

Decision Making in Appraisal of Medical Devices Purchasing System Through Human Factors

N. Alraqad, Royal Medical Services, Jordan; T. AlBqour, Royal Medical Services, Jordan; Sh. AlNajdawai, Institute of Biomedical Technology, Jordan; M. Ababaneh, Institute of Biomedical Technology, Jordan

Abstract: In spite of the huge number of published articles talked about human factors, in fact there is a very little article discuss the application of human factor in the medical sector in general and in the field of medical devices in specific. This paper describes a research conducted in 4 hospitals in Jordan which concerns with the philosophy of appraisal of medical devices purchasing through human factors. In this paper two stages of human factors appraisal of ventilators machines were conducted. The first stage was an indicative appraisal for all of the ventilators according for three criteria. The second stage was the operator testing which performed by the biomedical engineer by the ICU departments in four hospitals : Prince Hamza Hospital (PHH), Jordan University Hospital (JUH), King Hussein Hospital (KHH) and Zarqa Hospital (ZH) to notice the realistic clinical treatment performed with machine. It was found that there is an accord in the results of the two stages of human factors appraisal of ventilators machines. It was noticed that the pharmacist and biomedical engineers play an important role in the hospital in the supplying, logistic and tendering process of medical devices and so they were the basic elements in this research.

Key words: Jordan University Hospital (JUH), Human factors, Appraisal of Medical Devices

A Medical devices purchasing is one of most common and crucial processes in the medical field. There are a lot of risks associated with this process; one of them is the type and the nature of references we used to decide to purchase this device or that.

A lot of engineering tools can be used to enhance the suitability of our purchasing decision. One of the most flexible and integrated tools is the Human Factor Engineering (HFE). From a HFE point of view, assuring the evolution of high quality medical devices requires HFE method to be used at every stage of the medical devices purchasing process.

Implementing such that method will assure that the purchased device will be compatible with the place which it will work in it and the specific individual needs of the operators.

Based on Previous studies .In 2005, Guinsberg [1] conducting a research investigating medical device evaluation in hospital procurement decision-making , where he used two phases of the human factors evaluation of the infusion pumps .

The first phase involved a heuristic evaluation of each pump according to four sets of criteria. The second phase of the human factors evaluation consisted of user testing in which the Human Factors Engineer visited different clinical areas with the pumps and observed users as they performed realistic clinical scenarios with each infusion pump.

In this research we did some modifications on Guinsberg's research because we applied HFE in 4 different hospitals in Jordan specific on 3 different ventilator suppliers in ICU departments. We studied a lot of factors which influence the purchasing process and we got very interesting results.

Background

At first we will take a glimpse on the history of human factor engineering, the beginning was in the 1940's and 1950's. Analyzing errors helped engineers focusing on designing for the human worker. Task analysis provided a systematic procedure for understanding and predicting operator-system mismatches that could lead to errors [2].

A lot of researches were conducted in the human factors. For Instance; in the nuclear engineering, this discipline focuses on the interaction between technology, people, and their work context.

Human factors has sometimes been narrowly associated guidelines, such only with human-computer interface design as "minimize the load on user' memory," broader and consists of several activities [3].

In the aircraft maintenance field, Drury presented examples of two approaches to human error reduction interventions derived from analysis of incidents and from task analysis. He

concluded that human error will not be eliminated by frame-up. He found that firms should own information to pledge human factor programs [4].

In the field of medicine and surgery, stone et al described the relevance human factors principles and methodologies to medical and surgical practice, emphasizing the prominence of moving away from “technology push” (the assumption that a high tech approach to the design of information technology systems will always provide a robust, reliable solution to one that is more focused on the needs of the human in the design of medical equipment, systems, and processes [5].

In the field of application of human factors in medical devices, Sawyer et al [7] mentioned in report about the relationship between human factor and medical devices that the human factors can be used in the medical devices procurement process in the following procedure:

Before buying a new model, consider the means of assessing its usability, especially if it is a life-sustaining or life-supporting device. Following are some steps to consider:

- Determine whether or not the manufacturer conducted human factors/usability testing of the device in question.
- Check with staff, and possibly other facilities, about predecessor models made by the manufacturer.
- Check with other facilities that may also be using the new
- Check published evaluations of the new model.

Request a trial period prior to the actual purchase of a new device.

Methodology

In this research, two stages of human factors appraisal of ventilators machines were conducted. The first stage was an indicative appraisal for all of the ventilators according for three criteria. Ten human factors essentials constituted the first criterion. Most of these essentials were adopted from Guinsburg. The 9 essentials include.

- ❖ Matchmaking and standards adopting [6],
 - ❖ Flexibility and easiness of use [6],
 - ❖ Help operators diagnose and recover from errors [6],
 - ❖ Documentation Review [6]
 - ❖ Analysis [7].
 - ❖ Usability testing [7].
 - ❖ Segmentation and merging [7].

