Medical devices Inspection and Maintenance; A Literature Review

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Abstract

Modern medical devices and equipment have become very complex and sophisticated and are expected to operate under stringent environments. Hospitals must ensure that their critical medical devices are safe, accurate, reliable and operating at the required level of performance. Even though the importance, the application of all inspection, maintenance and optimization models to medical devices is fairly new. In Canada, most, if not all healthcare organizations include all their medical equipment in their maintenance program and just follow manufacturers’ recommendations for preventative maintenance. Then, current maintenance strategies employed in hospitals and healthcare organizations have difficulty in identifying specific risks and applying optimal risk reduction activities. This paper addresses these gaps found in literature for medical equipment inspection and maintenance and reviews various important aspects including current policies applied in hospitals. Finally we suggest future research which will be the starting point to develop tools and policies for better medical devices management in the future.

Keywords
Medical devices, Maintenance, Reliability, outsourcing, prioritization

1. Introduction

The maintenance of medical equipment is as important as its design and development. Usually, much more money is spent on maintaining a piece of equipment over its life span than on its procurement [1]. Medical equipment is extensively (from 5,000 to more than 10,000 different type) used in all aspects of health services, ranging from prevention, screening, diagnosis, monitoring, and therapeutics to rehabilitation. Nowadays, it is virtually impossible to provide health services without them. Unlike other types of healthcare technologies (i.e., drugs, implants, and disposable products), medical equipment requires maintenance (both scheduled and unscheduled) during its useful life. As the sophistication and cost of medical equipment continue to escalate, the complexity and cost of its maintenance have also risen sharply in the last few decades. Studies conducted using data collected from hundreds of acute-care hospitals indicate that on average, each hospital acquired about 15–20 pieces of medical equipment for each staffed bed, which translates into a capital investment of around US$200–400,000/staffed bed. Thus, it is common for a 500-bed hospital to own more than US$100–200 million worth of medical equipment and considerably more if it is affiliated with a medical school. The same studies have indicated that annual medical equipment maintenance and management cost is approximately 1% of the total hospital budget, so a 500-bed hospital spends typically around $5 million/year. In addition to its high maintenance costs, medical equipment is often involved in patient incidents that resulted in serious injuries or deaths. In fact, statistics accumulated by The Joint Commission (TJC) show medical equipment-related “sentinel events” is typically among the top ten types every year [2]. Therefore, Hospitals and healthcare organizations must ensure that their critical medical devices are safe, accurate, reliable and operating at the required level of performance.

Maintenance strategies and reliability engineering techniques have been significantly improved in the last two decades, and they have been successfully applied in many industries to improve the performance of equipment maintenance management. Numerous inspection and optimization models are developed and widely used to achieve maintenance excellence, i.e. the balance of performance, risk, resources and cost to reach to an optimal solution. However, most of hospitals and healthcare organizations do not benefit from maintenance excellence as much as other industries [3]. Unnecessary and excessive preventive maintenance could be also loss-making likewise inadequate level of maintenance. The time, which is spent doing the unnecessary preventive maintenance, is robbing an organization of a fraction of one of its most vital resources [4].Since 2004, when Joint Commission on Accreditation of Healthcare Organizations(JCAHO) introduced standard EC.6.10 [5], hospitals in US have started adopting their maintenance programs to put their maintenance resources where most needed. This standard
allows hospitals to not have schedule inspection or maintenance tasks for certain pieces or types of medical equipment, if these tasks are not needed for safe and reliable operation [6]. However, in Canada, most, if not all healthcare organizations include all their medical equipment in their maintenance program and just follow manufacturers’ recommendations for preventative maintenance [3]. Current maintenance strategies employed in hospitals and healthcare organizations have difficulty in identifying specific risks and applying optimal risk reduction activities [7]. Moreover, even though the use of reliability engineering tools is well established, their application to the medical industry is new. Most research in this area merely suggests how to assess or improve the reliability of devices in their design or manufacturing stages. To this point, best maintenance strategies for medical equipment in their operating context have not been considered. Hospitals, due to possessing a large number of different devices, can benefit significantly if the optimization techniques are used properly in the equipment management processes. In this paper we address these gaps and review the research literature regarding medical device inspection and maintenance. We consider various important aspects, concerned with MEIM including prioritization of medical equipment, maintenance optimization models applied for medical devices, maintenance outsourcing, and current MEIM policies applied in hospitals for improving medical equipment maintenance. Finally, in the discussion and conclusion section, we present the main research gaps found and suggestions for future research which will be the starting point to develop tools suitable for better medical devices management.

