

Dynamic Model for Evaluation of Medical Devices Maintenance in Developing Countries

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Abstract

Proper maintenance management policies can reduce overall medical devices operation cost, decrease degradation and increase availability. This paper presents a system dynamics simulation model that was designed to evaluate the initiative contributions of preventive maintenance and corrective maintenance towards improving the overall performance of medical devices in developing countries. The study proposes and formulates better maintenance strategies to achieve higher operational availability and lower deterioration for medical devices. Simulation results show that maintenance management could reduce corrective maintenance levels by increasing preventive maintenance level, therefore increasing medical devices availability and reducing maintenance cost. The results also show that the changing the workload and the frequency of preventive maintenance have an effect upon the performance of hemodialysis machines. The simulation results reveal that the workload and operational cycle time are inversely proportional with the hemodialysis availability and maintenance cost effectiveness and directly proportional with the hemodialysis degradation, breakdowns and total maintenance cost. The statistical analysis of the simulation results demonstrates that there is a significant improvement in the performance of medical devices with reduction in workloads and operational cycle times. This study investigates the applicability of maintenance policies in the hospitals of developing countries and how they can generate significant operational benefits.

Keywords: Maintenance Policies, Medical Devices, Statistical Analysis, System Dynamics.

1. INTRODUCTION

Medical devices are fundamental components of modern health services used for diagnosis, treatment and monitoring of patients. They are progressively being deployed to increase the capabilities of health diagnostic and treatment services. In developing countries, the problem that draws the most attention is maintenance. There is a lack of information about the assessment and planning of medical equipment decisions. On the other hand, the potential to manage and maintain medical equipment in most developing countries remain rather weak [1]. A study done by the world health organization (WHO) has shown that nearly 50% of medical devices in developing countries are not function and are used incorrectly or are not maintained properly due to the absence of an effective management policy. It is required to have practical methods and powerful management strategies to meet the challenges of ever increasing number and utilization of medical devices [1]. The approach to the maintenance of medical equipment has changed substantially over the years. In the 1970s the major activity was limited to the repair of equipment whenever it failed. This is called corrective maintenance. It was unpredictable and hence unscheduled, tedious, also time and cost consuming. Preventive maintenance practice slowly became prominent to overcome these difficulties. Through the years, medical electric products are becoming increasingly reliable. Preventive maintenance now demands beyond traditional requirements [2]. The operation of a particular component in a deteriorating condition will lead to a high machine downtime. This is due to the failure of a component at an unexpected instant of time, and as a result this will increase the cost of maintenance and the loss of productivity [3]. The quality improvement of medical equipment is usually determined by measuring some parameters such as overall equipment effectiveness, reliability of medical equipment, failure probability and the Mean Time between Failures [4]. Forward planning of maintenance requires the knowledge of maintenance requirements and the resources that are required in order to perform maintenance; these resources include labor, parts, and tool costs [5]. Chia-Hung Chien [6] described a framework to support the choice of

the maintenance service either in-house maintenance service or third party contract maintenance service. R. Ahmad [7] revised the preventive maintenance interval based on current machine state. Afshin Jamshidi [8] provided a literature review and assessment of the status of research dealing with the maintenance of medical devices. A system dynamic simulation model has become an important methodology for understanding and formalizing conceptual process models, used as a tool to evaluate the behavior of the system under some scenarios conducted from the simulation results of the model. There is a clear potential for system dynamics to be employed in the support of health care policy [9]. It can be used to provide the basis for a model of a feedback structure in decision-making [10]. This article presents an application of this methodology in the field of clinical engineering. System dynamics has several applications and uses such as investigating the dynamics of the implementation of Total Productive Maintenance, aiming to maximize equipment effectiveness [11]. The analysis of the dynamic implications of improving hemodialysis session performance by system dynamics modeling is given in [12], [13]. A system dynamics based model for medical equipment maintenance procedure planning in developing countries is presented in [14]. A system dynamics model for the replacement and overhaul policy for capital asset subject to technological change is presented in [15]. The effect of maintenance policy on system maintenance and system life-cycle cost is discussed in [16]. A system dynamics model for remanufacturing in closed-loop supply chains is presented in [17]. Goal setting, evaluation, learning and revision: A dynamic modeling approach is the theme of Ref. [18]. The aim of this paper is to build a system dynamics assessment model to monitor medical devices performance and to formulate maintenance strategies to increase the overall performance effectiveness of medical devices during their lifespan. A simple questionnaire was prepared to collect actual mean values for the model variables. It is to be noted that it focuses on the data of the dialysis department. We distributed the questionnaire by E-mail and personal communication (hand to hand). The distribution covered Egypt, Yemen, and the Sudan as samples of developing countries. The questionnaire was filled in Egypt by staff members of 3 hospitals (1 Private hospital: Ahmed Maher hospital, and 2 Educational hospitals: New and Old kasr Al-aini hospitals), in Yemen by 6 hospitals members (2 Private hospitals: Saudi-German hospital, Sciences and Technology hospital, and 4 Government hospitals: Althawra hospital, Military hospital in Sana'a, Dhamar General Hospital, and Al-Hodeidah hospital), and in the Sudan by 1 dialysis center members (Singa hemodialysis center). We analyzed the collected data and used to create actual mean values (initial condition) for the simulation model to help setting the variable ranges and to present actual scenarios.

2. METHODOLOGY

We used the Vensim PLE 6.2 simulation software to develop a simulation model [19] to build a system dynamics assessment model to monitor medical devices performance as an immediate goal and to formulate maintenance strategies to increase the overall performance effectiveness of medical devices during their lifespan as a long term goal for the clinical engineering departments in hospitals of developing countries. The simulation results with initial condition (actual mean values) and with different scenarios are presented in the results section. The actual mean values (initial condition) were selected based on the response from the maintenance managements in the hospitals of developing countries to a simple questionnaire which was prepared to collect actual values for model variables. Sterman in [20] classifies the modeling process phases into: problem articulation, formulation of dynamic hypothesis, formulation of a simulation model, model testing and policy design and evaluation. The modeling process was started by determining the problem articulation (boundary selection) in terms of:

- The definition of the problem;
- Identification of the key variables;
- Building the reference mode of the key variables;
- Representing the system feedback loops by diagrams.

The second step is a formulation of dynamic hypothesis, after that we formulated of a simulation model by linking the variables of the model with each other to develop the mental model (causal loop diagram of maintenance system) and explain the complex cause-effect relationships existing between maintenance policies and performance of medical devices, establish a stock and flow diagram to simulate the model, and finally apply the statistical analysis for the simulation results using a Microsoft Excel sheet to test validation and verification for these results. The following sections explain the work done in details. We chose the field of life support equipment as a case study, particularly hemodialysis machines for their value and need for continuous care.

2.1 Identification of key Variables

The key variables were determined by using various investigation means, including the study of different variables, and literature survey. Five key variables affect on the progress of medical devices maintenance. These variables, their definitions, types in Stock and flow diagram (SFD) and units are presented in Table I. Other variables could be added, but this set provides a reasonable starting point for the conceptualization of the feedback structure governing the dynamics [20].

