Published by :
http://www.ijert.org

International Journal of Engineering Research & Technology (IJERT)
ISSN: 2278-0181
Vol. 8 Issue 10, October-2019

A Simulation Study to organize a Hospital Sterilization-Process of Maternity-Service

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***Abstract*—An efficient Sterilization Process (SP) make the Reusable Medical Devices (RMD)s faster available for healthcare activities. The aim of this paper is to apply a Discrete-Event Simulation (DES)-based approach to help the hospital managers to improve the SP of each RMD category in the maternity services for a real case study of a governmental Hospital. Thus, the objective is to create a more efficient SP configuration through a suitable autoclaves machine layout. In the literature, the use of DES for SP management was very limited comparing to other healthcare areas. Even as some authors have applied the simulation technique in this context, they were only interested in the SP of metallic RMDs and neglect the process flow of other RMDs such as wraps of textiles and rubber materials. In addition to the current Decentralized configuration scenario S1, a two other design scenarios are proposed: (S2) Half-centralized configuration and (S3) Centralized configuration in which autoclaves are placed in a central room. The simulation results analysis confirms that the scenario S3 is the most efficient with reductions in the average process sojourn time of RMDs and the average utilization rate of autoclaves. Moreover, the average delay due to RMDs unavailability almost became null which would not lead to surgical operation delays. Based on three performance measures, the used approach confirms that the best scenario is to apply a central SP. This would be used by the three studied departments (gynecology, obstetrics and neonatology) instead of the current decentralizing layout.**

Keywords— Sterilization Process; Reusable Medical Devices; Maternity Service; Discrete Event Simulation

I. INTRODUCTION

A. Background and Motivation

In the last decade healthcare costs have increased massively. Moreover, increasing healthcare demand, limited government support and increasing competition, requires hospitals to use their resources as efficiently as possible. For these reasons, optimization issues in Healthcare have attracted increasing attentions from both researchers and practitioners.

In this context, operating theatre (OT) rooms has been considered as the most critical hospital department that generates highest costs. To realize the full potential for cost containment, OT management policies must consider both the operating suites and their interactions with other hospital areas. So the primary benefits to be derived from improved management policies would result from better coordination between the surgical patients demand and the resources availability (provided-beds, OT rooms, surgeons, anesthesiologists and surgical and floor nurses). And for the raison to run safely, quickly and effectively the surgery department, the surgical instruments such as Reusable Medical Devices (RMD)s must be washed, inspected, packaged and sterilized before each surgery operation. Furthermore, the hospital infection and the defects in sterilization can lead to catastrophic consequences, such as postoperative infections, resulting in significant economic losses for patients and facilities (Rutala and Weber, 2008).

The sterilization means applying physical and chemical methods to destruction and disruption of all viable microorganisms. The Sterilization Process (SP) must provide the required instrument packages at a rate and mix that supports the surgical schedule.

An efficient SP makes the equipment faster available for surgery and other healthcare activities. The main objective of a SP is to avoid unavailable sterile equipment, which lead to surgical operation delays, then affect the patient security and the operational and financial levels of the hospital.

B. Contributions and Paper Outline

Discrete-Event Simulation (DES) technique was considered as the popular tool to help healthcare decision-maker to study and to improve performance of healthcare systems (Aboueljinane *et al.* 2013). However the use of DES for SP organization and management was very limited comparing to other healthcare areas. Even as some authors have applied the simulation technique in this context, they were only interested in the SP of RMDs and neglect the process flow of reusable medical textiles treatment and rubber materials.

The contribution of this paper is to remedy these limits through a practical application of DES-based approach. The objective of the simulation study is to determine the more efficient autoclaves machine configuration of the maternity service at Hedi-Cheker Hospital in the governorate of Sfax in Tunisia. Therefore, the paper provides a contribution to the literature as there has been a limited use of this simulation modeling method to healthcare SPs.

The remainder of this manuscript is organized as follows. Section 2 presents a literature overview on sterilization services management. Section 3 introduces the studied process. Section 4 describes the data collection and modeling procedures. Section 5 presents the developed simulation model and all experiments results. Finally, section 6 concludes with brief remarks and some perspectives for future research.