2. Review of the existing literature

In this section, we assess the status of research on maintenance of medical devices. We consulted a range of academic archives including books, research papers and theses to identify relevant research for medical device maintenance. The source used for our study was academic journal articles published between 1985 and 2014. Publications in languages other than English were not included. The archives consulted included, Proquest, ScienceDirect, Emerald, Google scholar, and JSTOR. Moreover, a search for additional papers in the reference lists of all papers is carried out. Clinical engineering departments have struggled to optimize medical device risk management using various Medical Equipment Management Programs (MEMPs) for more than 25 years. Many risk based MEMPs, including the seminal Fennigkoh and Smith method and its variations, have been proposed and are currently in use. A common theme in these methods is that a single measure of a number of different risks is defined and used to guide safety and performance inspection and preventive maintenance activities. These methods, although simple to use, present a number of problems including difficulty in identifying specific risks and applying optimal, specific risk reduction activities. It is widely recognized that although current medical equipment management methods do reduce risks, they are not near optimal in minimizing risks [7].

A serious debate on preventive maintenance (PM) intervals is taking place among clinical engineering (CE) practitioners on various levels and in professional journals. The debate is focused on the standard requirements by regulating authorities and accreditation organisation in many countries that (PM) intervals should follow the equipment manufacturer’s recommendations [8]. Some devices that appear to be very similar in their function and design have manufacturer-recommended intervals that vary by a factor of two or more. The question has been raised about the credibility of these recommended intervals and whether it is based on meaningful test data. Debating the PM intervals with equipment manufacturers does not seem to be a practical approach because manufacturers may be reluctant to share that information with end-users if there are any documented data. Judging maintenance outcomes based on PM or safety and performance inspection (SPI) is not possible and the same applies to periodic replacement of parts or calibrations [6].

Clinical and biomedical engineering professionals are still holding on to process measures rather than analysing the outcome of maintenance in spite of the experience from other industries, which shows that traditional PM is often unnecessary, if not counterproductive [9]. In 1984, the Emergency Care Research Institute (ECRI) [10] published a recommendation to use risk as the primary criteria for deciding which piece of equipment should be subject to SM as well as the frequency of the SM and risk was categorised as high-medium-low. ECRI has developed scheduled (planned) maintenance (SM) for most of medical equipment which is known as health device inspection and preventive maintenance (IPM). The IPM includes guidelines on PM and SPI. Fennigkoh and Smith [11] introduced another approach, which classifies equipment using three parameters, i.e. function, physical risk, maintenance requirements. This approach was known later as the risk-based inclusion criteria and allowed CE professionals to focus their PM on a limited portion of medical devices (life support).
Ridgway [12] noted that PM does have some impact on the reliability of some items and therefore it does have some beneficial impact on equipment uptime. However, the discussion about what value properly executed PM brings to the facility’s maintenance program requires considering the impact of eliminating or increasing the intervals for some or all of the PM-related tests and results achieved: increased safety, reduced downtime and fewer expensive repairs. Ridgway [13] further noted that PM is an issue of declining importance-relative to several other equipment issues. Yet, US$300 million per year is still allocated to this in the USA hospitals. Ridgway further indicated that there is still no good consensus on the definition of PM or even why it is done, no rational process for defining a non-critical device and no good method for justifying PM intervals. PM does not prevent all types of equipment failure and only addresses failures that result from the degeneration of a device’s non-durable parts and hidden failure.

In this review, we divide the studies used in the literature into three main categories, which are prioritization of medical devices, empirical researches, and mathematical modeling. The three categories, each with their own related approaches and references, are reported in Table 1. In what follows, we more specifically go into the references and show what has been done.