Table I. THE KEY VARIABLES

Variable	Definition	Type in SFD	Unit
Hemodialysis Availability	It measures the overall availability of Hemodialysis machine over its operational phase.	Stock	Dimensionless
Hemodialysis Degradation ⁽¹⁾	It measures the state of the hemodialysis machines.	Converter	Dimensionless (0-1)
Breakdown	Number of hemodialysis machines out of service.	Stock	Device
Total Maintenance Cost	The total amount of money expense in year for preventive and corrective maintenance.	Converter	Dollars
Maintenance Effectiveness	It determines the effectiveness of maintenance policies.	Converter	Dimensionless (0-1)

(1) The urea reduction ratio (URR) was used as an indicator to measure the hemodialysis machines degradation.

2.2 Casual loop diagram (CLD)

After defining the model variables, we created the causal loop diagram. Fig. 2 shows the overall causal loop diagram (CLD) of maintenance system. Causal loop diagrams are used to represent the feedback structure of systems. Causal loop diagrams consist of two or more causal links that connect the various variables in the model. Each link is assigned a polarity, as shown in Fig.1, to indicate the direction of change of the affected variables with respect to the causing variable. Feedback is one of the core concepts of system dynamics. It captures interaction among the variables. There are two basic types of feedback loops—positive (self reinforcing) loops and negative (balancing) loops. As the name suggests, positive loops reinforce the effect to grow exponentially and negative loops approach the equilibrium state by continuously reducing the gap between the current state of the system and the equilibrium state [20].

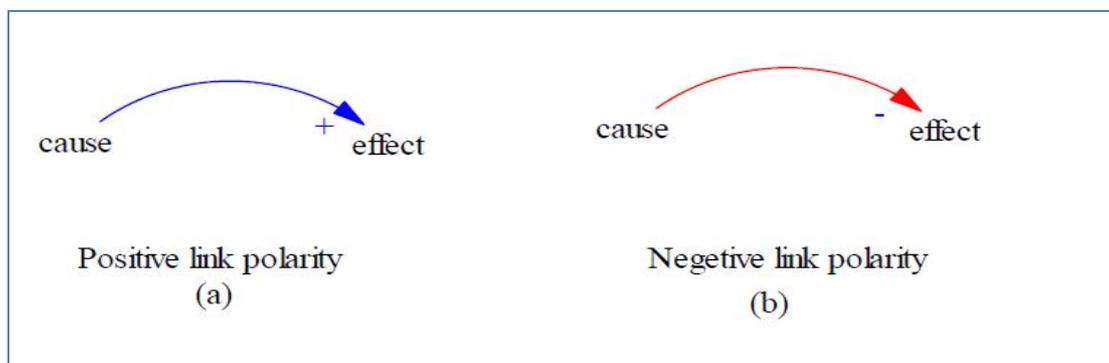


Figure1. Polarity [20]

The overall causal loop diagram in Fig.2 is divided into two parts: preventive maintenance policy and corrective maintenance policy, the two parts are connected together by various variables such as hemodialysis degradation, number of operating hours, available man-hours for maintenance, hiring rate and total maintenance cost which can effect on the two parts or affected by them. Each part consists of three variables represent the main concept of the maintenance policy they are: needed (required) maintenance, backlog (deferred) maintenance and the completed maintenance. Feedback loops in Fig.2 show that the increase in the number of operating hours of hemodialysis machines or increase the hemodialysis degradation leads to increase the needed preventive maintenance which generated to bring the hemodialysis machines back to as good as new condition, the increase in the needed preventive maintenance will force us to complete them as much as possible. Thus the available resources for maintenance will decrease and the increase in the backlog (deferred) of maintenance is the result. Therefore, we need to increase the available manpower by increasing the hiring rate. On the other hand for the second part, the increase in the number of operating hours or the increase in the hemodialysis degradation increases the number of defects which lead to increase the number of breakdowns. Thus the number of corrective maintenance which is generated due to the breakdowns is increased. The increase in the number of corrective maintenance leads to increase the unavailability of resources. Therefore, the decrease in the resources leads to increase the backlog (deferred) corrective maintenance. Thus the increase in the backlog or deferred maintenance will force us to increase the hiring rate to increase the availability of man-hours for maintenance.

Fig.3.a shows the preventive maintenance subsystem. This sub-system consists of three stocks: Required preventive maintenance, deferred preventive maintenance, and completed preventive maintenance. The required preventive maintenance stock (man-hours) is fed into by preventive maintenance increase rate (man-hours/month) and is depleted by preventive maintenance completion rate (man-hours/month) and deferred preventive maintenance increase rate (man-hours/month). The completed preventive maintenance stock (man-hours) is fed into by preventive maintenance completion rate (man-hours/month) and deferred preventive maintenance completion rate (man-hours/month). The deferred preventive maintenance stock (man-hours) is fed into by deferred preventive maintenance increase rate (man-hours/month) and is depleted by deferred preventive maintenance completion rate (man-hours/month).

