) Safety (ii) Efficiency (iii) Durability (iv) Regular monitoring
	Performance requirements	(i) Calibration (ii) Obvious operating instructions (iii) Quick response (iv) Designed for simple maintenance. (v) Suitable for the intended purpose
	Emotional requirements	(i) Back up availability (ii) Contact person 24 h (iii) Avoiding suspension of device services
2. Technical requirements (HOWs) a. Clinical engineering staff	Risk	(i) Function ability (ii) Physical risk (iii) Maintenance requirements
	Performance assurance	(i) Device mission criticality (ii) Functional verifications (iii) Age (iv) Labeling (v) Electrical safety testing (vi) Replacement of the parts (vii) Regular inspection
	User competence	(i) Qualification of technician (ii) Complexity of devices (iii) Equipped workshop (iv) Test equipment availability (v) Service manual availability (vi) Activities recording
	Cost	(i) Updating or loan (ii) Spare parts availability (iii) Type of service provider
	Standard	(i) Meet specific standard

design matrix. The HOQ matrix compares and contrasts the VOC (customer expectations) with VOE (technical needs). As shown in Figure 4, a three-domain framework for PM priority was developed using the requirement domain, function domain, and concept domain.

The model's HOQ in this project is the first domain, or requirement, that analyzes client needs and technology features that fulfill those criteria. The second domain is the function domain, which will place the first domain's top technical criteria to the test by specifying key criteria for PM prioritization or redefining the first domain's top HOWs with new criteria. The new WHATs for the second domain will be based on these criteria. To assess the PM priority of medical equipment in the last area, the concept or idea domain, a priority score (PS) index is created based on the weights of critical criteria.

3.1 | Domain for requirement

The HOQ of the PM prioritization model is the framework's requirement domain. The first step is to figure out what the customer needs and how to make it happen. A customer is someone who interacts directly with hospital medical devices and expects a variety of services. Customers (WHATs) of medical devices are patients and clinical workers. The customer's needs (WHATs) are addressed in three ways, as shown in Table 2: basic requirements, performance requirements and emotional requirements. In this situation, there are three types of technical requirements (HOWs): risk-based criteria, mission-based criteria, and maintenance-based criteria. Figure 9 illustrates the needed domain (HOQ).