2.1. Development of maintenance philosophies

Maintenance management techniques have been through a major process of metamorphosis over recent years. Today, the maintenance progress has been provoked by the increase in complexity in manufacturing processes and variety of products, growing awareness of the impact of maintenance on the environment and safety of personnel, the profitability of the business and quality of products. There is a paradigm shift in implementing maintenance strategies like condition-based maintenance (CBM) and reliability-centered maintenance (RCM). Then the risk-based maintenance (RBM) has been emphasized. The development of maintenance philosophies is shown in Figure 1. This figure reveals that maintenance policies are evolved over time and can be categorized as first, second, third and recent generations.

![Figure 1: Development of maintenance philosophies](image)

2.2. Empirical approaches versus mathematical models

Today, medical equipment maintenance suffers from the same ailments that traditional medicine was suffering from before. Rapid advance of medical technologies has proven that traditional maintenance is no longer enough to ensure that equipment is getting the best possible maintenance. Medical equipment industry has been following empirical approaches and very little was done on mathematical modelling. Preliminary data collected from some hospitals in USA and analysed show that current maintenance strategies might be effective but there is no clear evidence whether they are efficient. However, incorporating mission-criticality concept with patient risk might produce much higher impact on reduction of risk. Refocusing resources from scheduled maintenance to higher impact tasks, e.g., use error tracking, self-identified failures and repairs, user training and working with facilities and purchasing should lead to a balanced mix between needs and resources [15].

Literature review has shown that very little research has been done to measure the availability of medical equipment in relation to maintenance using mathematical modelling. The empirical approach is widely used in other sectors of industry and various mathematical models were developed to measure availability and reliability of equipment and systems. Evidence in literature shows that maintenance policies based on mathematical models are much more flexible than heuristic policies and the great advantage of the mathematical approach is that the outcomes can be optimised and maximum reliability or minimal cost can be achieved [16].
The empirical approach is based on experience and manufacturer’s recommendations. One method is called reliability centred maintenance (RCM), introduced about 30 years ago and considered to be empirical. RCM is based on condition monitoring, analysis of failure causes and investigation of operating needs and priorities. According to Endrenyi [16] RCM selects the critical components in equipment, which contribute to equipment failure or financial loss and initiates stringent maintenance programs for these components. Endrenyi further concluded that RCM helps to decide where to put the next dollar budget for maintenance and is good for comparing policies but not for true optimisation. In RCM, six basic patterns of failure have been identified based on industrial experience (very little data is available for medical equipment). A study done 1982, which analysed maintenance data from the USA Navy industry using six patterns, found the following information in Figure 2 [17].

Figure 2: Six basic patterns of failures in RCM [17]

Hall [18] noted that there are two keys to RCM method, the first is having a good maintenance history of medical equipment and the second key is the age. Hall further indicated that RCM might be a better strategy for younger equipment. To balance both sides of maintenance (preventive, corrective), condition based maintenance (CBM) was introduced, which observes and forecasts real time health of machines where RCM studies the failure causes over a period of time and initiates maintenance programmes to increase the up time of these equipment. Recent development in CBM revealed promising technologies for advanced fault detection and forecasting. In addition, CBM increases productivity, availability and safety of the machinery systems [19]. In CBM, machines are continuously monitored by various sensors to detect failures in real-time and therefore CBM is useful in estimating the time of a future failure and remaining useful life.