Although there are no specific standards concerning in applying the human factors neither in the field medical devices maintenance nor in the all fields on applications, The second criterion represents the standards and regulation issued by International organizations like the Food Drug Administration (FDA) and Emergency Care Research Institute ECRI.

Theses standers include the amount of anesthesia agents' drugs delivered by the machine, the reading of the machine, the easiness of troubleshooting of the machine.

The third criterion represents the Request For Proposal (RFP) the issued by the Pharmacists representing the procurement committee in the hospital for the suppliers before beginning the purchasing process. The RFP generally is determined by the requirements of the technical staff, doctors or biomedical engineer and it may include.

- ❖ Geometric and appearance characteristics like the device's dimension, Screen dimension, size, color and shape of the device.
- ❖ Functional characteristics like the therapeutically and diagnostically abilities, i.e. the medical cases that it can deal with.
- ❖ Technical options like existence of printer, Local Area Network (LAN) connections, internet connection.

The biomedical engineers and the Pharmacists rate all the ventilators machines according to the previous criteria on a scale from 1 up to 5, with 1 represents improper for use and 5 represents ideal for use.

We accumulated the score of all criteria for each ventilator machine to obtain the overall usability value. In addition to the previous and to determine the usability strengths and weaknesses of the machines, the committee conducted a function analysis for the common functions performed with the machine which may include.

- ❖ Installing the machine
- ❖ Switching on and off
- ❖ connecting the accessories
- ❖ Inserting the treatment setting (the amount of drugs & time of treatment)

The bio medical engineers investigated and recorded the applications faults occurred and sorted them into crucial and non crucial. The crucial fault is the one leads to hazard or death while the non crucial is the one leading to inconvenience.

The function analysis include an evaluation of the operator action to perform the function which represent the data provided by him , the response of the machine the data entered and it may include errors appeared with its trouble shooting.

The second stage of stages of human factors appraisal of ventilators machines includes the operator testing which performed by the biomedical engineer by the ICU departments in four hospitals : Prince Hamza Hospital (PHH), Jordan University Hospital (JUH), King Hussein Hospital (KHH) and Zarqa Hospital (ZH) to notice the realistic clinical treatment performed with machine. In general four ICU departments were visited and 34 staff nurses in the ICU participated.

Each clinical treatment for each department of was issued by each staff nurse leader depending on the nature of cases treated. Three types of ventilators were investigated .Each operator for each type of the machines. The same procedures were used for the all machines and the arrangement of machines was counterbalanced.

All staff nurse participants completed all procedures within two days. the end of each procedure, staff nurse participants completed a form to arrange the usability of a set of characteristics related to the function they had performed, and at the end of the third procedure participants filled out a comparison form to indicate which machine they preferred based on each characteristic.

Conclusions and recommendations

Table 1 shows the indicative appraisal stages of human factors. It had been found different usability matters associated with each machine. Three machines suppliers 1, 2, 3 were investigated and compared.

Table 1. Usability faults results of the investigated three criteria

Criterion	Supplier 1	Supplier 2	Supplier 3
human factors essen-	60	61	51
Regulations of FDA,	52	52	40

RFP pre	80	74	70
Over-all Usa-	192	187	161

Table 2 clarifies the advantages and disadvantages of the machines' usability. The indicative appraisal stages of human factors show that the advantages of one are the same disadvantages of the other one as shown below.

Table 2. The advantages and disadvantages of the machines' usability

	Advantages	Disadvantages
Supplier 1	Easy to operate Easy to extract the result via displaying all of them on high resolution screen Medium Shape	Touch screen which will malfunction due to misuse Needs an adapter because it work on American system Expensive spare parts
Supplier 2	Cheap spare parts Digital screen with high resolution Hard duty machine	Huge size Heavy weight
Supplier 3	Computerized machine with a lot of functions It does not need an adapter	Very complicated machine with the necessity of continues and intensive training. Expensive price

Figure 1, as shown below, shows the accumulated number of faults made by the operators in the investigated departments for each ventilator machine. The figure shows

that few faults were made in the supplier 1 in KHH and ZH compared with PHH and JUH. In addition, more faults were done with supplier 2 in PHH, JUH and KHH compared with ZH. For supplier 3 few faults were made in ZH compared with the other hospitals.

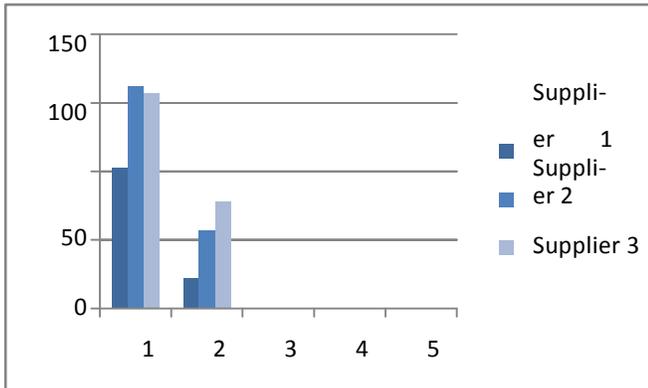


Figure 1. Accumulated number of usability faults done by departments operators

Where: 1: PHH
2: JUH
3: KHH
4: ZH

Figure 2 shows the accumulated number of crucial faults done by the investigated departments. It shows that for supplier 1, the fewest faults for supplier 1 were done in KHH and the hugest were in JUH. It shows also and for supplier 2, the fewest faults for supplier 2 were done in ZH and the hugest were in JHH and KHH. For supplier 3, the fewest faults for supplier 2 were done in ZH and the hugest were in JUH as shown below.