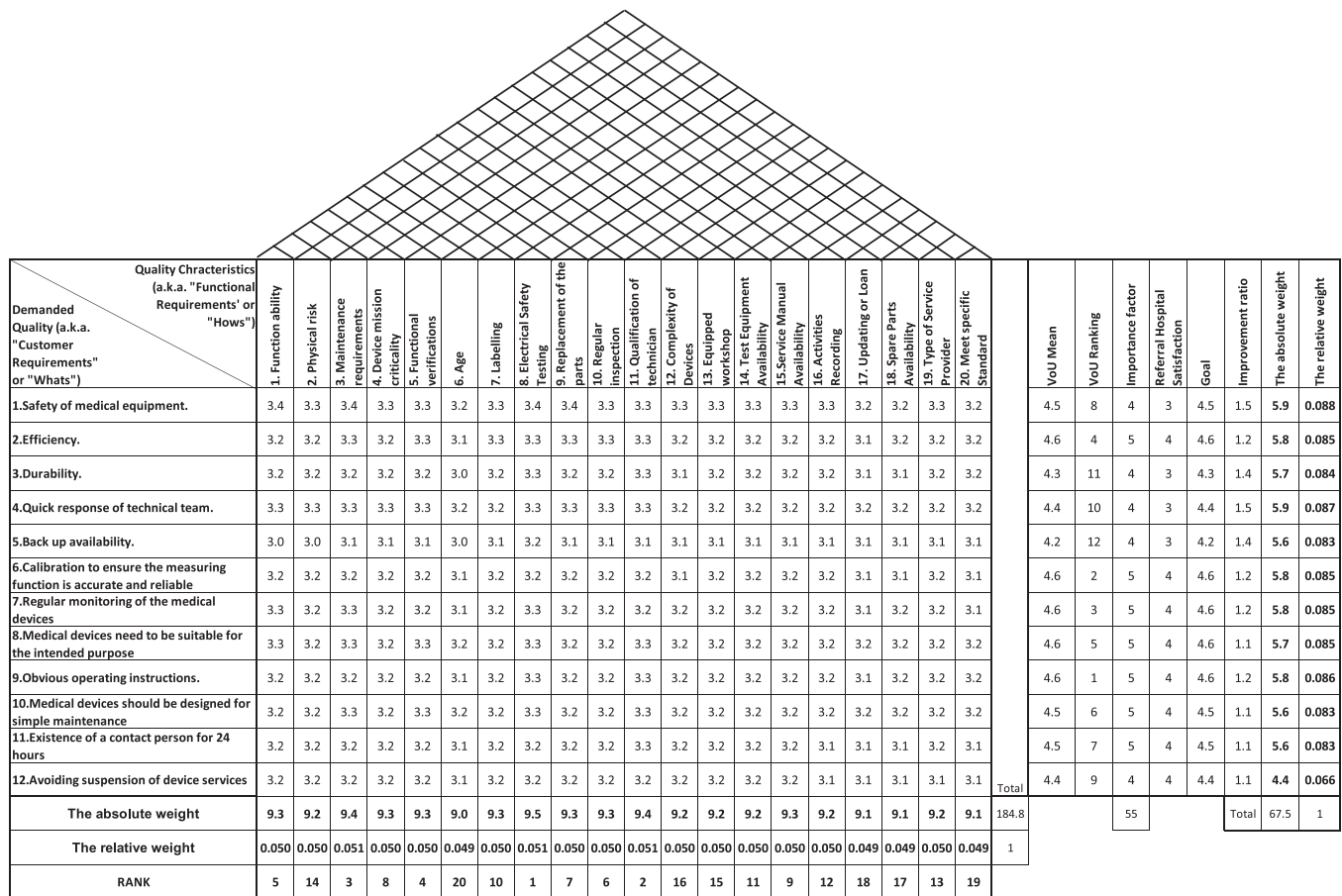


FIGURE 9 The HOQ for the requirement domain.

The matrix is organized as follows: the left column contains user needs (VOU), and a major part of the matrix contains technical features (VOE) separated into five columns, as well as the relationship matrix (see Figure 9). The HOQ planning matrix is in the right column and the technical target matrix is in the bottom chamber. Different ratings are used to assess the strength of relationships between WHATs and HOWs: four for a strong relationship, three for a medium relationship, two for a low relationship, and one for no relationship. Figure 9 depicts the sphere of needs (HOQ).

The findings shown in Figure 9 are based on a quantitative analysis comprising several of MOH's top hospitals. Questionnaires, interviews, site visits, and focus group discussions were used as approaches. Malaysia has more than 144 government hospitals, 15 state health departments, 167 health district offices, 2838 government clinics, 196 community clinics, 668 government dentistry clinics, and five public health laboratories that serve an estimated population of over 2000 employees.

According to Krejcie and Morgan⁷⁶ sample size chart, a sample size of 322 would be required to reflect a cross-section of a population of more than 2000 people. The survey was counted, and more than 400 people responded to the questionnaire. It was demonstrated that the sample size proposed by Krejcie and Morgan⁷⁶ is acceptable and sufficient for making confident decisions based on the findings.

3.2 | Function domain

The matrix model's next step is to choose the most important criteria for PM priority from among the technical requirements. To construct the second matrix's inputs (WHATs), all 20 technical terms criteria are chosen based on their weights and significance, as shown in Figure 10. The development of the design matrix is similar to the HOQ in Figure 9. The critical criteria for the HOWs of the second matrix are divided into three categories: risk-based criteria like safety alerts, mission-based criteria like asset condition and asset usage, and maintenance-based criteria like useful life remaining, asset