2.2.1. Classification and Prioritization of medical devices for maintenance activities

The ever-increasing number and complexity of medical devices demands that hospitals establish and regulate a Medical Equipment Management Program (MEMP) to ensure that critical devices are safe and reliable and that they operate at the required level of performance. As fundamental aspects of this program [20] inspection, preventive maintenance, and testing of medical equipment should be reviewed continuously to keep up with today’s technological improvements and the increasing expectations of healthcare organizations. No longer content to merely follow manufacturers’ recommendations, hospital clinical engineering departments all around the world including Canada, Australia, and United States have begun to employ more efficient and cost-effective maintenance strategies. Gentles et al [21] have begun to develop a unique database to collect comparative data on inventory and maintenance of the most critical devices used in hospitals across Canada and the United States. This project will provide a large statistical failure data set which could be used to establish optimum intervals for routine maintenance scheduling. Ridgway et al. [12] provide concise guidelines for maintenance management of medical equipment and address methods, which have been used for a long time in other industry segments, such as RCM. Significant and critical assets should be identified and prioritized, and many techniques have been developed for criticality assessment of devices. Most use some variation of the probability risk number or PRN, a product of the probability of failure of an asset, severity of the consequence of the failure, and detectability of the failure:

\[ \text{PRN} = \text{Probability of failure} \times \text{Severity} \times \text{Detectability} \]

In hospitals, risk is a criterion in criticality assessment of medical devices, but the definition of risk differs from that used in RCM. After running an evaluation on medical devices, clinical engineers decide which should be included in the MEMP of the hospital based on their risk scores.
Fennigkoh and Smith [11] proposed a risk assessment method to group medical devices on the basis of their Equipment Management (EM) numbers, or the sum of the numbers assigned to the device’s critical function, physical risk, and required maintenance:

\[
EM = \text{Critical Function} + \text{Physical Risk} + \text{Required Maintenance}.
\]

Devices with an EM number above a critical value 12 are considered to have critical risk and thus are included in inspection and maintenance plans. In 1989, JCAHO recognized importance of this method and eventually in 2004 approved it as the standard (EC6.10) [5]. This standard allows hospitals not to perform scheduled inspection or maintenance tasks for certain pieces or types of medical equipment, if these tasks are not needed for safe and reliable operation [6]. Since then, Fennigkoh and Smith’s method or its many variations have been used by clinical engineers [7]. Ridgway [12] in his recent paper emphasizes that preventive maintenance can provide a benefit for just a relatively few devices, and a significant number of repair calls are made due to random failures of device’s components. Wang and Rice [22] propose simplified version of gradient risk sampling and attribute sampling to select a portion of equipment for inclusion. Clinical engineers believe that risk is not the only inclusion criterion, however, even though it is the most important one [23]. Other criteria which reflect the needs and reality of a hospital should be considered, including mission criticality, availability of backup, hazard notice, and recall history (24,25).

Taghipour et al. [26] presented a multi-criteria decision-making model to prioritize medical devices according to their criticality. Devices with lower criticality scores can be assigned a lower priority in a maintenance management program. However, those with higher scores should be investigated in detail to find the reasons for their higher criticality, and appropriate actions, such as ‘preventive maintenance’, ‘user training’, ‘redesigning the device’, etc. should be taken. In this paper, the authors also describe how individual score values obtained for each criterion can be used to establish guidelines for appropriate maintenance strategies for different classes of devices. Recently, Jamshidi et al [27] developed a fuzzy healthcare failure modes and effects analysis (HFMEA) method for prioritization of medical devices. The authors calculated the risk based on conditional probability of failures and consequence analysis.

### 2.2.2. Inspection and maintenance optimization models

Wang and Leven son [24] proposed a new interpretation of the function parameter and called it mission criticality, which they defined as the “equipment role or importance within the organisation’s mission”. Later Wang et al. [6] proposed a more explicit maintenance approach that uses patient risk-mission criticality as a classification method and a maintenance-strategy selection. According to Wang [9] ideally PM should be performed at time intervals just below the mean-time-between-failure (MTBF), as this would allow one to minimise resources while preventing the majority of failures. Wang further proposed that the theoretical ideal interval for SPIs is (SPI period =2*(1- uptime)*MTBF). Uptime or availability of equipment for use is measured as a percentage of the planned operational time. Baker [28] assessed validity of some widely-used models of age-related failure rate, such as the power-law and loglinear Poisson process, using large database of failures of many types of medical equipment. According to his research the power-law process is the best proposed model to study the dependence of failure rate on equipment age and on time since repair, which demonstrated a complete methodology for deriving optimum equipment replacement policies. The above study was limited to the use of mathematical models to assess failure rate and excluded the effect of PM on failure rate. Khalaf [29] suggested a maintenance model for minimizing the risk and optimizing the cost-effectiveness of medical equipment. The elements of both risk management and cost-effectiveness were evaluated together with the role of medical equipment suppliers. The results showed a poor overall performance and lack of effective procedures regarding risk and costs of maintenance programs. Therefore, Khalaf revised the model to suit clinical engineering departments in Palestinian hospitals. Khalaf et al [15] developed a mathematical model using a mixed integer based approach for maintenance operations schedules for medical equipment. In addition, they proposed a greedy algorithm to give an initial solution for the model. Tentative conclusions from preliminary analysis done by ARAMARK Healthcare's Clinical Technology Services show that current maintenance strategies are effective.

