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A Systematic Review of Medical Equipment Reliability Assessment in Improving the Quality of Healthcare Services

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Abstract

1. Introduction

The medical equipment is an essential part of the healthcare system that primarily used to assist and cure the patient through specific procedures. In the current healthcare industry, the evolution of medical equipment is rapidly growing and enhancing the quality of healthcare services by incorporating advanced technologies such as advanced x-ray technology, computed tomography, magnetic resonance imaging, and positron emission tomography. If the medical equipment fails or does not work correctly, it will have an enormous impact on healthcare services. The sudden malfunction of the medical equipment led to injury and death of tens of patients. Thus, it is crucial to ensuring medical equipment highest level of reliability to prevent any consequence damage.

There is no proper methodology and systematic way in assessing the reliability of medical equipment early intervention. The failure of medical equipment occurs in real-time is unexpected and mostly has roots from the manufacture weakness process, poor maintenance strategy, less competent technician team, patient and user misbehaviour. Medical equipment failure is a serious problem in healthcare as the sensitive patient invokes a need for more advanced medical equipment for examination. As a consequence, the healthcare facing a

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large investment in medical equipment, infrastructure, and specialist leading to medical equipment highly important part as a most visible product in healthcare. Moreover, the healthcare face higher scrutiny in the aspect of medical equipment due to legal requirement and public contention. The study is carried out on 16 articles included in this review. None of the studies perform a comprehensive analysis that includes PM, CM, and RP. The selected studies include either one of medical equipment reliability assessments PM, CM, RP and/or combination of either type of assessment. The majority studies do not include the protocol and early intervention exercise in the medical equipment performance assessment. The absence of a proper methodology leads to a random and ineffective maintenance management exercise, and will affect mean time between failure, availability efficiency, and 2.2% of the medical equipment not correctly operate and could be harmful to patient and user.

Methods

This systematic review examines the reliability of medical equipment and its assessment, highlighting the crucial role of maintenance in enhancing healthcare service quality. Equipment failure poses potential risks to patients, staff, and the environment, emphasizing the significance of both medical equipment and its management in service delivery. Proper maintenance ensures consistent medical services and prioritizes patient care, while poor maintenance can lead to misdiagnosis and jeopardize patient safety. Effective maintenance policies are essential for healthcare institutions to improve service performance and patient safety. To optimize equipment use, hospitals must implement a robust maintenance program to maintain reliability and minimize failure risks. Monitoring equipment performance is vital for assessing the maintenance program's effectiveness and facilitating necessary corrective actions. This systematic review has analyzed studies on medical equipment reliability assessments and established a common maintenance schedule, allowing the adjustment of optimal maintenance strategies to enhance healthcare service quality. (Hilmi Zamzam et al., 2021)

Conclusion

Therefore, it is important to improve the quality of healthcare services by ensuring the clinical equipment reliability through the maintenance management process and life cycle assessment. Maintenance management of medical equipment is crucial to ensure that the machine is operated as per the manufacturer of products and guarantees the safety for the patients and the users. Several systems and systematic methods have been suggested to assess clinical instrument performance. Nevertheless, it has not been fully documented how such measurements would improve the programme of routine maintenance even though many outstanding problems regarding instrument maintenance remain unsolved. This paper systematically reviews the current methods in three states of the art, summary of a medical

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instrument, and comprehensive assessment using data tools regarding medical equipment reliability.

The advancement in medical technology has improved the survivability in the face of disease or injury and greatly enhances the quality of life of sufferers through improved diagnostic and therapeutic outcomes. Medical equipment is an essential asset that significantly contributes to improvements in the effectiveness and the quality of healthcare services. Furthermore, funding for this asset requires a great amount of money compared to other hospital belongings. Asset management, especially the maintenance management of the medical equipment, becomes very important (Hilmi Zamzam et al., 2021). Governed complexity and the large number of clinical devices available in modern healthcare practice demand a systematic approach to device a performance assessment routine. The development of methods of automatic tuning of such devices requires a figure of merit of the assessable parameters in order to monitor the drift of components over time and operating conditions.