II. LITERATURE REVIEW

The hospital SP was considered us an essential activity for proper functioning of the OT. It is a cyclic process, beginning

International Journal of Engineering Research & Technology (IJERT)
ISSN: 2278-0181
Vol. 8 Issue 10, October-2019

by the use of the RMDs in the OT (Reymondon and Marcon, 2008). After use, the medical supplies were transported to the sterilization central service where all devices (i.e., metallic and no-metallic instruments or items) were thoroughly cleaned, inspected and assembled if necessary. All devices must then be packaged individually or grouped in packages before sterilization. The next step is the packages' sterilization and the last process step is the storage of the sterile RMDs for future use.

The subject of managing the consumable, disposable and RMDs in hospitals has been widely explored using principally inventory theoretic concepts such as in (Reisman, 1983, 1984) which indicate that a materials management system should integrate three basic notions: management infrastructure, materials management information system, and a set of decision rules for all repetitive decisions, such as for the replenishment of stocks.

In the literature, methods based on continuous improvement process were frequently proposed. For instance, Nilsen (2005) proposes a quantitative methodology which is used to determine appropriate inventories of devices in OT and shows how expense reduction initiatives can have a positive effect on operational performance and staff member and patient satisfaction. In addition, Johnson (2005, 2011) present a quiz on the optimization of sterile processing workflow, sources of ideas for process improvement and primary tools used to optimize workflow. All these studies highlight the difficulties of managing the hospital sterilization activities. In fact, the arrival pattern of used (dirty) devices is inconsistent because trays (called also containers or nets) of used devices do not arrive at a constant rate, but arrive in bursts that coincide with surgery completions. This can result in significant accumulations of devices at different points in the SPs, and it complicates staff scheduling and equipment capacity specifications (Lin *et al.* 2008). Furthermore, the surgical lists that indicate the required number of each type of instrument for each tray may be inaccurate or incomplete, resulting in missing instruments during surgery, rushed sterilization orders, cannibalization of packaged trays, and delayed surgeries (Johnson, 2005).

There are many approaches have been developed to support decision making in healthcare systems. It's better to divide theses approaches in literature into two main categories: analytical approaches such as in Van de Klundert *et al*. (2008), Rais and Viana (2011), Lakshmi and Appa Iyer (2013), etc. and computer simulation approaches such as in Jun et al. (1999), Fone et al. (2003), Sobolev *el al*. (2011), Aboueljinane *et al.* (2013), Kammoun *el al*. (2014), Díaz-López *el al.* (2018) etc. A simulation approach is based on the execution of a model represented by a computer program that gives information about the system being investigated. The simulation approach of analyzing a model is opposed to the analytical approach, where the method of analyzing the system is purely theoretical. As this approach is more reliable, the simulation approach gives more flexibility and convenience. As far we are aware, in general operation research, computer simulation and mostly DES-based approaches are arguably the most powerful because stochastic and dynamic system characteristics may be incorporated into the model relatively easily; so that a high degree of realism can be achieved such as in Hachicha *et al.* (2010), Hachicha (2011), Liu and Xiang (2018), Kundu *et al.* (2019), and Khan and Standridge (2019).

In addition, DES-based methods allows both material and information flow to be modeled as well as sophisticated decision logic for planning and control. As a consequence, many researchers have provided excellent surveys of models and methods for the use of DES in healthcare systems (Kammoun, *et al.* 2014). In brief, DES has been widely used in the healthcare field namely into two areas: (1) optimization and analysis of patient flow and (2) allocation of assets to improve the delivery of services. The first area considers patient flow through hospitals, with the primary objective of identifying efficiencies that can be realized to improve patient throughput, reduce patient waiting times, and improve medical staff utilization. The second area considers the number of beds and staffing requirements necessary to provide efficient and effective healthcare services.