Taghipour et al. [26] considered a repairable system with components subject to hard and soft failures; soft failures are only rectified at periodic inspections and are fixed with minimal repairs. They propose a model to find the optimal periodic inspection interval on a finite time horizon. Taghipour and Banjevic [30] further present two inspection optimization models over finite and infinite time horizon for a multi-component repairable system subject to hidden failures. Recently, Zhang [31] demonstrated how a Condition Based Maintenance (CBM) program can be used to utilize field data and usage data, to minimize unnecessary maintenance, and to reduce service costs. In the case study, the service order data, local dispensing station logs, and install asset data on medicine dispensing products were
analyzed. The case study shows that a significant cost saving can be achieved by utilizing the existing field and usage data to establish the CBM program in medicine dispensing product service. In addition, Khalaf et al. [32] proposed a global model to measure the probability of equipment being available using real data extracted from maintenance history of infusion pumps and ventilators and analysed using Matlab. To confirm the validity of the developed model, the survival analysis approach was used to develop a model that measures the survival of equipment as a function of maintenance and age of equipment. The method was first tested using simulated data and the findings confirm the validity of the proposed approach.

2.3. Maintenance outsourcing
When a health care institution lacks the technical skills or specialized assets needed for the maintenance of its medical technology, maintenance should be outsourced. Yet while outsourcing has grown in popularity, research on maintenance outsourcing for medical devices in academic literature remains scarce. Research into the outsourcing of medical device maintenance services and its associated risks in hospitals is still in its infancy stages, and that further progress in this field would benefit from additional empirical study grounded in management theory. In the healthcare environment this problem is worthy of study, as healthcare institutions lacking the capacity to deal with these issues may face significantly higher costs [33].

Figure 3: Results of Ridgway’s 2009 study [34].

3. Medical device-related facts and figures
3.1. Repair calls
A recent study conducted by Ridgway et al. [34] in which the authors used nine categories of codes to analyse ongoing repair calls cause coding and applied that to data captured from Master plan’s database. They studied three different groups of facilities, one of which consists of 14 hospitals and analysed 2,598 repair calls made over three months during 2009. Some of the interesting findings are (Fig.3):

- 46.3 per cent of repair calls are due to random, unpredicted failures associated with the device inherent reliability.
- 32.2 per cent of repair calls are due to equipment management issues such as accessories, physical stress, environmental stress and user related.
- 7.8 per cent of repair calls are battery related.
- 13.7 per cent is related to inadequate PM, set-up and uncategorised repair calls.

Another study was conducted by Wang et al. [35] in which the authors used maintenance data collected from 40,496 equipment records in various hospitals and applied specific failure codes developed by the team to measure maintenance effectiveness. The codes are assigned by CE professionals when completing SM and CM activities for all kinds of medical equipment. The summary of the preliminary findings of the above study is:

* Current maintenance strategies are effective but it is not clear whether they are efficient.
* It would be preferable to drop SPI on some equipment and use the time saved to help user. The time saved is estimated to be 25 per cent.
* Refocus resources from SM (SPI+PM) to higher impact tasks, e.g. use error tracking, self-identified failures, and repairs.
3.2. Observations

We looked at scholarly papers tackling the maintenance problems, scrutinizing three major branches of papers, including: mathematical models, empirical research on the maintenance of medical devices, and prioritization of medical devices for maintenance activities. Table 1 shows the existing literature on maintenance of medical devices between 1989 and 2014.

