Problems of identification in information systems

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THE ANALYSIS OF MEDICAL EXPERT SYSTEMS' USE RISKS

Abstract. In the following paper the characteristics of medical information computer systems are presented. There were separated out medical expert systems as having significant features. Actual medical expert systems are considered as critical ones, especially sensitive to the occurrence of risks and risk situations. In general, there are common approaches to risk analysis in the development and operation of software. In this work, the classification of risks in accordance with selected methodologies associated with information support, or automation of the diagnostic process is presented. The abovementioned systems are complex software and computer combinations. When creating such complexes, a large number of risks arise, which in turn can cause abnormal situations that, first of all, can lead to serious consequences. Therefore, the identification and qualification of risks in advance, according to existing risk classifications, can prevent such extraordinary situations. To create such risk-qualifying systems, certain databases have been developed that are founded on studies conducted by a large number of people. In turn, we need to use the work of a large number of specialists to create the necessary knowledge base. Among the chosen risks classification systems, the MSF systemizing was selected for the following study. In order to realize the comparative characteristics of the known MES, the method of inconstant (variant) networks was used based on the selected classification. According to this method, each system was evaluated. Based on the analysis of several methodologies, it has been determined that the use of the MSF methodology is most appropriate when it comes to medical expert systems. The most significant risks that arise during the operation of such systems are identified. When analyzing each risk, the probability of its occurrence is determined and the consequences of its implementation are taken into account. In the abovementioned MES we have taken into account the risks associated with the operation, interface and user qualification. The selected classification has a large number of risk categories that are relevant to the various stages of the product life cycle, and it makes it possible to identify, classify and deal with the risks arising from the operation of the MES.

Keywords: critical software; risk analysis; medical expert systems; MES classification methods; risk classification according to MSF.

Introduction

Medical expert systems (MES) can be categorized as critical software systems and therefore have many features that require consideration of the risks involved in their development and operation. The main feature of MES is that refusal or extra-ordinary functioning of such systems can cause a significant damage to health and endanger the life of the patient. Taking into account such essential features, MES during the work with them require considerable attention. Actually not all existing methods and approaches used to reveal, identify, and analyze risks are fully suitable for critical-purpose systems, and therefore for medical expert systems. Anyway, to effectively compare the methods of risk analysis, it is necessary to involve a wide range of sources related to the development and use of software, namely, expert systems in medicine.

In order to carry out an analysis of operational risks with regard to MES, it is necessary to determine the requirements for their characteristics and assess the impact of possible damage from their violation. As a result of this analysis, it is necessary to create a plan for measuring and tracking risks in the life cycle of the MES, especially in the phase of operation. The main objective of risk management is the detection, identification and control of situations and factors that lead to negative consequences. It should be noted that the most significant aftereffects are precisely the MES exploitation risks, since they are directly related to the possible harm to human health. Therefore, it is necessary to carry out the analysis of risks under various conditions, differing in their sources and the reasons of the risks threat appearance, the probability degree of their emergence from a large number of possible, in the severity of the consequences. In conducting the analysis and risk management, it is necessary first of all to identify the most characteristic ones (for the certain type of software) that is the object of the study, in our case it is the MES. Thus, the problem of qualitative and quantitative analysis of the MES operation risks is relevant, because it will enable the functioning of this type of software systems without failures and extraordinary situations.

The article is devoted to the problem of carrying out qualitative analysis of operational risks, which will allow us to choose a method of risks classification. The result is a list of software exploitation risks that need to be identified, analyzed and evaluated in a timely manner when using MES in medical practice.

The purpose of the paper is to analyze existing risk classifications and to select the one that will be used to detect, identify and eliminate risks arising from the operation of the MES.

The problem formulation

To effectively solve this problem we need: to define the concept, to consider the purpose and classification of the MES; to examine the methodologies for the

classification of software operation risks; to characterize the MES operation risks; to analyze the existing types of software use risks and choose their classification, which most of all correspond exactly to the risks of the MES exploiting.

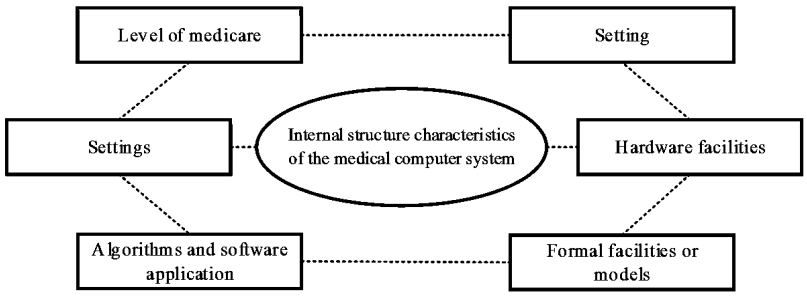

Fig. 1. The internal structure of the medical computer system

Medical information computer systems, their definition and classification

It should be noted that the important kind of medical information systems are medical computer systems (MCS). [4]. The use of software in medical practice allows us to create effective means for providing the automated getting all the necessary information of the person's health, its processing in real time and management of the patient's condition [2].