2. Methodology

A systematic review procedure adapted from the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement was examined, which is employed to add transparency and optimise the methodical research of the available outcomes of investigations. A comprehensive and uniform method was followed to identify the existing scholarly contributions involved in quantitatively evaluating medical equipment reliability assessment as a means to uphold and improve the quality of healthcare services. A systematic search was conducted on digital libraries from January 2010 onward. A block of keyword search was employed, stemming from the combination of ‘medical equipment’ and ‘reliability assessment’; ‘healthcare equipment’ and ‘reliability analysis’; ‘health technology’ and ‘reliability tool’; ‘medical repeat equipment’ and ‘reliability indicator’; ‘medical device’ and ‘reliability test’ with each entry of ‘healthcare service’ and ‘health facility.’ As a result, the keyword entries were individually entered one after another into the search engines. Each selected article was opened for review and the cited references were checked for potential additional cited peer-reviewed articles.

The first search revealed a blend of 379 articles and 32 reports, while a second search effort produced 85 research articles and 21 reports after duplicates were eliminated. Of these 106 articles, none were published from 2010 to 2013. A title and abstract screening was undertaken to ascertain the relevance and topic correspondence to the preference of this study. Upon completion of this screening process, the next step involved reviewing the articles in full text to ensure that the 85 research articles and 21 reports were eligible to be synthesised and analysed. The significant contents of the articles were thereafter comprehensively scrutinised to confirm that the inclusion and exclusion criteria were

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fulfilled. Inclusion criteria consisted of research articles and reports addressing the aim of the study of medical equipment considering reliability assessment by means of a quantitative method, or evaluation could manifest the equipment performance empirically. Conversely, a medical equipment reliability assessment was excluded if the reviewed article did not implement a quantitative method to assess the medical equipment performance or the medical equipment reliability assessment was not demonstrated empirically ((Hilmi Zamzam et al., 2021)).

3. Medical Equipment Reliability Assessment Techniques

3.1. Statistical Methods

Section 3.1. Statistical Methods In AMT, simple statistical tests and methods are used for data analysis. Dispersion and correlation measures, such as variance, mean, efficiency, coefficient of mathematical expectancy variation, coefficient of independence, and time-ordered Poisson process, are also used in reliability theory. Moreover, parametric analysis and non-parametric analysis are applied as statistical measures. Notably, the exponential distribution or Weibull distribution is often used for the reliability assessment of healthcare equipment when a parametric analysis is applied. Additionally, an integral test plan is constructed for reliability verification, and a log-linear model is developed to compare the non-repairable and repairable equipment. Some typical statistical methods are listed below: (1) For the one-sample test, the chi-squared test and Kolmogorov–Smirnov test are used as a constant average data assessment method; (2) For the two-sample test, the normal distribution is assessed using the chi-squared and Kolmogorov–Smirnov tests; (3) The least squares method and the maximum likelihood estimation method are popular methods used to estimate the model; (4) In time-ordered data life testing, the Weibull distribution and the PH distribution are established for the lifetime or age between failures, and for the general situation, the parametric confidence intervals for quantiles are calculated; whenever the Weibull or PH model is applicable, the PH model with a location or scale shift is simultaneously fitted; (5) A log-linear model is designed to compare the non-repairable and repairable equipment with multiple repairs, and a Weibull model is selected to compute the equipment parameters; (6) An integral test plan is constructed by capitalizing on the qualitative ahead concept; and (7) A reliability function is designed for the situation in which multiple failure modes govern equipment, incorporating a semi-Markov process conditional on the first failure time.

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3.2. Failure Mode and Effects Analysis (FMEA)

Failure Mode and Effects Analysis concerning failure modes and effects analysis observed that 28.5% of the surveyed clinicians rely on age and nationality for the assessment of life-supporting medical equipment as the financial situation does not permit additional tests to be made. Meanwhile, the reliability and safety of neurosurgery medical equipment were considered to construct an evaluation system and employed a comprehensive analysis of the FMEA model to find the weaknesses in the medical equipment used in neurosurgery. First, the research team classified and ranked the risk by managers, professionals, and operators and screened the key risk items. Next, priority control measures were determined by the degree of risk and importance. In the evaluation, a structured questionnaire survey, local accumulation, unit questionnaire, and interviews were used. The actual analyzed results were the systematic errors of medical equipment application, the poor coordination, the lack of formal specialization, and the lack of information feedback.