<table>
<thead>
<tr>
<th>Author/Year</th>
<th>Optimization/ Prioritization/</th>
<th>Book/Paper/Thesis</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dhillon, 2000 [36]</td>
<td>Empirical Book</td>
<td>Medical device Reliability</td>
<td></td>
</tr>
<tr>
<td>Wang and Rice (2003) [22]</td>
<td>Empirical Paper</td>
<td>proposed simplified version of gradient risk sampling and attribute sampling</td>
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<tr>
<td>Ridgway, M. 2003 [37]</td>
<td>Prioritization Paper</td>
<td>Analysing PM data by FMEA</td>
<td></td>
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<tr>
<td>Wang et al. (2006a) [6]</td>
<td>Empirical Paper</td>
<td>Interview with Larry Fennigkoh</td>
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<tr>
<td>Wang et al. (2006b) [38]</td>
<td>Empirical Paper</td>
<td>An strategy for incorporating multiple criteria</td>
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<tr>
<td>Ridgway (2009b) [12]</td>
<td>Empirical Paper</td>
<td>Optimizing PM programs</td>
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<tr>
<td>Ridgway et al.(2009c) [34]</td>
<td>Empirical Paper</td>
<td>Reducing Equipment Downtime</td>
<td></td>
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<tr>
<td>Gentles et al. 2010 [21]</td>
<td>Empirical Paper</td>
<td>Collecting comparative data on inventory and maintenance of the most critical devices used in hospitals</td>
<td></td>
</tr>
<tr>
<td>Taghipour (2008-12) [3,26,30]</td>
<td>Optimization&amp; Prioritization Thesis</td>
<td>Reliability and Maintenance of Medical devices</td>
<td></td>
</tr>
<tr>
<td>Cruz and Rincon (2012) [33]</td>
<td>Empirical mapping review</td>
<td>Medical device maintenance outsourcing</td>
<td></td>
</tr>
<tr>
<td>Jamshidi et al. (2012) [27]</td>
<td>Prioritization Paper</td>
<td>A risk-based Maintenance Strategy for prioritization of Medical Equipment</td>
<td></td>
</tr>
<tr>
<td>Afsin Jamshidi(2012-16) [40]</td>
<td>Optimization&amp; Prioritization Thesis</td>
<td>Risk-based Inspection&amp; Maintenance of Medical Devices</td>
<td></td>
</tr>
<tr>
<td>Wang et al. (2013a) [41]</td>
<td>Empirical Paper</td>
<td>An estimate of patient incidents caused by medical equipment maintenance omissions</td>
<td></td>
</tr>
<tr>
<td>Wang et al. (2013b) [42]</td>
<td>Empirical Paper</td>
<td>Evidence-Based Maintenance</td>
<td></td>
</tr>
<tr>
<td>Richard C. Foux (2013) [44]</td>
<td>Empirical Book</td>
<td>Reliable design of Medical Devices</td>
<td></td>
</tr>
<tr>
<td>Quan Zhang (2013) [31]</td>
<td>Optimization Paper</td>
<td>Condition Based Maintenance Used in Medical Devices</td>
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3.3. Patient incidents caused by medical equipment maintenance omissions

Patient incidents involving medical equipment are fairly common, but it is unclear how many of them are actually caused by maintenance omissions, i.e., improper or lack of scheduled and unscheduled maintenance. This question is important because hospitals have been allowed by The Joint Commission (TJC) to develop their own maintenance practice instead of following manufacturers' recommended frequencies and procedures. Wang et al. [42] reported an attempt to estimate the magnitude of such incidents using the sentinel events database collected by TJC. Using worst-case assumptions, the estimates ranged 0.14-0.74 in 2011, which translates into .00011-0.0006 per million equipment uses. These extremely low values were confirmed by a survey conducted by AAMI in which 1,526 participants reported no known patient incidents traceable to maintenance practice. Wang states that it seems unwise to mandate clinical engineering (CE) professionals to refocus their attention to manufacturers' maintenance recommendations versus active involvement in technology management and, especially, user training and assistance, to address the most frequent root causes of sentinel events.

