

INFORMATION MODELS OF A MEDICAL DEVICE FOR ITS EVALUATION*

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Abstract: Health-care delivery depends greatly upon the medical devices that are used in hospitals. The choice and the procurement of medical devices, however, is often influenced by many factors, an example of which, being aggressive marketing policies. For a decision-maker in a hospital it is not feasible economically nor justifiable in practice to procure a medical device without a detailed evaluation and comparison to the alternatives. In order to optimize the process of medical device procurement and to raise the health-care level, the authors propose a methodology which is based on information modeling.

Introduction

Medical devices belong to the complex equipment that has numerous parameters and characteristics [1, 2]. The construction of a data-set containing information about medical devices is a crucial task when it comes to the evaluating of the equipment.

One of the crucial requirements for evaluating a medical device is the construction of a data-set containing information about the equipment. Indeed, relevant parameters are sometimes difficult to acquire due to the large amount of diffused, heterogeneous data to be collected, so an important improvement to the relevance of the extracted knowledge regarding the choice of medical devices will be to construct a data-set which is centered on what interests decision-makers in the hospital; solutions representing high-performance system behavior. The search of high-performance solutions is the aim of many optimizations methods [3]. In order to find these solutions, it is necessary to research which decision variables are important to build a "good solution" in order to find an optimal model of medical device. It is also crucial to know how to identify the characteristics of the medical device.

Indeed, relevant parameters are sometimes difficult to acquire due to the large amount of diffused, heterogeneous data to be collected. Data-set must be centered on the parameters that are needed in the in the hospital. It is crucial to know how to identify the characteristics of the medical device. When a database of medical devices is being developed of when several medical devices are to be compared, a certain approach must be implemented to evaluate these devices.

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Information Models

The proposed methodology is based on the development of information models of a medical device. The information models help, firstly, to characterize and evaluate medical devices and, secondly, by this characterization, to find an optimal solution – models that fulfill all of the requirements and have the minimal associated costs.

Moreover, via the characterization of high-performance solutions, we can propose to decision-makers several models of a medical device that fulfill all of the requirements of the hospital. This aspect is highly interesting because conditions could change and one solution could become difficult to implement for economic reasons. With the proposed methodology, another sufficiently effective solution is proposed without an additional complete study. Several alternative solutions could be proposed.

With this approach decision-makers could focus their attention on the evaluation of the parameters that are important to their hospital. These parameters being targeted could then stimulate operational performance and the level of health-care will be raised. In addition, the selection of optimal models that is undertaken by the decision support system will help decision-makers to improve their profits through the analysis of the best solutions.

Our methodology requires the development of information models which will allow for not only the structuring of all of the parameters of medical devices, but also to introduce the hierarchy of parameters according to their criticality and their impact on the work of the hospital.

An information model is an organizational framework that is used to categorize information resources [4]. Designing an effective, comprehensive information model is a critical and sometimes formidable step in developing a resource that will help with the understanding of a medical device structure. A decision support system that will make information accessible must be built upon an information model of medical devices.

In order to list all parameters that can be used in the information models, procurement of medical devices in Russia have been analyzed. Tender documentation has been investigated with the help of the official site zakupki.gov.ru [5]. The overall goal of this analysis was to identify the most important factors associated with the procurement of medical devices.

The analysis has also shown that the most significant factor during the health-care agency procurement of medical devices is the specification of the medical device detailing its options and configurations. To better understand and evaluate medical devices it is suggested to develop information models for medical devices.

We suggest an approach of theoretical multiplicity to be used in the decision support system for the development of information models. The aim of the information model is to categorize all of the parameters of the medical device, so that the decision support system can be created.

In order to develop such a model, all of the parameters of the medical device should be divided into the following groups. Table details these groups.

Examples of the parameters that we study are: Height, Length, Depth; Throughput; Number of different measured assays onboard simultaneously; Number of user defined open channels; Number of reagent containers accommodated on board; Test per container set; Shortest Onboard stability; On board Refrigeration; Shortest Onboard stability; Median onboard reagent stability; Number of direct ISE channels; Ability to directly place reagent container on analyzer; Bar-coded reagents; Supplied with UPS; Requires floor Drain; Requires Dedicated water system; Water Consumption; Noise generated in decibels; Connectable to automation; Uses disposable cuvettes; Uses Washable cuvettes; Number of cuvettes stored on board; Primary Tube Sampling; Sample Bar code Reading Capabilities; Auto Calibration or autocalibration alert; Minimum sample volume aspirated at once; Data Management Capabilities etc.