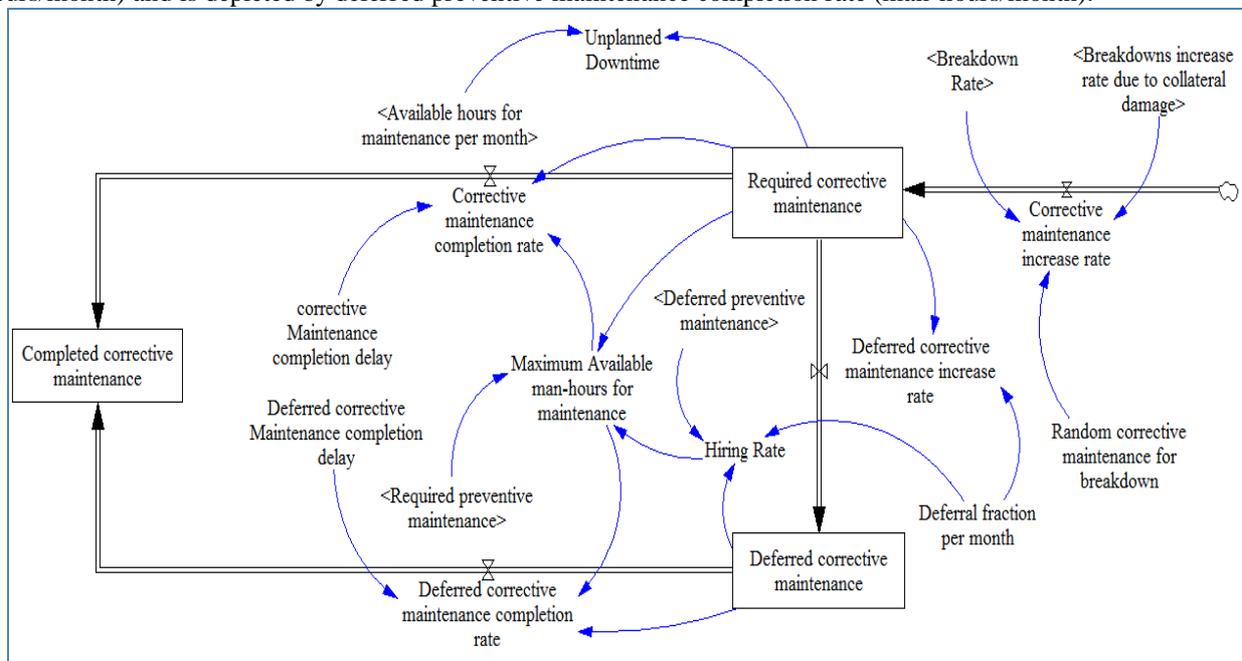


Figure 3.b. Corrective maintenance sub-system

The corrective maintenance sub-system consists of three stocks: Required corrective maintenance, deferred corrective maintenance, and completed corrective maintenance as shown in Fig. 3.b. The required corrective maintenance stock (man-hours) is fed into by corrective maintenance increase rate (man-hours/month) and is depleted by corrective maintenance completion rate (man-hours/month) and deferred corrective maintenance increase rate (man-hours/month). The deferred corrective maintenance stock (man-hours) is fed into by deferred corrective maintenance increase rate (man-hours/month) and is depleted by deferred corrective maintenance completion rate (man-hours/month). The completed corrective maintenance stock (man-hours) is fed into by corrective maintenance completion rate (man-hours/month) and deferred corrective maintenance completion rate (man-hours/month).

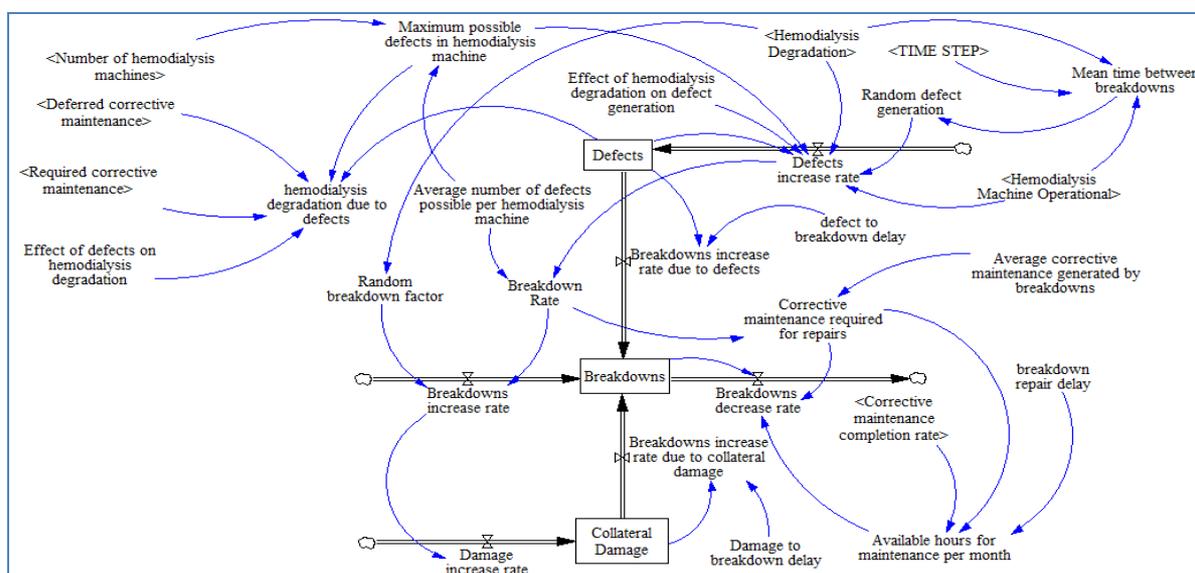


Figure 3.c. Breakdown sub-system

The breakdown subsystem consists of three stocks: breakdowns, defects and collateral damages as shown in Fig.3.c. The breakdowns stock (device) is fed into by breakdowns increase rate (device/month), breakdowns increase rate due to defects (device/month) and breakdowns increase rate due to collateral damage (device/month) and is depleted by breakdowns decrease rate (device/month). The defects stock (device) is fed into by defect increase rate (device/month) and is depleted by breakdowns increase rate due to defects (device/month). The defects stock is an integral of the defect increase rate less the breakdowns increase rate due to defects. The collateral damage stock (device) is fed into by damage increase rate (device/month) and is depleted by breakdowns increase rate due to collateral damage (device/month).