Despite, the use of DES in the field of SP management has not received the same degree of attention comparing to other healthcare activities. Only a few research articles, which deal with this concern were founded, include the following. (1) Lin, *et al.* (2008) illustrates how DES can facilitate the design of a central sterilization department and to improve surgical sterilization operations. (2) Di Mascolo and Gouin (2013), proposes a generic simulation model, able to represent any sterilization service in a French health establishment. This model can be used to improve the performance of a specific sterilization service and/or to dimension its resources. It can also serve for quantitative comparison of performance indicators of various sterilization services. (3) Cassettari *et al.* (2013) describes a clear picture of process inefficiencies through the development of two DES models. After that, a costs optimization was achieved by means of a process reengineering. At the end, supposing to share the considered sterilization plant with other healthcare partners, a new strategy to manage the plant was evaluated.

Based on this literature review, the majority of studies was interested in the SP of metallic RMDs and neglects the process flow of other RMDs, such as wraps of textiles and rubber materials.

III. METHOD AND PROBLEM SETTING

A. Proposed Simulation-Based Approach

A DES-based approach was proposed to help the hospital managers to make the best decisions about the configuration of the SP and autoclaves layout. It should be noted that DES is essentially a trial-and-error approach, and therefore, it's time-consuming and doesn't provide an optimal solution. Indeed, since the 90s authors are carrying on researches on DES models integrated with various optimization tools. This is due to the capability of a simulation-optimization method to point out the existing relationship between the target function and the independent variables affecting the system behavior (Ammeri *et al.* 2011). Despite much simulation software developers today have become more aware of the importance of finding optimal and near-optimal solutions, in the examined case, a classical "what-if" analysis has been

International Journal of Engineering Research & Technology (IJERT)
ISSN: 2278-0181
Vol. 8 Issue 10, October-2019

preferred. Because the creation of easily understandable scenarios would have a better hospital management support.

In this study our goal is to analyze and improve a hospital SP. A five-phases approach is proposed to achieve the target of the present study include the following: (1) SP overview and description as will be presented in the next subsection 3.2, (2) Data collection and modelling as will be mentioned in subsection 4, (3) Model assumptions and structure as will be described in subsection 5.1, (4)Verification and validation of the simulation models as will be presented in subsection 5.2, and (5) Experimentation and results as will be described in subsection 5.3.

B. Sterilization Process Overview

The maternity Service of Hedi-Cheker Hospital performs approximately 15,000 surgical procedures per year. This high volume was accompanied by relatively weak systems for tracking equipment and instruments. Often, this entails delays in procedures because RMDs were not available. Each delay generated can cause significant delays in the subsequent procedures. Accordingly, surgeons were frustrated, the work-place environment was poor, and patients were negatively affected. The simple solution was to buy more equipment and instruments which however increases hospital expenses.

The Maternity surgical services of Hedi-Cheker Hospital were constructed by two floors, six OT rooms and three surgical departments: department of gynecology (Gyn-dep), department of obstetrics (Obs-dep), and department of neonatology (Neo-dep). Each department contains two OT rooms. Both Gyn-dep and Obs-dep were placed in the ground floor. Neo-dep and baby hospitalization were placed in the first floor. The SP at the Obs-dep working 24 hours per day but at the Gyn-dep and Neo-dep was a standard working day, i.e. from 7 a.m to 1 p.m.

Each department includes numerous surgical procedures with a large variety of RMDs constituted by metallic RMDs (instruments devices) and no-metallic (clothing, small plastic equipment, etc.) At the end of every surgical operation, each RMD went through an accurate SP before being re-used.

The studied SP is shown in Fig. 1; the flow is started from the sterile storage of the OT rooms, where the sterile RMDs are placed in stock. For the metallic RMDs, they are not stocked individually, but grouped in trays.

The SP in the studied maternity service was structured by three main macro-phases, each one is decomposable in several activities include the following.

1) Washing phase: The metallic RMDs firstly were thoroughly cleaned and disinfected, then washed and rinsed whereas the no-metallic RMDs (textile) were washed by washing machine.

2) Drying and packing phase: After the drying of the cleaned surgical instruments and the reception of the cleaned linen from the washing area, the RMDs were packaged as single pieces or in specific containers.

3) Sterilization phase: The sterilization phase was carried out using an autoclave machine. When the process completed, the RMDs were stocked for future use at the OTs.