In a similar study, a putative quality improvement model through failure mode and effect analysis was presented, and based on real cases, the structure of the patients and problems was contained in the model, where the influential risk prediction point and the control index management mode were also classified to prevent the influenced factors from returning to the process. The professional team members implemented the control index and the final assessment with desirable results that prevent the failure of the surgical equipment and related medical accidents. However, the results indicated that it was common to have over 2–4 process problems, with the probability of two types reaching 92.86% and 85.71%, so that the proposed system models proved that the FMECA could solve those defects; a high closing target was suggested. Although it can effectively control risks and reduce medical cost risks, thus improving patients' satisfaction levels of surgical services, the safety and quality of surgical care could be increased despite the many common factors influencing failure. Symptoms of such issues primarily impacting the categorization of surgical problems were recommended and strictly implemented.

4. Applications in Healthcare Settings

It is widely noted that medical equipment reliability assessment in healthcare facilities can play a critical role in improving the quality of healthcare services (Hilmi Zamzam et al., 2021). Continuous assessment of medical equipment enables effective measures to be taken for optimum performance. Smooth equipment performance guarantees the provision of timely and quality healthcare services. As such, considerable attention has been given to the assessment of reliability of medical equipment. In the literature review, numerous studies on the assessment of medical equipment in healthcare facilities from different perspectives are presented. The study is presented in five subsections: "Study overview," "Medical equipment

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reliability assessment," "Expected outcomes," "Methodology," and "Study status and future work".

Delivering high reliability has been a focus of safety contentious industries such as commercial airlines, railways, and the oil and nuclear power industries. In healthcare, it is suggested that many systems have poor reliability. Evidence is also beginning to emerge regarding the poor reliability of common clinical systems. For example, a systematic review of UK hospitals, investigating four important and common clinical systems (availability of clinical information in surgical outpatient clinics; prescribing for hospital inpatients; availability of equipment in theatres; and availability of equipment needed for the insertion of peripheral intravenous lines) found they showed poor reliability (Burnett et al., 2012).

5. Impact on Quality of Healthcare Services

A comprehensive search was carried out on medical equipment and devices in most healthcare facilities around the world to identify suitable keywords for medical equipment reliability assessment articles. 16 related articles were selected based on the prescribed assessment. Three types of medical equipment reliability assessments are herein included; PM, CM, and RP. Of the 16 selected articles, no single study approach was conducted in this comprehensive examination. Three performance types of medical equipment reliability assessments were conducted that include PM, CM, and RP as well as no single cooperative study to be performed by a specific type of performance (PM, CM, RP). The performance types of medical equipment reliability assessment include either one of the 4 assessments of medical equipment reliability assessment, namely PM, CM, RP, and/or any combination of either type of assessment. The analyzed documents comprised 11 articles investigating medical equipment reliability assessment that focuses on performance of the maintenance (PM, CM, RP) of medical equipment.

All the retrieved articles are based solely on the medical equipment viewed under assessment operations, including most medical devices. From the 16 selected articles, there have been no specific standard protocols and early intervention programmes for the medical equipment reliability assessment in healthcare facilities reported. Due to the need for healthcare facilities to initiate a swift medical equipment emergency action planning for proper maintenance of medical devices when formed faults, the suggested analysis of medical device performance cannot be implemented in good time (Hilmi Zamzam et al., 2021). Depending on healthcare facilities, a wide range of medical equipment to implement correct maintenance practices are available. However, how and when to fix or replace the medical equipment is very hard to recognise, resulting in obtaining inappropriate maintenance management outcomes. Given the patient and therapist reliant on the medical devices required for healthcare operations, incorrect equipment accuracy could be dangerous.