MCS intended for information support or automation of the diagnostic process. They are actually complex computer software combinations.

MCS can and should be classified according to their functionality and purpose. Expert systems belong to a class of artificial intelligence complexes that contain a knowledge base with a set of heuristic algorithms. The most important areas of the consulting and diagnostic systems use are urgent and life-threatening conditions characterized by time shortage, limited possibilities of examination and counseling, and often by low clinical symptoms with a high level of threat to the patient's life and rapid rate of the process' development [6].

The experience of consulting and diagnostic systems' use demonstrates a significant improvement in the quality of diagnosis, which not only reduces unjustified losses, but also allows to specialists more efficient use of health care resources, to regulate the volume of necessary research and, finally, to increase qualification level of the doctor, for which such a system undoubtedly serves also as an educational one [5].

Among computer expert systems, the medical expert systems (MES) occupy a prominent place. The main purpose of MES is to establish a diagnosis. Diagnosis is a process of phased information entry into the "doctor-patient" system, the purpose of which is to create the most adequate model of the patient's body state [1]. In cases of difficult diagnostic solutions, medical expert systems give physicians the opportunity to automatically check their own diagnostic assumptions, or to consult a computer for advice.

In the narrow sense the medical information system is a complex combination of technical and mathematical support that is intended directly for the collection and analysis of medical and biological information, as well as for the delivery of results in a user-friendly form. Thus, the following definition can be allotted: the medical information system is a software and hardware complex that prepares and provides the processes of collecting, storing and handling information in medicine and healthcare branch (Fig. 1) [2].

Anyway, medical computer systems are an important kind of medical information systems. The use of software in medical practice allows us to create effective tools for automated collection of information about the person's body condition, its real time processing and patient's health status management.

The main purpose of medical computer systems is the information support or automation of the diagnostic process. They represent compound software-computer complexes. The peculiarity of mentioned complexes is the formation of databases founded on the large number of people observation; and the creation of a knowledge database requires the highly skilled professionals' participation. And it should be specialists in a particular medical field.

The main risk of medical expert systems is a situation that can lead to the recognition of a healthy person ill or, even worse, a sick person as a healthy one. To avoid this, especially in systems designed to automate the diagnostic process, statistic indicators such as: sensitivity (true positive proportion) and specificity (true negative proportion) were specially calculated. In this regard, medical computer systems must undergo thorough and lengthy testing to analyze all possible risks.

Medical computer systems can be classified according to their functional capabilities and their purpose as well (Fig. 2) [3].

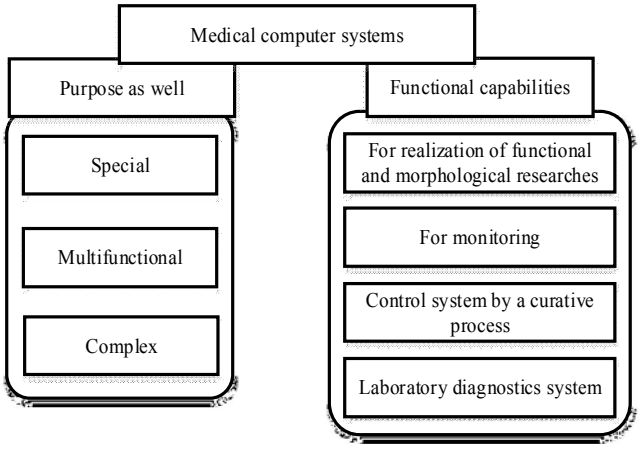

Fig. 2. The MCS classification

Medical expert systems

The key point of the entire diagnostic-medical process is to establish a diagnosis. Complex processes of comprehension and comparison of a large factors number of factors by the doctor are the basis of traditional diagnostic technology. To establish the diagnosis, one should make a general patient survey, clinical and biochemical tests, then compare all the data with the standards of the selected MES and note the risks that may interfere with the diagnosis of the patient.

Diagnosis is a process of phased information processing in the "doctor-patient" system, the purpose of which is to create the most adequate model of the patient's body state. The diagnostic process can be divided into four related phases: collecting information about the patient's health condition (symptoms' detection); the most significant features selection; conducting analyzes; comparison with the illnesses' symptoms [1].

Expert systems belong to a class of artificial intelligence systems that contain a knowledge base with a set of heuristic algorithms. The most important areas of consulting and diagnostic systems' application are urgent and life-threatening conditions characterized by time deficiencies, limited possibilities of examination and counseling and, often, by low clinical symptoms with a high level of threat to the sick person's life and the rapid pace of the process' development at the same time. The experience of using medical advisory and diagnostic systems proves a significant increase in the quality of diagnosis, which not only reduces the losses, but also allows to more effectively apply the resources of health care, regulate the volume of necessary research, and finally, to increase the level of illnesses' diagnostics by doctors [4].

Among the diagnostic types of MES most well-known systems are: "Home Doctor" [5], "Chronos Expert" [5], DIOGEN SYSTEM [6], System for the diagnosis of urgent conditions in children DIN [6].