It should be noted that there are four possible handling equipments for maintaining sterility of RMDs during transport and storage include the following: (1) Wrapped perforated medical instrument containers (MIC), (2) Washing machine drum of textiles which can be either woven or unwoven (WMD), (3) Peel-pouches for plastic and rubber materials (PPR), and (4) Bags for Baby-Bottle (BBB). Only the first handling equipment is used for metallic RMDs but the others are used for no-metallic RMDs.

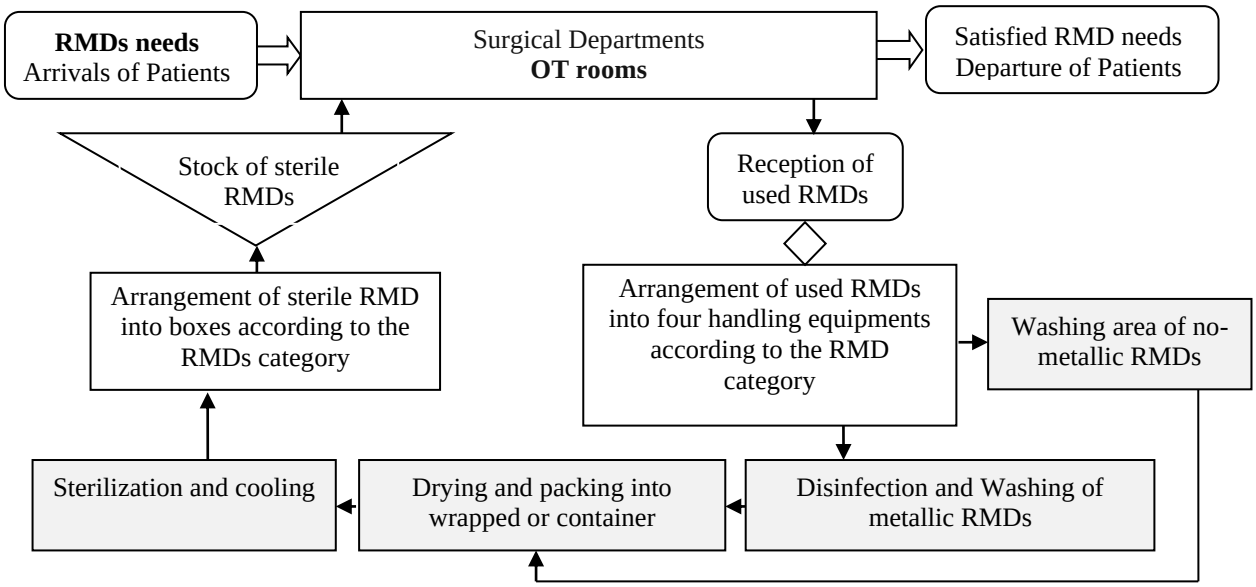

Fig. 1. Sterilization Process Flow

International Journal of Engineering Research & Technology (IJERT)
ISSN: 2278-0181
Vol. 8 Issue 10, October-2019

Typically, the metallic RMDs (instruments) made in the same tray, represent the items needed for a particular surgery operation. For this reason, three possible sizes were used to distingue one operation' tray to each other: great, medium, and small. Shortly before an operation, the required RMDs were taken from the storage, put onto a cart, and this cart was taken to the required OT room. During the surgical operation, the RMDs, whether they were used or not, was considered contaminated. When the surgery operation was finished, all materials were brought to the contaminated storage of the OT room. From where, they were transported to the SP.

IV. DATA COLLECTION AND MODELING

In order to get all the essential parameters to run the simulation models, a thirty-day data collection phase in each of the three departments was carried out. Only steady state operating system data was taken into account. The collected data concerns the flow of metallic and no-metallic RMDs throughout the process as described in Fig. 1. It should be noted that some of collected data had stochastic nature, in particular patients' arrivals process, process times related to human-performed tasks, such as "washing, drying and packing". Some others, like machining times of washing textile and autoclaves were totally deterministic.