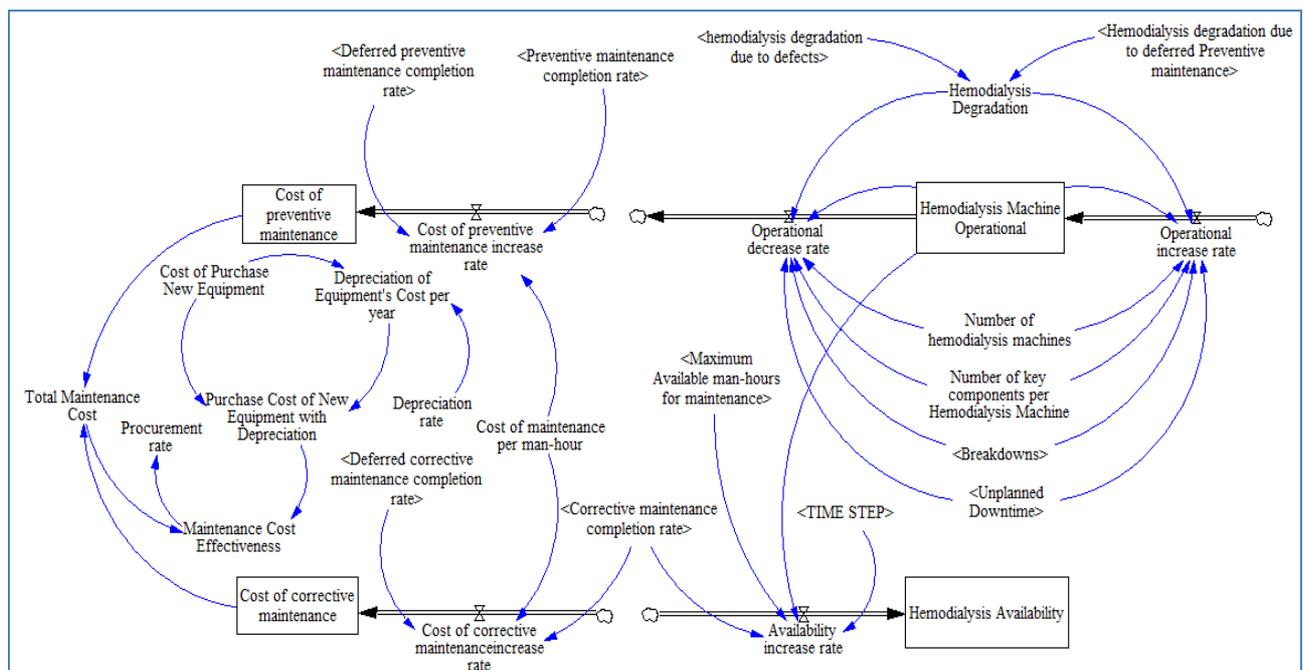


Figure 3.d. Performance sub-system

The performance subsystem consists of four stocks: hemodialysis machine operating, hemodialysis availability, cost of preventive maintenance and cost of corrective maintenance as shown in fig.3.d. The hemodialysis machine operating stock (Dimensionless) is fed into by operational increase rate (Dimensionless /month) and is depleted by operational decrease rate (Dimensionless /month). The hemodialysis machine operational stock is an integral of the operational increase rate less the operational decrease rate. The hemodialysis machine availability stock (Dimensionless) is fed into by availability increase rate (Dimensionless /month). The hemodialysis machine availability stock is an integral of the availability increase rate. Cost of corrective maintenance stock (Dollars) is fed into by cost of corrective maintenance increase rate (Dollars/month). The cost of corrective maintenance stock is an integral of the cost of corrective maintenance increase rate. Cost of preventive maintenance stock (Dollars) is fed into by cost of preventive maintenance increase rate (Dollars/month). The cost of preventive maintenance stock is an integral of the cost of preventive maintenance increase rate.

2.4 Statistical analysis

Statistical analysis was performed using Microsoft Excel. Comparison of means between the simulated results and the actual results for the hemodialysis degradation, hemodialysis availability, breakdown, total maintenance cost, and maintenance effectiveness was made using a paired-sample t-test for both paired and non-paired data. The t-test tells us if the variation between the means of two groups in the results is "significant". P-values below 0.05 were considered as statistically significant [21].

3. RESULTS AND DISCUSSION

Various runs were conducted and the results were relatively compared against each other to show the effect of maintenance policies in the behaviors of the 5 key variables of the simulation model in table I. The model was structured based on the answers from the experts in the field of maintenance management to a simple questionnaire, which was prepared to collect actual values for model variables. Table II was set up based on the actual mean value of each variable. The observed behaviors result from the interactions of numerous feedback loops present in the structure.

The values of exogenous variables, to certain extent, determine the dominance of feedback loops which ultimately result into a specific system behavior. These values can be changed to observe their impact on the system's behavior. We took the workload and operational cycle time (OCT) as an example of exogenous variables to run the model under various scenarios with different values of workloads and operational cycle times.

Table II. Model Parameter Values

Parameter	Mean value	Range
Workload	1	0.33-1.7
Actual number of sessions per day	3	1-5
Number of hours per session (hours/session)	4	3-5
Operational cycle time (month)	3	2-12
Maintenance cost ratio	11.5%	10-15%
Maintenance completion delay (month)	0.25	0.25-1
Deferred maintenance completion delay (month)	1	1-2
Deferral fraction	0.2	0.1-0.3

3.1. First scenario:

The simulation model was run 3 times with workloads of 0.7, 1 and 1.7 to study the effect of varying workload on the performance of hemodialysis machines in terms of hemodialysis operational availability, hemodialysis degradation, and total maintenance cost and maintenance cost effectiveness. All other parameters in table II were set to the initial condition (actual mean values). A lower workload means that the hemodialysis machine is operated for 1 or 2 sessions/day (where each dialysis session = 4 hours). A workload = 1, when the actual sessions already performed per day were 3 sessions/day. A higher workload means that the hemodialysis machine is operated 4, or 5sessions/day. We can calculate the workload according to the following equation:

$$WL = \frac{A_s}{R_s} \quad (1)$$

Where

WL = Workload

A_s

= Actual number of sessions per day

R_s

= Number of recommended sessions per day

The following graphs show the simulation results for the first scenario:

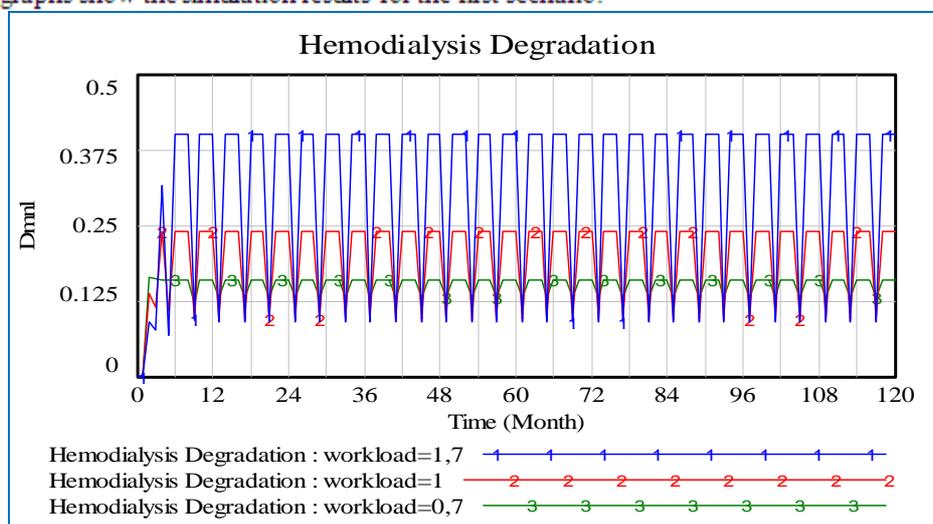


Figure 4 Hemodialysis Degradation – at various workloads

preventive maintenance or corrective maintenance also reduces the availability of hemodialysis machines, since a planned preventive maintenance frequently requires operable equipment to be taken out of service, so that the needed work can be done, also the corrective maintenance increases because of the breakdowns which cause unplanned downtime. Statistical analysis revealed that the hemodialysis availability was increased when reducing the workload from 1.7 to 1, and to 0.7.