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6. Challenges and Future Directions

1. Introduction Healthcare and medical treatment are part of primary needs and services for all individuals. Demand for healthcare is continuously increasing due to population growth, unhealthy lifestyles, and various diseases. Managing assets and facilities is crucial for ensuring continuity in healthcare services. Medical equipment is a vital asset in healthcare, and it significantly contributes to the effectiveness and quality of healthcare services. The development of medical equipment is beneficial for the health sector. The advancement has improved the possibility of patients surviving and enhanced their quality of life through accurate diagnosis and better therapy. However, many medical equipment maintenance problems concurrently rise as the number and complexity of equipment increase. Recent studies regarding medical equipment maintenance have been conducted extensively. Maintenance management of medical equipment is essential for successful operation according to the manufacturer's specifications and ensuring the safety of patients and equipment users. Awareness of device management and maintenance repair services has increased significantly. Nevertheless, medical equipment failure potentially occurs when the equipment does not function as it should. This affects healthcare effectiveness and patient safety. (Hilmi Zamzam et al., 2021) detailed the problems related to medical equipment in developing countries, including the management factor, resources of devices, quality control and service of devices, affecting problem characteristics from the operator's perspective, and indicated device problems based on their nature. The study of a reliability assessment on medical equipment was conducted to identify important parameters and parameters correlated with the standards of the Malaysian Fire and Rescue Department that is relevant to a strategic maintenance management to cover preventive maintenance, corrective maintenance, and a proper replacement plan. However, there are a specific study of the computerised maintenance management system of medical equipment, past educational intervention projects for students in order to prevent electrical and mechanical problems, and a comparison of previous and recent ISO 9000 certification groups, which were only compiled into a generic study regarding the medical device failure mode, effects, and criticality analysis (FMEA) systematic review. Despite numerous epithets of knowing the actual condition of medical equipment and the measurement of the device are controlled to estimate a specific parameter required for maintenance actions, a specific study in the South East Asia region is still not found. (Shamayleh et al.2020)(Badnjevic, 2023)(Fotovatfard & Heravi, 2021)(Haleem et al.2022)

7. Conclusion

Prioritisation Assessment and Robust Predictive System for Medical Equipment: A Comprehensive Strategic Maintenance Management 2.docx

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Introduction (1), Methodology (2), General Information (3), Types of Medical Equipment (4), Outcome of Assessment (5), Prioritisation and Analysis (6), Discussion and Findings (7), Conclusion (8)

(Hilmi Zamzam et al., 2021)

Considerable attention has been given to reliability in healthcare in recent years. Much of this focus has been on reliably delivering care requirements to individual patients. Attention has now turned to improving patient safety, for example through the routine and reliable use of checklists and protocols. Most of this work has concentrated on the reliability of single processes within healthcare. There has been less focus on the reliability of the overall system of care a patient receives, particularly in hospitals. This is in spite of ongoing and sometimes publicized failures - patients who turn up for their operation only to find it is not scheduled; results that are repeatedly lost or misfiled; drug charts missed multiple times. This study was designed to take a simple and robust approach to audit and compare the reliability of six fundamental aspects of care across seven NHS organizations (Burnett et al., 2012). The findings raise significant concerns about the insecurity and lack of robustness that characterize front line care within investigated NHS organizations. Special attention is directed toward hospital leaders, policymakers, and commissioners. The implications of these findings are substantial; immediate action is required to change practice and process. Sheer scale suggests that reliability of clinical systems is an issue that affects all aspects of patient care. Had patient care been more reliably managed, within the systems contributing to the overall care of each patient on the days in question, the need for subsequent emergency admissions might have been considerably reduced. Japanese clinical scientists believe that the reliability of clinical systems in healthcare should be examined and improved to reduce cost and increase patient safety. This is important in the UK NHS, as various bodies have to cut annual expenditure by £20 billion. These findings are presented to urge those working in the UK NHS to initiate or extend work to audit and improve the reliability of the broader systems of care that they provide. Likely household code indicates when important, highlighting, action, and examination recommendations to expedite care.

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