For stochastic distribution fitting, the input analyzer tool in Arena® simulation software was utilized. For example, the distribution fitting of drying and packing duration of MIC cycle in Gyn-dep is provided in Fig. 2. As mentioned in Table 3, there are 4 sterilization cycles per day for MIC in Gyn-dep which results logically 120 recording times during the 30-day data collection. However, only 82 recording points among them were included in this modeling data sample. These missed data (i.e. 38) were excluded because they are taken during the warm-up period either in the beginning starts period of work or in abnormal situations such bottlenecks periods. The Fig. 2 caption contains the following data ; (1) Data which was displayed as a histogram, broken down the data range between 30 min and 45 min in 9 equal intervals, (2) The parameters that fit the distribution function to the data which corresponds to a uniform distribution function and its corresponding curve-fitting information and (3) Chi-square statistical test which evaluated the goodness-of-fit of the candidate distribution function (i.e. uniform distribution function) of the used sample. The chi-square test has been used habitually by the Arena® Input Analyzer to compute the corresponding statistic test and the associated p-value. The Fig. 2 indicates clearly that the null hypothesis cannot be rejected even at significance levels as large as 0.75. Thus, the null hypothesis was assured to accept that drying and packing duration follows to a uniform fit distribution between 30 and 45 min in Gyn-dep at the comfortably high confidence.

In the same way, all parameters of the simulation model were developed and presented in Tables 3 and 4. Moreover, the arrival process data were not stored in the hospital database. Thereby, there were collected by means of linking sheet forms: each form was associated with a surgical operation and allowed data to be transferred between each OT rooms and the SP.

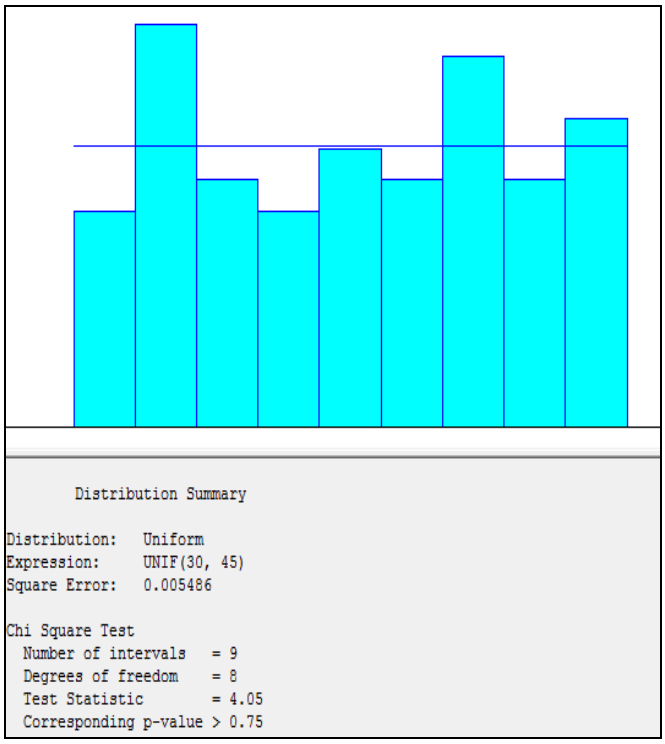

Fig. 2. Example of uniform distribution function assigned to the duration of drying and packing for Gyn-dep (min)

V. SIMULATION MODEL AND RESULTS

A. Model Assumptions and Structure

The simulation model was constructed based on the following assumptions:

1) Assumption 1: The surgical lists indicate the required number of each type of instrument for each tray was accurate and complete. Thereby, there were no missing instruments during surgery and no delayed surgeries for this reason. Moreover, it was assumed that all surgeries and resulting sterile instrument net usage were predictable. In this case, sterile items can be delivered just in time before a surgery begins.

2) Assumption 2: Loading and unloading times of the washers and autoclaves were included in the operating time as mentioned in table 4.

3) Assumption 3: For each department, the maximum capacity of autoclaves was 25 cycles per day.

4) Assumption 4: All autoclaves in the maternity service were available simultaneously and independently. The failure and repair times were exponentially distributed. In the event of a breakdown, the loaded RMDs assigned to a failed autoclave were assigned to other good autoclave of the same department.