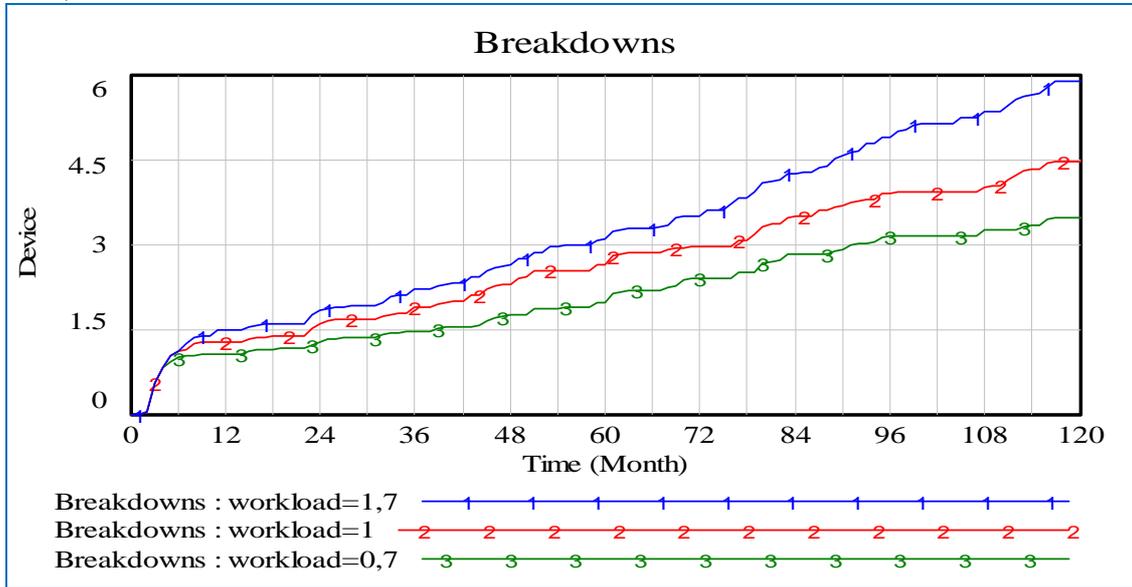


Figure6. Breakdowns– at various workloads

Fig. 6 shows the effect of varying the workload on the breakdowns during the hemodialysis machine's lifespan, where the x-axis represents the final time for the simulation (i.e. represents the hemodialysis machine's lifespan with the unit of month) and the y-axis represents the breakdowns with the unit of device. The higher breakdowns can be achieved with a workload of 1.7 rather than with workloads of 1 or 0.7 as shown in Fig. 6. Hence a 0.7-workload creates reduced breakdowns and hence reduces the corrective maintenance which reduces the machines downtime.

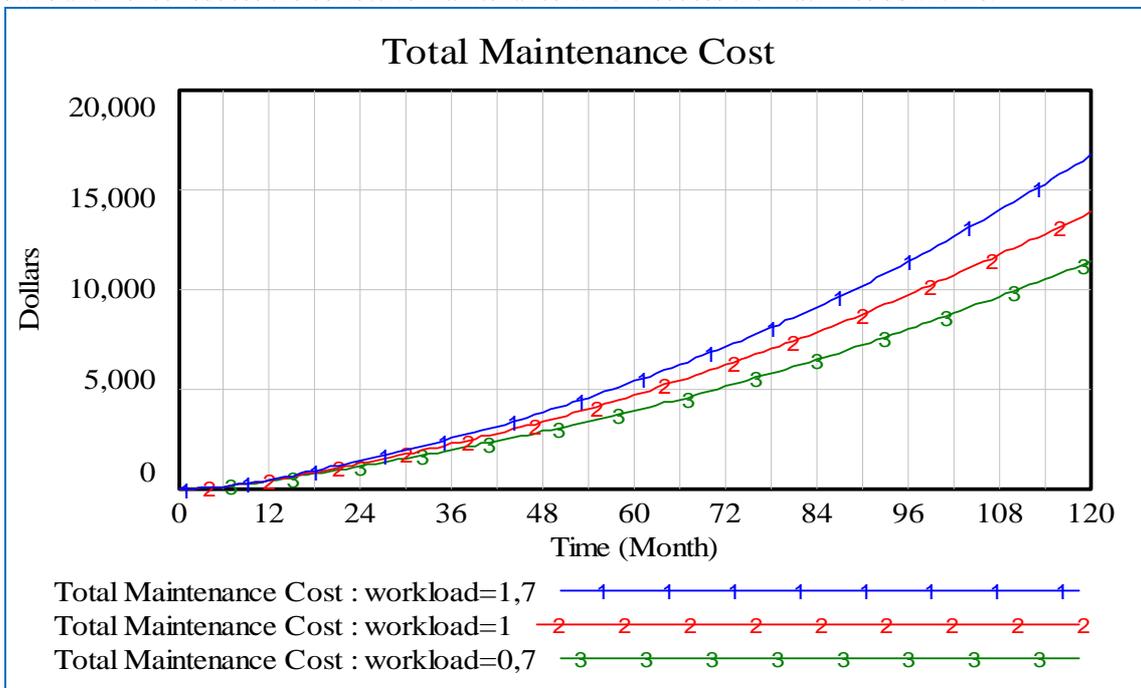


Figure7. Total maintenance cost – at various workloads

Fig. 7 shows the effect of varying the workload on the total maintenance cost during the hemodialysis machine's lifespan, where the x-axis represents the final time for the simulation (i.e. represents the hemodialysis machine's lifespan with the unit of month) and the y-axis represents the total maintenance cost with the unit of dollars. The total maintenance cost is increased with increased workload as shown in Fig.7. It can also be noted that the total maintenance cost for the scenario with a workload of 0.7 is lower than the other two scenarios. Various other scenarios with

workloads close to 0.7 were run to identify the optimal value. The statistical analysis revealed that the total maintenance cost was reduced when we reduce the workloads from 1.7 to 1, and to 0.7.