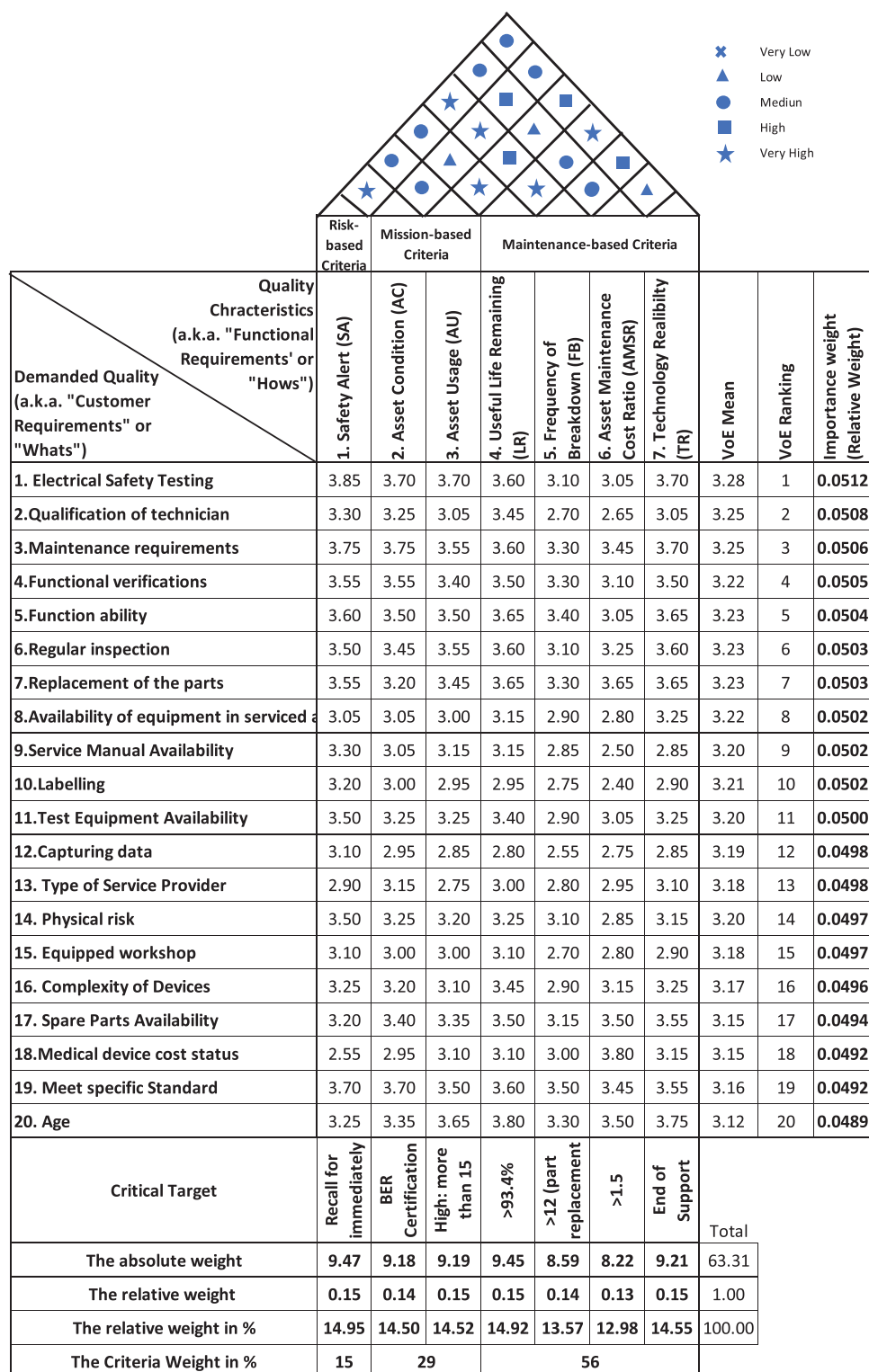


FIGURE 10 The HOQ for the function domain.

availability, and asset maintenance cost ratio, and asset obsolescence. The criteria were chosen based on engineering and maintenance department recommendations.

The planning element of the design matrix (the importance of WHATs), as shown in Figure 10, is the resultant relative weight of 20 criteria from the first domain. The recommended thresholds, as shown in Table 3, are used to determine the technical criteria's important goals. Technical targets, on the other hand, such as the absolute and relative weight of

TABLE 3 Critical criteria definition and proposed scoring.

No	Criterion	Description	Threshold	Score
1	Safety alert (SA)	Safety alert issued by authority or manufacturer	Asset with field safety notice (minor)—frequency more than 3 notification	2
			Asset with field safety notice (minor)—frequency within 1–3 notification	1
			None of above	0
2	Asset usage (AU)	Medical devices operating hours based on department	High: more than 15 h a day	4
			Medium: $8 < AU \leq 15$ h a day	3
			Normal: ≤ 8 h a day	2
			Not in use	1
3	Remaining useful life (RUL)	The ratio between the device age and “Life Expectancy Projection” by ASHE and AHA guideline	$<33.3\%$	4
			$53.3\%–33.4\%$	3
			$93.3\%–53.4\%$	2
			$>93.4\%$	1
4	Asset reliability (AR)	A proportionate measure of a machine’s functional availability, using Asset Availability, A_o computation via Equation (2.7)	$0\% \leq A_o \leq 25\%$	4
			$26\% < A_o \leq 50\%$	3
			$50\% < A_o \leq 80\%$	2
			$80\% < A_o \leq 99\%$	1
			$A_o = 100\%$	0
5	Technology availability (TA)	The capability of asset as accordance to current requirement	Orphaned asset/manufacturer not available	2
		Outdated technology (defined by end user)	1	
		None of above	0	
6	Asset maintenance cost ratio (AMCR)	Total maintenance cost over purchase cost	>1.5	4
			$1.0–1.5$	3
			$0.5–1.0$	2
			<0.5	1
7	Asset condition (AC)	Beyond economical repair (BER) or others	BER certification approved	3
			Request for BER	2
			Others (i.e., Request for exemption, upgrading, etc.)	1
			Good	0

technical criteria, are computed for the demand domain in the same way. In reality, the results show that maintenance-based criteria are the most important reason for PM prioritizing (56%), followed by mission-based criteria (29%) and risk-based criteria (15%). Table 3 lists the characteristics that have been identified as crucial for PM, as well as their respective scores.