Figure 4 shows the classification of 2011 sentinel events reviewed by TJC as a percentage of the 1,242 events reported that year. Medical equipment-related events totaled 39 (3.1%) and represented the 10th highest category. These values are consistent with prior years ‘data, as there were 176 events related to medical equipment in the period of 2004-2011, representing 2.9% of the grand total of 6,093 events and the 11th highest category. Healthcare organizations that
report sentinel events to TJC are required to share its RCA results and TJC reviews them and assign one or more root causes to each event. Multiple causes are often assigned for each event because the outcome is typically the consequence of the failure or inefficiency of one or more processes instead of a single cause. Figure 5 shows the root causes of the medical equipment-related events as determined by TJC for the medical equipment-related events for the period of 2004-2011 as a percentage of the 620 causes identified. Since TJC did not provide the root causes of the 39 medical equipment-related events reported in 2011, it was not possible to assess if these causes differ significantly from those of prior years [42].

**Figure 4:** Number of sentinel events reported to TJC in 2011

**Figure 5:** Number of root causes of sentinel events in the period of 2004-2011

### 3.4 The effect of maintenance on the survival of medical equipment

The recent analysis using survival approach reveals that conducting preventive maintenance (PM) on the selected medical equipment had an impact on survival of equipment. However, the manufacturer’s recommended PM intervals do not correlate to the failure rate encountered. This will contribute to the debate on PM manufacturer’s recommended intervals and might lead to the revision of maintenance strategies implemented by hospitals and clinical engineering (CE) practitioners [32].

### 4. Conclusion and directions for future works

This paper has attempted to provide a literature review and assessment of the status of research dealing with the maintenance of medical devices. To the best of our knowledge, this is the first paper that has tackled this issue in a review. Based on literature published so far, totally 34 studies exist. These studies include 27 papers, 2 theses and 5 books regarding maintenance of medical devices. As Fig. 6 shows, majority of papers are empirical. According to this figure, out of 34 research studies, 64% are empirical, 19% are prioritization and 17% are optimization models. In addition, Fig 7 shows the distribution of the reviewed articles. This figure depicts increasing status of research papers during 1989 till 2014. However it reveals that not much research has been presented in the literature during 25 years to address proper strategies and the methods for implementing them, while maintenance optimization models are widely developed and applied in other industries. In addition, this review shows that most of researches have been done in US, while research status on maintenance strategies in other developed countries such as Canada remain scarce. The most significant finding of this review is the need for further research in the field of maintenance of medical devices, as indicated by the gaps in existing research detailed above. The main suggestions for future work are as follows:

1. Although there are several research works on maintenance strategy selection in different industries, there is still a need to use a systematic mathematical approach to help the decision maker in taking an appropriate decision for selecting the maintenance strategy in healthcare industries. There is no study done in healthcare area for selecting best maintenance strategy. There are a large number of tangible and intangible criteria, which often are in conflict with each other, that should be considered in selection of the best maintenance strategy. For these reasons, it is particularly difficult to equipment managers choose the best maintenance strategy for each piece of equipment from a set of feasible alternatives. As a result, using multi attribute decision making methods can be useful.
2. Although there are a number of research works on maintenance strategy selection in healthcare industries, there is still a need to use a comprehensive framework for prioritizing critical medical devices.

3. Research into the outsourcing of medical device maintenance services in hospitals is still in its infancy stages, and that further progress in this field would benefit from additional empirical study grounded in management theory.

4. Researcher need to measure outcomes such as uptimes and failure rates as part of their PM.

5. The use of suitable techniques and methodologies, careful investigation during the risk analysis phase, and its detailed and structured results are necessary to make proper risk-based maintenance decisions.

6. Last but not least, authors working in this area should apply new integrated risk-based maintenance models rather than traditional methods to consider different uncertainties in hospital environment, expert’s opinion, and etc.

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