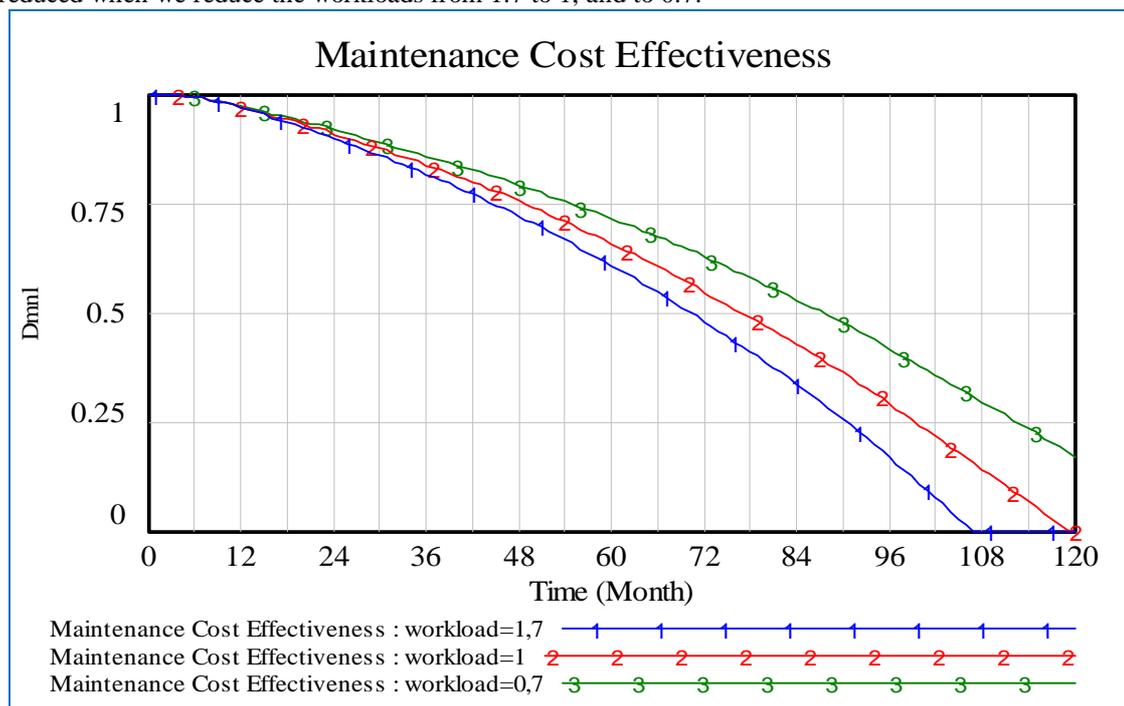


Figure8. Maintenance cost effectiveness at various workloads

Fig. 8 shows the effect of varying the workload on the maintenance cost effectiveness during the hemodialysis machine's lifespan, where the x-axis represents the final time for the simulation (i.e. represents the hemodialysis machine's lifespan with the unit of month) and the y-axis represents the maintenance cost effectiveness with a dimensionless unit. The higher maintenance cost effectiveness can be achieved with a 0.7-workload rather than the other two scenarios (i.e. with a 1 or 1.7 workload) as shown in Fig.8. Maintenance cost effectiveness is determined by comparing the total maintenance cost with the purchase cost of new equipment, according to the following equation.

$$ME = \begin{cases} \frac{C_{ne} - T_{mc}}{C_{ne}}, & \text{If } T_{mc} < C_{ne} \\ 0, & \text{Other wise} \end{cases} \quad (4)$$

Where

ME = Maintenance cost effectiveness

C_{ne} = Purchase Cost of New Equipment with Depreciation

T_{mc} = Total maintenance cost

Maintenance cost effectiveness = 0, If the total maintenance cost \geq purchase cost of new equipment. When the maintenance cost effectiveness reaches to zero, the procurement decision has to be taken and scrapping the old equipment becomes a must. From Fig. 8 we can also determine the average lifetime of hemodialysis machines. At a 0.7-workload (i.e. when the actual sessions already performed per day were 2 sessions/day) the average lifetime of hemodialysis machine was more than 120 months, while at unity workload (i.e. at 3 actual sessions per day) the average lifetime was 120 months. Finally, at a 1.7-workload the average lifetime was about 106 months. From the first scenario we deduced that based on the previous results, it was observed that a 0.7- workload results into optimal performance, increases safety of hemodialysis machines, reduces downtime, and fewer expensive repairs.

3.2 The second scenario

The simulation model was run 3 times with operational cycle times of 3, 6 and 12 months to study the effect of varying operational cycle time on the performance of hemodialysis machines. In other words, we analyze here the effect of changing the frequency of preventive maintenance upon the performance of hemodialysis machines. All other parameters in table II were set to the initial condition (actual mean values). The following graphs show the simulation results for the second scenario:

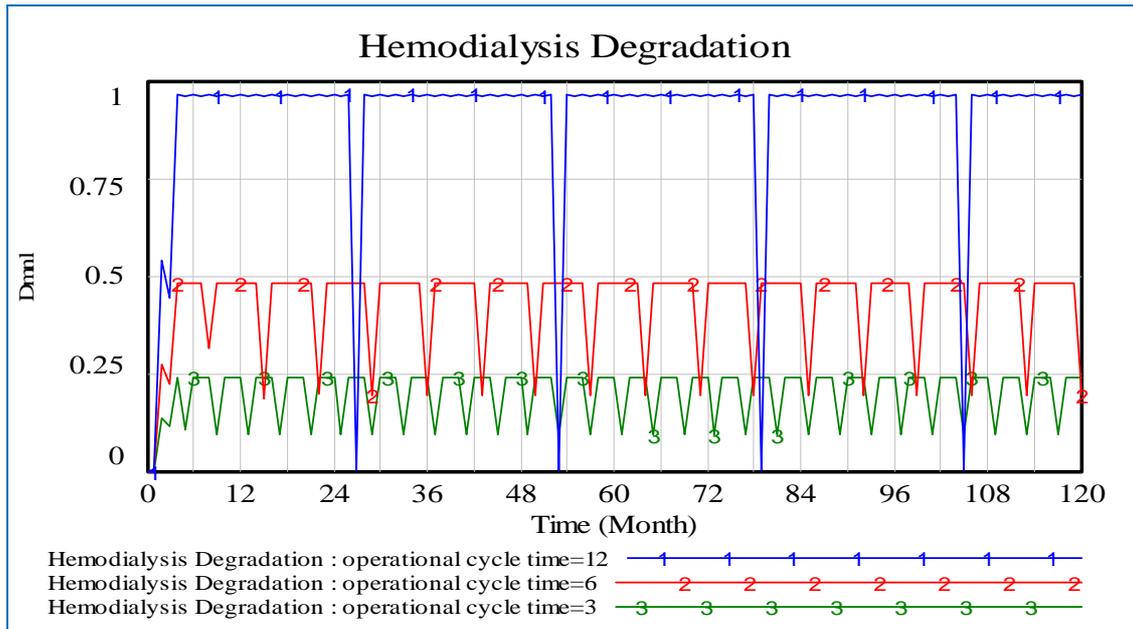


Figure9. Hemodialysis Degradation at various operational cycles

Fig. 9 shows the effect of varying the operational cycle time on the hemodialysis degradation during its lifespan, where the x-axis represents the final time for the simulation (i.e. represents the hemodialysis machine's lifespan with the unit of month) and the y-axis represents the hemodialysis degradation with a dimensionless unit. The level of hemodialysis degradation increases with increase in operational cycle times as shown in Fig.4.9. It can be noted that the variation in hemodialysis degradation for a 12 month operational cycle is very high and is certainly not desirable. The variation in hemodialysis degradation decreases with a decrease in operational cycle time. Hence 6 months operational cycle shows a higher mean hemodialysis degradation as compared to 3 months operational cycle.