3.3 | Development of HOQ

As previously mentioned (as shown in Figure 3), the important components of the HOQ matrix are represented as a simpler matrix. In most cases, the procedure is followed in the order recommended by the letter’s “A” through “F”. Room “B” contains the findings, which include absolute and relative weights for prioritizing client expectations. Room “A” features a listing of client requests that are all compared to the competition. Room “C” holds the data needed to transform consumer expectations into technical qualities, while Room “D” keeps track of the relationship between each customer requirement and technology solution. Room “E” on the roof assesses how effective the technological responses complement are, to one another. Technical target weights, competitive information and priority of technical features all go into “F”.

TABLE 4 The indicator of the used symbols.

×	Very low
▲	Low
●	Medium
■	High
★	Very high

The sections “B” and “F” in HOQ are the most important. A comparison of a hospital’s planned service with those of other hospitals yields the planning matrix “B”. In this matrix, the relevancy of client needs is evaluated and authentic customer requirements assessments are assigned. The improvement ratio is calculated by dividing the goal by the evaluation of the planned needs, with the goal being each requirement’s expected value. The aim is multiplied by the importance ratio to obtain the absolute weight, but the relative weight is determined by normalizing the absolute weight. The relative weight of technical goals, room “F”, is determined by computing the absolute weight of HOWs as stated in Equation (3.1).

$$\text{Absolute weight} = \Sigma + id \text{ WHAT} \times RWH \quad (3.1)$$

where, *id WHAT* is the importance degree of WHAT and; *RWH* is the relationship value between WHAT and HOW.

The matrix is organized as follows: the left column comprises user needs (VOU), while the main body of the matrix comprises technical features (VOE) divided into five columns, including the relationship matrix, as shown in Figure 9. The HOQ planning matrix is in the right column. The technical target matrix is in the bottom room. Scores of 4 indicate a strong association, 3 suggest a medium relationship, 2 indicate a moderate relationship, and 1 shows no relationship between WHATs and HOWs.

Consider, for example, the “safety” requirement. Importance 4 is rated on a five-point scale, referral hospital 3 on a five-point scale, and target 4.5 on the “VOU Mean” scale. In terms of referral hospitals, the improvement ratio is calculated by dividing the target by the number of referral hospitals, that is, 4.5/3. The absolute weight is derived by multiplying the improvement ratio by importance (1.5 × 4) and the relative weight is obtained by normalizing the absolute weight (5.7/67.5) × 100. As an illustration of how technical criteria priority is determined for technical aims, consider “function ability” of which the absolute weight of “function ability” equals the following using Equation (3.2):

$$\begin{aligned} I &= (3.4 \times 0.1) + (3.2 \times 0.1) + (3.2 \times 0.1) + (3.3 \times 0.1) + (3.0 \times 0.1) + (3.2 \times 0.1) \\ &+ (3.3 \times 0.1) + (3.3 \times 0.1) + (3.2 \times 0.1) + (3.2 \times 0.1) + (3.2 \times 0.1) + (3.2 \times 0.1) = 9.3 \end{aligned} \quad (3.2)$$

As shown in Figure 10, all 20 technical terminology criteria are chosen based on their weights and relevance to become the second matrix’s inputs (WHATs). The design matrix is created in the same manner as the HOQ in Figure 9. For the HOWs of the second matrix, we divided the key requirements into three categories: Safety Alert (SA) is one of the risk-based criteria; mission-based criteria including Asset Condition (AC) and Asset Usage (AU); and finally maintenance-based criteria incorporating, Remaining Useful Life (RUL), Asset Reliability (AR), Asset Maintenance Cost Ratio (AMCR), and Technology Availability (TA). The criteria were selected based upon the literature, in addition to the head of engineer and maintenance team experience.

The relationships between HOWs are depicted by the matrix roof. As illustrated in Table 4, the “Very Low,” “Low,” “Medium,” “High,” and “Very High” indicators are represented by symbols. Pearson Correlation, derived from statistical analysis tools, is used to propose the correlations. The resultant relative weight of 20 criterion in the first domain is the planning element of the design matrix (importance of WHATs), as shown in Figure 3. Table 3 shows the appropriate levels for determining the technical criteria’s significant aims. The technical aims, that is, the absolute and relative weights of the technical criteria, are derived in the same way for the demand domain.