Parameters that characterize information models

Description	Value	Example
1. Parameters with a logical value	True/false	There are two values for a logical variable: “Reusable reaction cuvettes” – “ <i>true</i> ” – if the device supports this function, “ <i>false</i> ” – if the device does not support this function
2. Parameters with an integer value	Number	Integer value for “Minimum reaction volume” can be 180 μl
3. Parameters with a floating point value	Fractions	The value for “Step, sample volume” can be 0,2 μl
4. Parameters with an interval value	Interval	Interval value for the parameter “Sample volume for a biochemistry analyzer” can be [2, 70] μl
5. The name of the model	Name	Biochemistry analyzer XL 200, Erba
6. Fixed procurement costs	Price	The price that the hospital should pay for the medical device is shown

Let MD_k represent the multiplicity of medical devices of a certain class. Information model of this class of medical devices can be presented as a multiplicity

$$MD_k = \{s_k, L_k, N_k, A_k, B_k, c_k\}, \quad k = \overline{1, K}, \quad (1)$$

where s_k – denotes the name the medical device k (5th group in the Table); L_k is the multiplicity of MD_k parameters with the logical value; N_k is the multiplicity of MD_k parameters with the integer value; A_k is the multiplicity of MD_k parameters with the float value; B_k is the multiplicity of MD_k parameters with the interval value; c_k denotes the price of a medical device (6th group in the Table). This information model represents medical device k ; K is the quantity of the models of the medical devices that are currently on the market.

Shown approach can describe medical devices.

When a medical device is procured in the hospital, all of these parameters should be manually evaluated by the decision-maker in order to choose an optimal biochemistry analyzer. In addition, the price should be taken into consideration. This tedious process can be optimized with the help of decision support system.

Conclusions

Now, the exploitation and future performance of medical devices in the hospital are essentially dependent on the characteristics that this medical device possess. The decision-makers at the hospital who deal with procurement of medical devices must well understand the market and have a wide knowledge of all of the devices. To do that, they need to know the interactions between the different parameters of the medical device, its price as well the current demands of the hospital.

The way to evaluate a medical device is to use its information model and its specification. With this definition of the equipment, we are able to help health-care professionals make the best choice of medical devices for the treatment and care of patients.

As it was shown above there still significant gaps and opportunities for new contributions in the performance management and decision making process of medical device procurement. Considering these gaps the described decision support system can be applied because it can be well suited to group decision making environments in health-care. For example, it appears to be a promising support tool for shared decision making between health-care professionals and decision-makers in the hospitals.

On the presented application, we proved that this decision support system will advance innovative medical care by the fact that a medical device will only be procured if it complies with all of the requirements of the hospital and the price that the hospital can pay for it.

Although the presented application was the choice of a biochemistry analyzer, our methodology is also adapted to the study of other problems, especially when the studied systems are complex. Only information models of new products should be developed in order to use this approach in a different area. Future research will address multi-objective optimization with the induced problem of information model development and the application of the decision support system.

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Информационные модели для оценки медицинской техники

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Ключевые слова: закупки в области здравоохранения; информационная модель; медицинская техника.

Аннотация: Качество медико-санитарной помощи в значительной степени зависит от медицинских приборов, которые используются в больницах. Выбор и закупка медицинского оборудования, однако, происходит часто под влиянием многих факторов, примером которых является агрессивная маркетинговая кампания производителей. Для лица, принимающего решения в больнице, становится невозможным адекватно оценить медицинский прибор без его детальной оценки и сравнения с аналогами. Для оптимизации процесса закупок медицинского оборудования и повышения уровня здравоохранения предложена методика, основанная на информационном моделировании.

Informationsmodelle für die Einschätzung der medizinischen Technik

Zusammenfassung: Die Qualität der medizinisch-sanitären Hilfe hängt von den medizinischen Geräten in bedeutendem Grade ab, die in den Krankenhäusern verwendet werden. Die Auswahl und der Einkauf der medizinischen Ausrüstung geschieht oft unter Einfluß vieler Faktoren, deren Beispiel die aggressive Vermarktungskampagne der Produzenten ist. Für die Person, die einen Beschluss im Krankenhaus fasst, wird es unmöglich, das medizinische Gerät ohne seinen ausführlichen Einschätzung und den Vergleich mit den Analoga adäquat einzuschätzen. Um den Prozess der Einkäufe der medizinischen Ausrüstung zu optimieren und das Niveau des Gesundheitswesens zu erhöhen, bieten die Autoren die Methodik an, die auf der informativen Modellierung gegründet ist.

Modèles informatiques pour l'évaluation de la technique médicale

Résumé: La qualité des soins médicaux et sanitaires dépend dans une grande mesure des dispositifs médicaux utilisés dans les hôpitaux. Cependant, le choix et l'achat du matériel médical se produit souvent sous l'influence de nombreux facteurs, dont l'exemple est la campagne de marketing agressive des fabricants. Pour un décideur à l'hôpital, il devient impossible d'évaluer correctement l'appareil médical sans son évaluation en détails et en comparaison avec des analogues. Afin d'optimiser le processus d'achat du matériel médical et d'améliorer le niveau des soins de santé, les auteurs proposent une méthode qui est basée sur le modélage informatique.

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