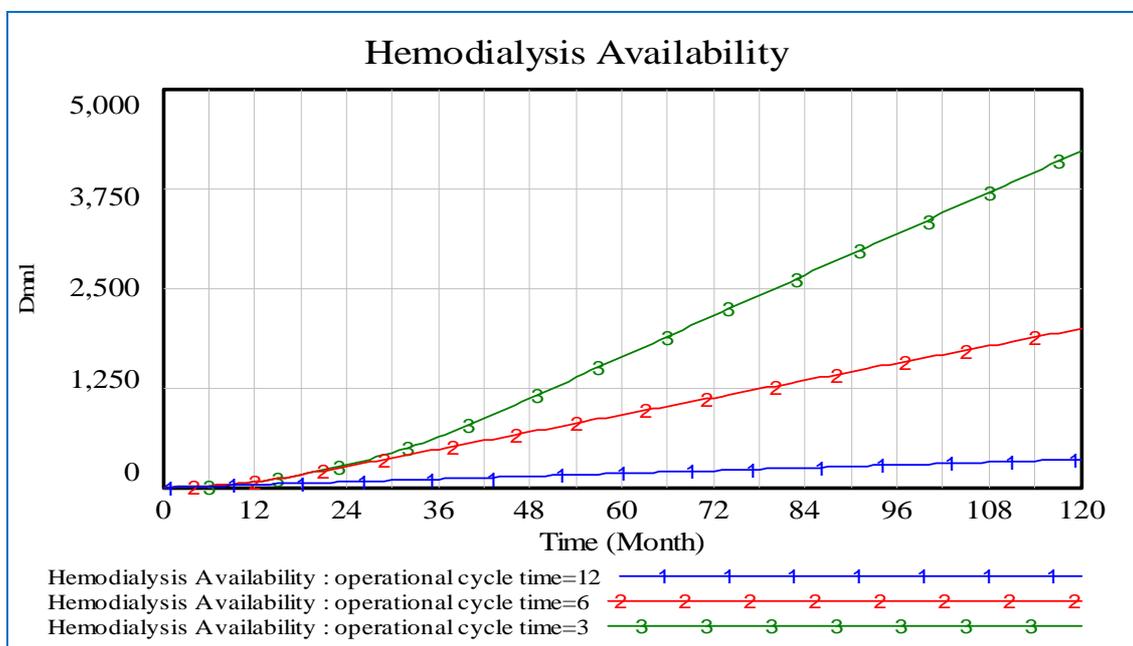


Figure10. Hemodialysis availability at various operational cycles

Fig. 10 shows the effect of varying the operational cycle time on the hemodialysis availability during its lifespan, where the x-axis represents the final time for the simulation (i.e. represents the hemodialysis machine's lifespan with the unit of month) and the y-axis represents the hemodialysis availability with a dimensionless unit. The higher hemodialysis availability can be achieved with 3 months operational cycle than with 6 months or 12 months operational cycle as shown in Fig. 10. The statistical analysis revealed that the hemodialysis availability for this scenario was increased when the operational cycle time was reduced from 12 months to 6, and to 3 months.

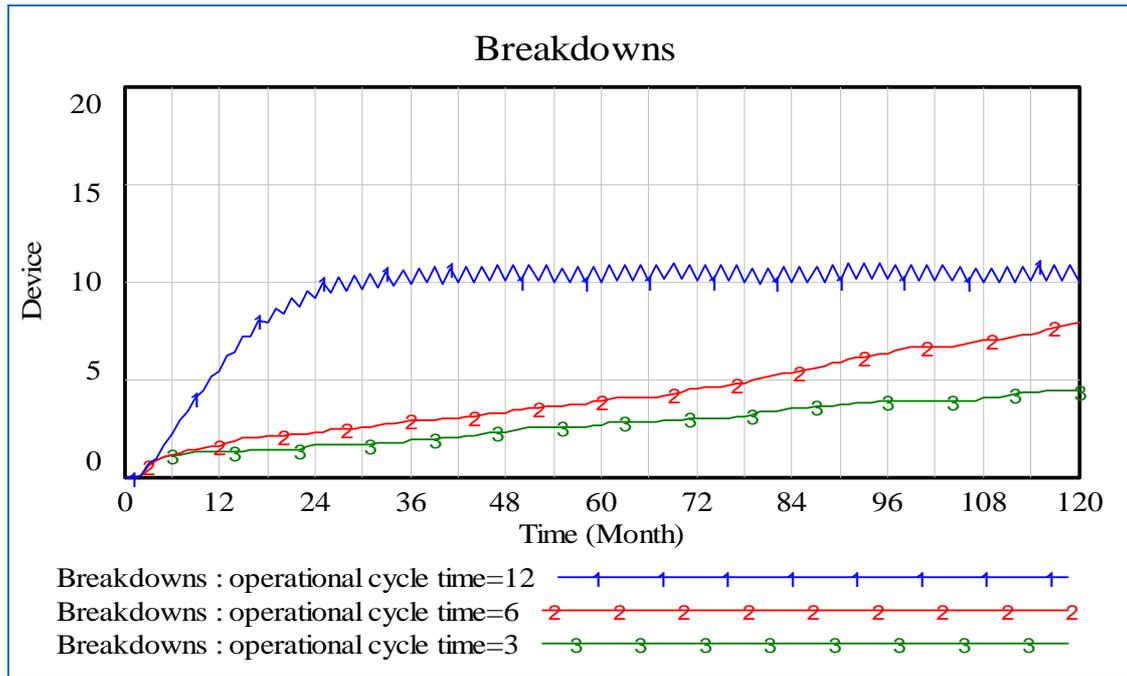


Figure11. Breakdowns at various operational cycles

Fig. 11 shows the effect of varying the operational cycle time on the breakdowns during the hemodialysis machine's lifespan, where the x-axis represents the final time for the simulation (i.e. represents the hemodialysis machine's lifespan with the unit of month) and the y-axis represents the breakdowns with the unit of device. The higher breakdowns can be achieved with a 12-month operational cycle time than with a 6-month or a 3-month operational cycle as shown in Fig.11. Hence a 3-month operational cycle creates fewer breakdowns and hence less corrective maintenance is needed, and less downtime is the result.