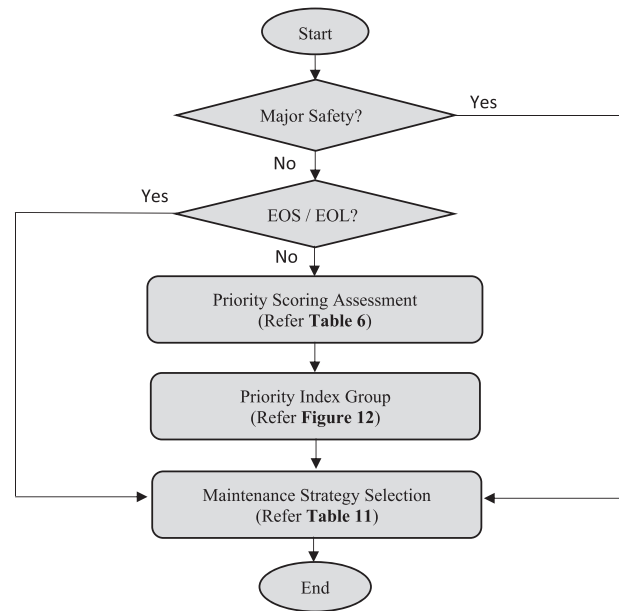


FIGURE 11 The assessment process for priority ranking.

TABLE 5 Three ageing conditions via conventional method.

High priority	Medium priority	Low priority
Equipment >10 years	Equipment 5–10 Years	Equipment <5 Years

3.4 | Concept domain

The design matrix's output is the concept domain. The outcome is a prioritization equation that takes into account seven of the most important elements and assigns weights to them. The priority score (PS) is calculated using Equation (3.3) and the results are reported as scores.

$$PS = 5.0(SA) + 14.5(AU) + 14.5(RUL) + 24.9(AR) + 13.5(TA) + 13.0(AMCR) + 14.6(AC) \quad (3.3)$$

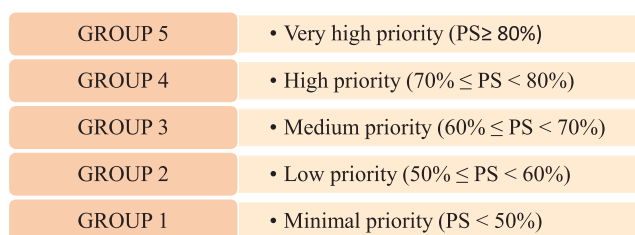
Before the computation of PS is conducted, the initial screening is required to identify whether the occurrences of non-measurable based parameters, that is, the notification of major SA, the End of Support (EOS) and the End of Life (EOL) from the original equipment manufacturer has been issued or not. The overall assessment as accordance to Figure 11.

Following that, real data of four selected device type-codes, that is, computed tomography scanner (CT Scan), hemodialysis unit (HDU), mobile X-ray, and water purification reverse osmosis (RO) system from multiple MOH hospitals is extracted from ASIS,¹³ which is then simulated to show a useful comparable end-result between the conventional practice method and via using the proposed ACA. The traditional practice is based on three benchmarking levels of equipment uptime as a reflection of the contract's three ageing conditions,²² as illustrated in Table 5, which corresponds to “High Priority”, “Medium Priority”, and “Low Priority”, respectively.

Meanwhile, Table 6 provides the results of the simulation, utilizing the proposed ACA model. It summarizes the available customized ACA assessment model, as well as the essential criteria, sub-criteria and their proposed score. Benchmarking the outcome, on the other hand, is done using a priority index group given by⁴⁶ as shown in Figure 12. In terms of the validity and transparency of the outcomes, a comparison of these two methodologies is explored.

TABLE 6 Brief description of the proposed priority scoring assessment criteria, sub-criteria and the proposed scoring.

No.	Criterion	Code	Threshold	Score	Weightage (%)
1	Safety alert	SA	Asset with field safety notice (minor)—frequency more than 3 notification	2	5.0
			Asset with field safety notice (minor)—frequency within 1–3 notification	1	
			None of above	0	
2	Asset usage	AU	High: more than 15 h a day	4	14.5
			Medium: $8 < AU \leq 15$ h a day	3	
			Normal: ≤ 8 h a day	2	
			Not in use	1	
3	Remaining useful life	RUL	$<33.3\%$	4	14.5
			$53.3\%–33.4\%$	3	
			$93.3\%–53.4\%$	2	
			$>93.4\%$	1	
4	Asset reliability	AR	$0\%–25\%$	4	24.9
			$26\%–50\%$	3	
			$51\%–80\%$	2	
			$81\%–99\%$	1	
			100%	0	
5	Technology availability	TA	Orphaned asset/Manufacturer not available	2	13.5
			Outdated technology (Defined by end user)	1	
			None of above	0	
6	Asset maintenance cost ratio	AMCR	>1.5	4	13.0
			$1.0–1.5$	3	
			$0.5–1.0$	2	
			<0.5	1	
7	Asset condition	AC	BER certification approved	3	14.6
			Request for BER	2	
			Others (i.e., Request for exemption, upgrading (etc.))	1	
			Good	0	

**FIGURE 12** Proposed priority index group for benchmarking the outcome.

3.5 | Maintenance strategy identification via fuzzy logic

The concept of fuzzy logic, first proposed by Zadeh,⁷⁷ is utilized to determine the appropriate maintenance plan for four device type-codes, as well as the simulated ACA outcome. The essential idea of fuzzy logic is fuzzy sets, which are classes with unsharp bounds (no crisp boundaries). The fuzzy number is graphically illustrated, as shown in Figure 13, which is made up of four essential components^{53,59}:

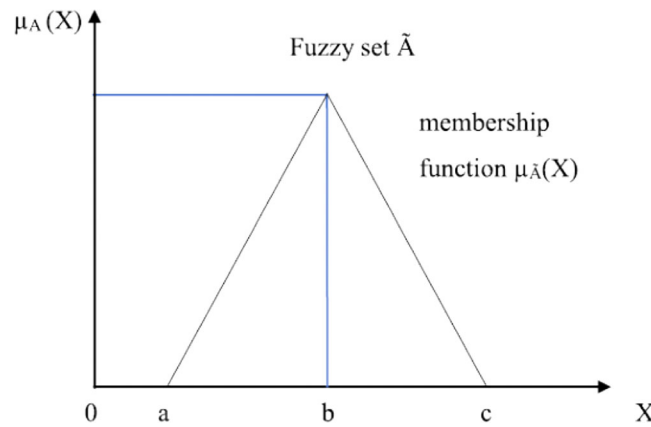


FIGURE 13 Triangular membership function.

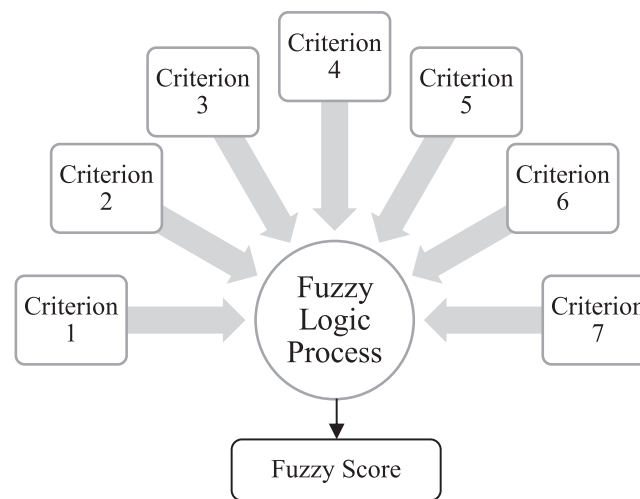


FIGURE 14 Fuzzy logic model.

- Fuzzifier (fuzzification).
- Rule-base/Knowledge-base.
- Linguistic inference.
- Defuzzifier (defuzzification).

3.6 | Development of fuzzy logic modelling

The key objective of fuzzy logic modeling is to prioritize the list of medical devices requiring PM based on the seven most important criteria in the QFD model. As a result, the proposed Fuzzy Logic Model has seven inputs (Figure 14) and one output, priority, which is ordered into five levels in Table 11.

3.7 | Fuzzification and defuzzification

Fuzzification, according to Jamshidi et al.³⁹ and Taghipour et al.,³⁷ is the process of transforming data from an input variable into a fuzzy format in order to incorporate the required uncertainty. That is, to create a fuzzy set that represents all degrees of membership of the linguistic values that correspond to the input variable data. The fuzzification process accepts either crisp or fuzzy values as input, but the outcome is always a fuzzy set.

TABLE 7 Comparison of priority group outcome for CT scan equipment from all hospitals in the Sarawak Region via (a) current approach in asset ageing assessment; and (b) via ACA (QFD-based setup).

(a)	
Priority group	Number of equipment
High priority	5
Medium priority	4
Low priority	1
Total	10
(b)	
Priority group	Number of equipment
Very high priority	3
High priority	0
Medium priority	0
Low priority	2
Minimal priority	5
Total	10

TABLE 8 Comparison of priority group outcome for HDU equipment from one selected hospital in the Southern Region via (a) current approach in asset ageing assessment; and (b) via ACA (QFD-based setup).

(a)	
Priority group	Number of equipment
High priority	8
Medium priority	14
Low priority	12
Total	34
(b)	
Priority group	Number of equipment
Very high priority	2
High priority	2
Medium priority	5
Low priority	6
Minimal priority	19
Total	34

Unlike fuzzification, defuzzification involves converting a fuzzy output value to a single crisp value, which is necessary for many real-world applications. Several strategies for defuzzification have been proposed in the literature. Some of the most commonly used defuzzification algorithms include Weighted Average, Centroid, and Mean-Max. In this paper, the defuzzification is done using the Weighted Average method.

The equation for the Weighted Average method is as follows:

$$x^* = \frac{\sum \mu_C(\bar{x}) \cdot \bar{x}}{\sum \mu_C(\bar{x})} \quad (3.4)$$

4 | RESULTS AND DISCUSSIONS

The demographics of the conventional practice method in prioritizing the critical medical devices, and the one using the proposed ACA model are shown in Tables 7–10, represented by multiple Malaysian MOH hospitals.