5) Assumption 5: Automatic washing was considered for WMD, however manual washing was adopted for MIC, PPR and BBB.

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ISSN: 2278-0181
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6) Assumption 6: A First-In-First-Out (FIFO) rule was applied for each process.

B. Verification and Validation of the Simulation Models

The verification step deals with assessing the accuracy of the computer programming and implementation, while the validation step aims at ensuring that the simulation model is an accurate representation of the system for the intended goal of the study (Law and Kelton, 1991). In this study, the simulation model was validated through extensive discussion of simulation results with the hospital managers. The first scenario concerns the simulation modeled an existing system, it was possible to compare its output with current configuration, which is a common validation tactic. Furthermore, the hospital managers participated fully in specifying the system operating logic, however, and thus were able to provide significant intuitive assessments about the model's validity. To validate the proposed simulation model with detailed data, its behavior is checked and compared with the real system. However before proceeding simulation experiments, the hospital managers (decision makers) should be sure that the steady state is established. After some simulation runs, it seemed easily that 100 day run a length was more than enough for the model to be settled and the effect of warm-up period is rapidly diluted. Hence a 200-day simulation run test made and its performances measures were compared with real performance measure data. The Average daily number of Autoclave cycles was used as a validation criteria as mentioned in Table 1. It should be noted that the simulation results were virtually similar to actual results. When the values were rounded, the same numbers of autoclave cycles for each department were obtained. Thereby, the proposed model was accurate enough to be used to study the impact of different parameter changes on the SP performance.

TABLE I. COMPARISON BETWEEN SIMULATION AND REAL-LIFE PERFORMANCE MEASURES

	Average daily number of autoclave cycles		
Department	**Gyn-dep**	**Obs-dep**	**Neo-dep**
Real system based results	8.50	20.00	9.50
Simulation-based results	8.45	19.56	9.85

C. Experimentation and Results

There are two possible configurations for the SP: a centralized sterilization room for the entire hospital or each department has its specific sterilization shop (decentralization). After discussions with the hospital managers, three scenarios were granted include the following:

(S1) Decentralized process (the current layout): 1 autoclave for Gyn-dep, 2 autoclaves for Obs-dep, and 2 autoclaves for Neo-dep.

(S2) Half-centralized: 3 autoclaves for both (Gyn-dep and Obs-dep), and 2 autoclaves for Neo-dep. In this scenario managers thought only to combine Obs-dep and Gyn-dep but not Neo-dep with either of them, because Obs-dep and Gyn-dep belonged to the same floor, and it would be more convenient, according to them, to manage the SP and to reduce transportation delays of RMDs.

(S3) Centralized process: a central room includes 5 autoclaves for all departments: Gyn-dep, Obs-dep and Neo-dep.

In order to conduct this study, three simulation models has been developed using the Arena® simulation software. There are namely two methods to attain simulation results. The first method, which was called truncated replications, need to know how many replications are required to achieve a given confidence half width. The second method, which was widely used in literature, was to run the model for a long period of time (Law and Kelton, 1991). In this study, the second method was used because its simplicity does not require advanced statistical analysis unlike the first method. Thereby, a simulation length was fixed to 100 000 days as a very high value to be sure of the precision of results. If the simulation length is increased again, it will have no change in the results.

Three performance measures were considered in this study in order to analyze each scenario: average Process Sojourn Time (PST), average Delay due to RMDs Unavailability (DU), and average Utilization Rate of Autoclaves (URA). The PST was defined as the time for a dirty RMD to be transported to the sterilization room, disassembled, washed, inspected, wrapped, and sterilized. The hospital managers defined the delayed procedure as one in which a surgery was ready to begin at the scheduled time but the required RMD handling equipments had not yet been delivered. Finally, the URA was important for estimating resources requirements. The simulation results are shown in Table 2. As can be noted from this Table, the scenario S3 was the best according to each performance measure. On the first hand, the average PST of RMDs in SP significantly decreased from 126.67 minutes for S1 (current configuration) to 79.77 minutes for scenario S3. On the second hand, the average DU almost became null for both S3 and S2 relative to that in S1. On the third hand, the Average URA of all hospital autoclaves decreased from 63% for S1 to 26.6% for scenario S3. Thereby, the proposed approach confirms that maternity services (gynecology, obstetrics, and neonatology) of the Hedi-Cheker hospital should apply a central sterilization design configuration, which included the five autoclaves. There were both reductions in the average process sojourn time of RMDs and in the average utilization rate of autoclaves. Moreover, the average delay due to RMDs unavailability almost became null which would not lead to surgical operation delays.