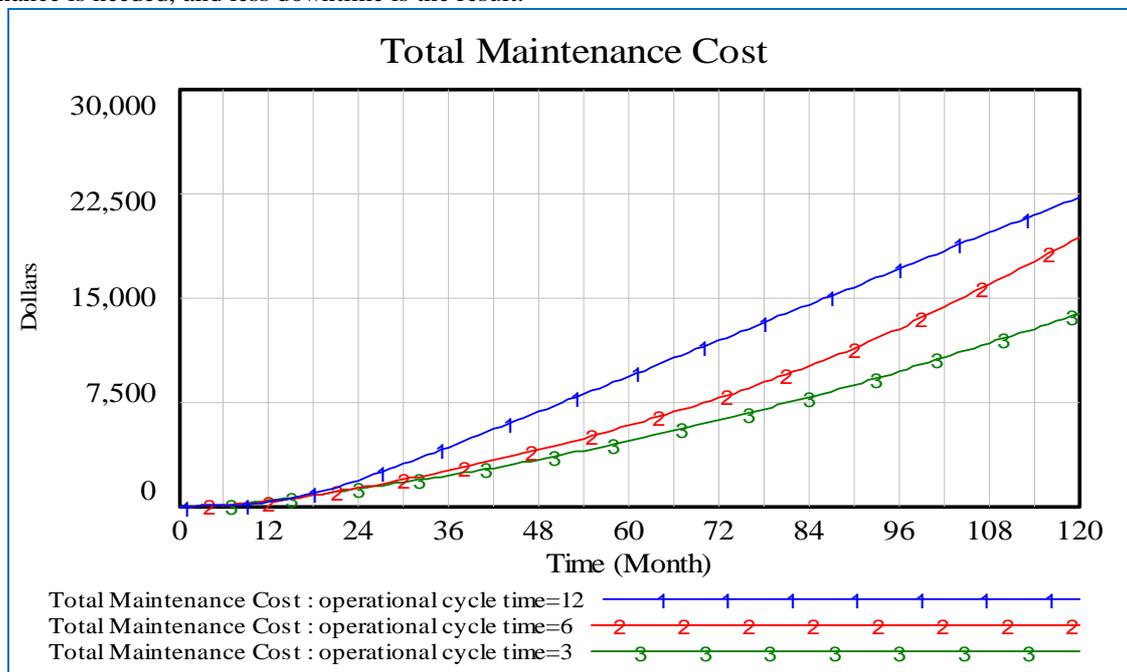


Figure12. Total maintenance cost at various operational cycles

Fig. 12 shows the effect of varying the operational cycle time on the total maintenance cost during the hemodialysis machine's lifespan, where the x-axis represents the final time for the simulation (i.e. represents the hemodialysis machine's lifespan with the unit of month) and the y-axis represents the total maintenance cost with the unit of dollars. The total maintenance cost for an operational cycle of 3 months is lower than the other two cycles as shown in Fig. 12. Various other scenarios with operational cycle value close to 3 months were run to identify the optimal value.

Statistical analysis revealed that the total maintenance cost of this scenario was reduced when the operational cycle time was reduced from 12 month to 6, and 3 month.

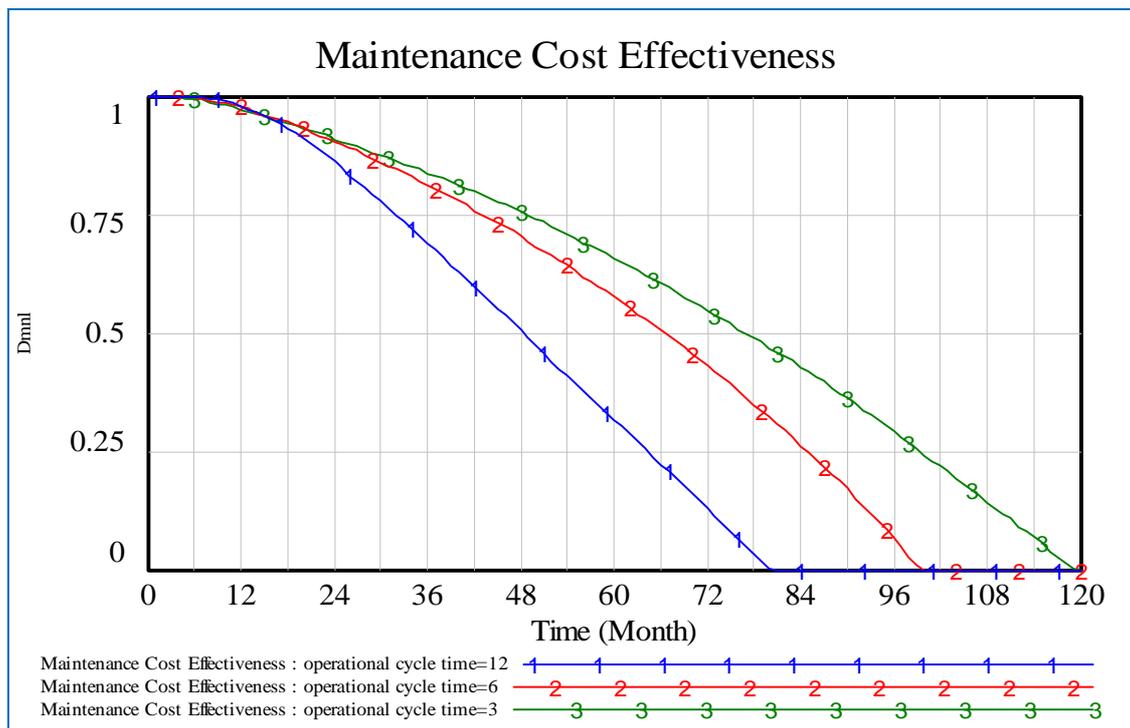


Figure13. Maintenance cost effectiveness at various operational cycles

Fig. 13 shows the effect of varying the operational cycle time on the maintenance cost effectiveness during the hemodialysis machine's lifespan, where the x-axis represents the final time for the simulation (i.e. represents the hemodialysis machine's lifespan with the unit of month) and the y-axis represents the maintenance cost effectiveness with a dimensionless unit. The higher maintenance cost effectiveness can be achieved with a 3-month operational cycle time than with a 6- or 12-month operational cycle time as shown in Fig.13. Maintenance cost effectiveness is determined by comparing the total maintenance cost with the cost of purchasing new equipment, according to the equation (4). Maintenance cost effectiveness = 0, If the total maintenance cost \geq cost of purchasing new equipment.

When the maintenance cost effectiveness reaches to zero, the procurement decision has to be taken to scrap the old equipment and purchase new one. From Fig. 13 we can also determine the average lifetime of hemodialysis machines. At a 3-month operational cycle time the average lifetime of a hemodialysis machine was about 120 months, while at a 6-month operational cycle time the average lifetime was 99 months. Finally, the average lifetime was about 80 months at a 12-months operational cycle time. From the second scenario we deduced that based on the previous results, it was observed that when we applied the preventive maintenance policy every 3-months leads into optimal performance for hemodialysis machines, increases safety of hemodialysis machines, reduces downtime, and fewer expensive repairs.

4. CONCLUSION

The model in this article was built based on the response from the maintenance managements in the hospitals of developing countries to a simple questionnaire which was prepared to collect actual mean values for model variables. Ten hospitals in Egypt, Yemen and the Sudan replied positively to the questionnaires. The results of the questionnaire were analyzed using Microsoft Excel sheet. This paper has shown that the application of an appropriate preventive maintenance policy is able to minimize the total maintenance cost per operational cycle time. In most hospitals of developing countries the preventive maintenance policy on the medical devices does not take priority over corrective maintenance policy. In developing countries most government hospitals have no quality control system for the repair and preventive maintenance. Also In most hospitals of developing countries the maintenance of medical equipment is not done in the specified time frame. Deferred of maintenance may be required due to unavailability of manpower or lack of spare parts. In conclusion, the availability of resources for maintenance work determines the decision for deferring the maintenance, the number of deferred maintenance determines the decision for hiring new staff and the workload determines the decision for increasing the preventive maintenance. Finally, the total maintenance cost, maintenance cost effectiveness, the breakdown rate, and availability of medical devices determines the decision for continuing the maintenance system or taking the decision to purchase new equipment. The statistical analysis of the

simulation results demonstrated that there was a significant improvement in the performance of hemodialysis machines with reduction in workloads and operational cycle times. From the scenarios we deduced that based on the previous results, it was observed that a 0.7- workload and when we applied the preventive maintenance policy every 3-months lead into optimal performance for medical devices, increases safety of medical devices, reduces downtime, and fewer expensive repairs.

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