The conventional method is completely offset from the benchmarking pattern of the suggested method, as seen in Tables 7–10. Due to the inclusion of a broad element in the input parameter setting, the ACA model provides a broader

TABLE 9 Comparison of priority group outcome for mobile X-Ray equipment from all hospitals in the Kedah Region via (a) current approach in asset ageing assessment; and (b) via ACA (QFD-based setup).

(a)	
Priority group	Number of equipment
High priority	14
Medium priority	10
Low priority	13
Total	37
(b)	
Priority group	Number of equipment
Very high priority	2
High priority	1
Medium priority	1
Low priority	2
Minimal priority	31
Total	37

TABLE 10 Comparison of priority group outcome for RO system from one selected hospital in the Southern Region via (a) current approach in asset ageing assessment; and (b) via ACA (QFD-based setup).

(a)	
Priority group	Number of equipment
High priority	14
Medium priority	9
Low priority	6
Total	29
(b)	
Priority group	Number of equipment
Very high priority	1
High priority	0
Medium priority	2
Low priority	9
Minimal priority	17
Total	29

range of medical device prioritization options. Unjustified assessments can lead to misinformation in decision making and overestimation of asset replacement costs. Therefore, a transparent, justified and professional judgement are both promising and practicable.

Figure 15 depicts the demographics of the overall priority index group for four selected medical device type codes. It demonstrates that 65.45% of medical devices are classified as “minimal priority”, 7.27% of medical devices are classified as “low priority”, 17.27% as “medium priority”, 2.73% as “high priority”, and 7.27% as “very high priority”.

Finally, due to the capital impact for the replacement of assets on large scale, the prioritize benchmark is proposed to be classified into six categories, as illustrated in Table 11:

- (i) Medical devices which carry the issuance of major safety, EOL and EOS by the original manufacturer, are classified as “very high priority” assets and the maintenance strategy selection shall be neglected (remove from active equipment list for maintenance).
- (ii) Group 5 classified medical devices as “very high priority” assets in the need for replacement (PS > 80 condition), with the optional maintenance strategy proposed to be implemented under PM, as per expert opinion (with $4.5 < FS \leq 5.0$ condition).

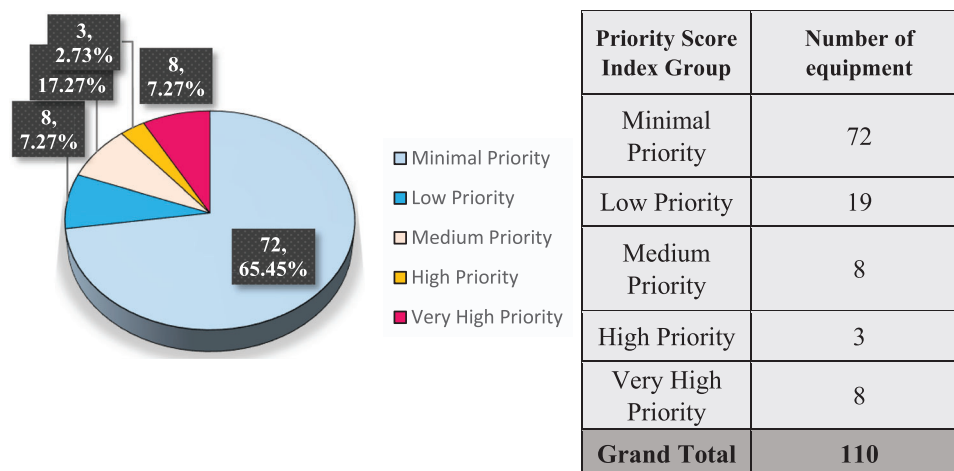


FIGURE 15 The overall Priority Index Group for the four selected medical devices type code.

TABLE 11 Priority index groups and proposed type of maintenance strategy based on PS and FS scoring respectively.

Group	Fuzzy scoring (FS)	Maintenance type (Recommendation)	Percentage (PS)	Priority for asset replacement
Major safety EOS/EOL		Focus only on replacement		Very high priority
5	$4.5 < FS \leq 5.0$	PM	$PS > 80$	
4	$3.5 < FS \leq 4.4$		$70 < PS < 80$	High priority
3	$2.5 < FS \leq 3.4$	PdM	$60 < PS < 70$	Medium priority
2	$1.5 < FS \leq 2.4$	PM + CBM	$50 < PS < 60$	Low priority
1	$1.0 < FS \leq 1.4$	CM/BM	$PS < 50$	Minimal priority