VI. CONCLUSIONS AND FUTURE WORKS

The aim of this paper was to propose a simulation-based approach to improve the hospital SP of all RMD categories used in the maternity service of Hedi-Cheker Hospital in Tunisia and consequently to make the SP more efficient. Based on some selected performance measures, the proposed approach has confirmed that the best scenario was to create a central SP, which should be used by each of the three studied departments (gynecology, obstetrics, and neonatology) instead of current decentralizing layout. The objective was to

International Journal of Engineering Research & Technology (IJERT)
ISSN: 2278-0181
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avoid unavailable sterile equipment which would lead to surgical operation delays with impacts on patients as well as on operational and financial levels of the hospital.

TABLE II. SIMULATION RESULTS

	Average Sojourn Process Time of RMDs in SP (mn)			Average Delay due to RMDs unavailability (mn)			Average Utilization Rate of Autoclaves (%)		
Department	**S1**	**S2**	**S3**	**S1**	**S2**	**S3**	**S1**	**S2**	**S3**
Gyn-dep	126.96	73.52	67.86	50.35	0.33	0.57	88%	35.25%	26.8%
Obs-dep	130.94	106.33	81.54	0.16	0.28	0.32	46.5%		
Neo-dep	122.10	122.10	89.91	0.42	0.42	0.00	53%	53%	
Average	126.67	100.65	79.77	16.97	0.34	0.29	63%	44.12%	26.8%

TABLE III. THE DAILY NUMBER OF SP ACCORDING TO DEPARTMENT

Department	**Number of surgery operations per day**		**Number of working posts**	**Number of autoclaves**	**Number of handling equipments sterilization cycles per day**			
	Range of variation	**Average**			**MIC**	**WMD**	**PPR**	**BBB**
Gyn-dep	[5, 10]	7.48	1	1	4	2	1	0
Obs-dep	[14, 27]	19.30	3	2	5	2	0	0
Neo-dep	[2, 8]	6.38	1	2	1	2	1	2

MIC: Medical Instrument containers
WMD: Washing Machine-Drum
PPR: Plastic and Rubber materials
BBB: Bags for Baby-Bottle

TABLE IV. THE DURATION OD SP ACTIVITIES ACCORDING TO HANDLING EQUIPMENTS

Material types	**Duration of washing and disinfection (min)**	**Duration of Drying and packing (min)**	**Duration of Sterilization and cooling (min)**
Cycle MIC	UNIFORM [20, 30]	UNIFORM [10, 30]	60
Cycle SWT	External laundry room	UNIFORM [30, 45]	45
Cycle PPR	UNIFORM [25, 35]	UNIFORM [30, 45]	35
Cycle BBB	UNIFORM [20, 30]	UNIFORM [30, 45]	60

However, due to the complex nature of this problem, the proposed method provides a first step in addressing a very important sterilization autoclaves configuration and layout issue. Indeed, for some of the hospitals managers, it appears that it was obvious from the start that combining autoclaves of the three departments into a same center would give preferential results, specifically in terms of utilization rate. However, after building and manipulating a valid simulation model, several other operational and tactic problems can be studied. For instance, the optimum number of resources such as the required number of autoclaves, the number of units that the autoclave accepts in order to reduce delays, etc. will be considered in futures studies. In fact, theses problems have naturally an impact on healthcare cost, so some balance between cost and delay should be also considered. Extending the project in this direction is our interesting research perspective.

ACKNOWLEDGMENTS

This paper is not subscribed under any lucrative university project. The authors would like to thank all workers and managers of the CHU Hedi-Cheker Hospital, especially Dr. Kais Chaaben.

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Vol. 8 Issue 10, October-2019

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