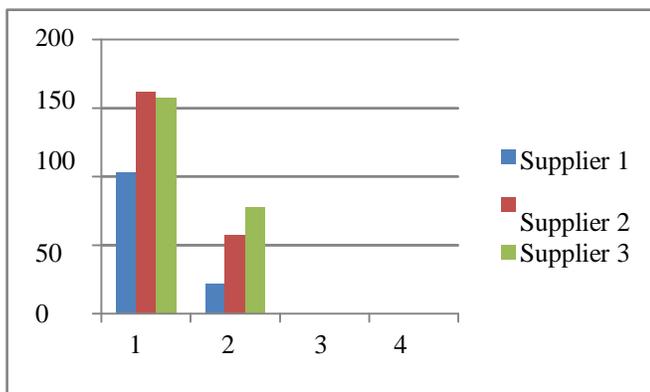


Figure 2. The accumulated number of crucial faults done by the investigated departments.

Where:

- 1: PHH
- 2: JUH
- 3: KHH
- 4: ZH

Figure 3 represents a combination of usability and crucial faults done the operators in the investigated departments for the machines. The figure shows that the performance of supplier 1 was the best compared with the two other suppliers as shown below.

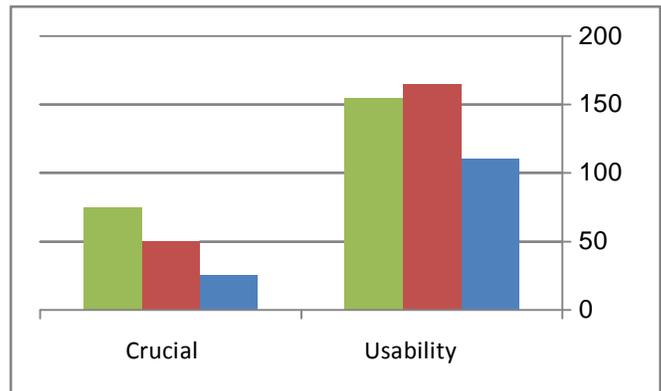


Figure 3. The accumulated amount of usability and crucial faults done by operators.

Conclusions:

In this research, it has been found that the human factors engineering is a suitable tool for analyzing the ventilator machines and it should be applied for the supplying of other types of medical devices.

It has been found that there is an accord in the results of the two stages of human factors appraisal of ventilators machines. In general, the staff of the investigated department preferred supplier 1 machines over the other 2 suppliers.

This research emphasis the worth of conducting the investigation of the stages of human factor appraisal of medical devices and an indicative assessment stage because they are integrative stages. The pharmacists and bio medical engineers played important role in supplying supplying, logistic and tendering process of medical devices in the hospital and so they were the basic element in this research.

The indicative assessment stage reveals valuable data on the portion of the design. Information gained from the indicative evaluation phase can also be used to guide for modifications of the devices to improve their usability and performance.

References

- [1] G. Ginsburg, "Human factors engineering: A tool for medical device evaluation in hospital procurement decision-making", *Journal of Biomedical Informatics* 38, pp. 213–219, 2005.
- [2] www.faa.gov/about/initiatives/maintenance_hf/library_documents/media/human_factors_maintenance.
- [3] I. Özbilgina, and M. Imamoglu, "The impact of dynamic purchasing systems in the electronic public procurement processes", *WCIT 2010, Procedia Computer Science* 3, pp. 1571–1575, 2011.
- [4] C. Drury, "Human Factors in Aircraft Maintenance". Paper presented at the RTO AVT Lecture Series on "Aging Aircraft Fleets: Structural and Other Subsystem Aspects", Sofia, Bulgaria, 13-16 November 2000.
- [5] R. Stone, and R. McCloy, "Ergonomics in medicine and surgery", *BMJ.*; 328(7448), pp. 1115–1118, 2004.
- [6]- K. Aziz, C. Backinger, E. Beers, A. Lowery, S Sykes, A. Thomas, and A. Trautman, "Do It By Design , An Introduction to Human Factors in Medical Devices", Dick Sawyer Office of Health and Industry Programs, 1996.
- [7]- S. Caplan, M. Tschirhart, and J. Hipple, "40 Principles with Examples: Human Factors & Ergonomics", *Triz journal*, Feb 2010