- (iii) Group 4 classified medical devices as “high priority” assets in the need for replacement ($70 < PS < 80$ conditions), with the optional maintenance strategy proposed to be implemented under PM, as per expert opinion ($3.5 < FS \leq 4.4$ conditions).
- (iv) Group 3 classified medical devices as “medium priority” assets in the need of replacement ($60 < PS < 70$ conditions), with the optional maintenance strategy proposed to be implemented under PdM, as per expert opinion ($2.5 < FS \leq 3.4$ conditions).
- (v) Group 2 classified medical devices as “low priority” assets in the need of replacement ($50 < PS < 60$ conditions), with the optional maintenance strategy proposed to be implemented under PM + CBM, as per expert opinion ($1.5 < FS \leq 2.4$ conditions).
- (vi) Group 1 classified medical devices as “minimal priority” assets in need of replacement ($PS < 50$ conditions), with the optional maintenance strategy proposed to be implemented under CM or BM, as per expert opinion ($1.0 < FS \leq 1.4$ conditions).

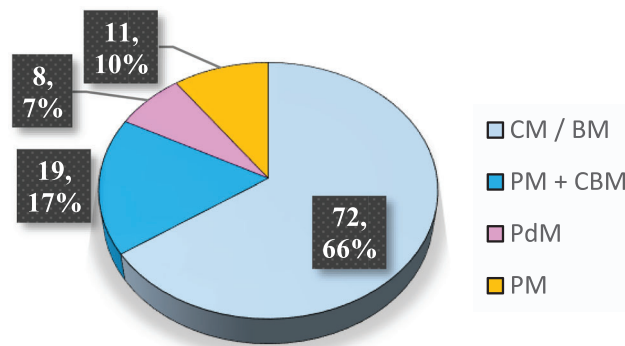
The simulation on a total four medical device type codes is then carried out (see Table 12 for more details), with the outcome presented in Figure 16. It demonstrates that 66% of medical devices are classified under CM or BM, 17% under PM + CBM, 7% under PdM and 10% under PM. However, it is also recommended that an in-depth risk assessment for each medical device type code should be addressed in multiple dimensions as well for future research work, particularly on life-support equipment, to determine a more thorough and contractually effective maintenance strategy.

5 | CONCLUSION

Providing high quality medical care necessitates a significant effort in prioritizing medical devices through effective critical evaluation that considers many input factors such as technical capabilities, reliability and maintenance expenses. For

TABLE 12 The maintenance decision for each of the selected four medical devices type codes from selected MOH hospitals.

Maintenance decision	Total equipment in each maintenance selection	List of equipment	Number of each equipment
CM/BM	72	CT scan	5
		HDU	19
		Mobile X-Ray	31
		RO system	17
PM + CBM	19	CT scan	2
		HDU	6
		Mobile X-Ray	2
		RO system	9
PdM	8	CT scan	0
		HDU	5
		Mobile X-Ray	1
		RO system	2
PM	11	CT scan	3
		HDU	4
		Mobile X-Ray	3
		RO system	1
Total	110	Total	110

**FIGURE 16** The main distribution of maintenance decisions for overall selected-four medical devices type codes from selected MOH hospitals.

proper usage and maintenance of medical equipment, a defined field strategy, technical guidance, and practical instruments for maintaining the operational parameters of medical devices are all necessary. Using functional medical devices, it will be possible to significantly improve the quality of the medical necessity, as well as the efficiency, of such a service. In this domain, consistent management strategies will benefit in boosting healthcare efficiency.

A rigorous evaluation of medical device reliability, replacement prioritization, and maintenance criteria is carried out to determine the proper condition across the equipment's life cycle, which can be extended or shortened based on the activities performed. The importance of maintenance in extending the life of equipment cannot be overstated. If maintenance periods are not reached on time and on a regular basis, medical devices will be damaged to the point where repair would cost more than replacement. If no decisions are made about their upkeep, medical devices will deteriorate irreversibly. The importance of maintenance operations is in the efficient management of the equipment and this responsibility needs an in-depth knowledge on medical devices.

In response, an ACA model must be created, that considers the equipment's history, how it has been mistreated in the past if the situation is improving, and what lessons can be learned from previous occurrences. Finally, records equip staff with critical technical information and evidence that they may use to back up their arguments, as well as when they

need help or extra resources. The upkeep of the database system aids in keeping track of repair services and other chores required for medical device operation. Prioritizing the right devices for the right replacement, and then making a strong governance choice on maintenance strategy.

ACKNOWLEDGMENTS

The authors would like to thank the Director General of Health Malaysia for the permission to publish this paper. Appreciation is given to the Ministry of Health and Universiti Teknologi Malaysia under the Contract Research DTD, R.K130000.7617.4C568 grants for the financial support provided throughout this research project.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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How to cite this article: Amran ME, Aziz SA, Muhtazaruddin MN, et al. Critical assessment of medical devices on reliability, replacement prioritization and maintenance strategy criterion: Case study of Malaysian hospitals. *Qual Reliab Eng Int*. 2024;40:970–1001. <https://doi.org/10.1002/qre.3447>

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