MES "Home Doctor"(in Ukrainian "Domashniy Likar") is a simple medical expert system. It is intended only for the initial determination of the disease nature, when it is not yet possible to consult a specialist. At the earliest possible opportunity, one should consult a doctor, regardless of the diagnosis posed by the system.

The hypothesis window is always in working order, that is, after each response, the system changes its assumption about your illness. The results should be taken into account only after answering all the suggested questions.

Substantiation of risks classification choice associated with the MES operation

In the MES, considered in this paper, the risks relating to the functioning, interface and qualifications of the user, that is, the physician who works with the system should be taken into account. Paying a certain attention to the risks it is necessary to choose the classification of well-known methodologies for their estimation. The used classification is based on: MSF; studies by Shafer D., Fatrell R., Shafer L.; Barry Boehm's methodology. In the work carried out by Shafer D., Fatrell R., Shafer L. [7], the risks of software projects are proposed to be divided into twelve categories, each of which contains factors, risks and criteria for their evaluation. The list of categories is as follows:

- tasks and goals factors;
- factors related to the organization management;
- customer related factors;
- factors of budget/payments;
- schedule related factors;
- contain of the project;
- factors which effect the project's completing;
- factors related to the project's control;
- factors which effect the project's development;
- development medium factors;
- factors related to the staff;
- factors related to supporting.

Barry Boehm [8, 9] proposed the list containing ten the most wide-spread risks related to the program project:

- shortage of specialists;
- unrealistic terms and financial means;
- implementation of inappropriate functionality;
- wrong interface development;
- unnecessary optimization,dwelling on details;
- incorrect flow of changes;
- insufficient information about external components that determine the environment of the system or involved in its integration;
- deficiencies in the work performed by external (in relation to the project) resources;
- insufficient productivity of the received system;
- "gaps" in qualifications of specialists in various branches of knowledge.

The classification of risks within the MSF divides all sources of risks into four classes that contain the corresponding elements (Table 1) [10].

Table1 – **Classification of risks within MSF**

People	Technologies
Customers	Security
End users	Development and testing environment
Sponsors	Toolkit
Interested parties	Introduction
Staff	Conduct
Institution	Operating environment
Professional skills	Accessibility
Policy	External conditions
Morality	Legal base
Process	Industrial specifications
Goals and tasks	Competition
Decision-making	Economy conditions
Project characteristics	Technologies
Budget, expenses, terms	Business conditions
Requirements	Safety (security)
Designing	Development and testing environment
Realization (fulfillment)	Toolkit
Testing	Introduction

In order to compare the classifications, we use the method of variant(alternative) networks. According to the method, it is necessary to distinguish the evaluation criteria and indicate their degree of importance. The results of the variant networks method are presented in Table 2. We evaluate the following criteria on a five-point scale: the number of risks categories (a); the prevalence of the methodology (b); the versatility (c). Actually, for each criterion the importance is indicated in the following way: very important (5); important (4); rather important (3). In fact, Barry Boehm's risk classification is not perfect for risks analysis in MES, since it has the smallest number of categories from the above classifications.

Table 2 – **The results of the variant(alternative) networks method**

Characteristics / Classification	1a(5)	2b(4)	3b(3)	Total
MSF	5	5	4	57
By Shafer D., Fatrell R., Shafer L.	3	3	4	38
By Barry Boehm	2	3	4	34

As a matter of fact, classification by Shafer D., Fatrell R., Shafer L. has more risk categories than the previous one. But in spite of this, it is more appropriate for risk analysis at the development stage of the MES, but not during the process of operation. Also, this classification isn't widespread. Anyway, after conducting an assessment of risk classifications using the method of variant (alternative) networks, it can be concluded that the classification of MSF risks has a significant basis for identifying MES risks during the operation phase. Namely, a large number of risk categories, among which there are many categories that relate to different stages of the software product's life cycle. MSF is also the most widespread system that allows you to find a lot of information about the methodology.

Actually, the classification of MSF risks detects the risks associated with the operation of the MES. The consequences of risks implementation are also taken into account, each risk has a priority: high (1), medium (2), low (3). Risks according to MSF classification:

- project's functionality (1) - failure or incorrect operation of system's separate functions.
- user's interface (3) - The interface does not meet the basic requirements, such as simplicity, usability and functionality.
- inadequate knowledge base (1) – Insufficient amount of information about specific illnesses in the knowledge base, or complete absence of data about the disease.
- user's experience (3) – inadequate qualification or inattention of a specialist who works with a system.
- system's failure (2) – the possibility of information loss after the failure of system's individual modules or total collapse of the system.
- system support (2) – No developer help if necessary.

Anyway, based on the classification, MSF detects the following risks in the MES that were considered during the study (Table 3). These risks are significant when it comes to the work of the MES. It is proved that timely detection of these risks can minimize or completely prevent the occurrence of emergency cases in MES operation. This suggests a more effective diagnosis of diseases, and, consequently, more effective treatment of patients.

Table 3 – **The significant risks in medical expert systems**

№	MES	Purposes	MES specialization	The significant risks in MES by means of MSF
1	"Chronos Expert"	Diagnostics	Predicting the periods of exacerbation and remission in pathological status	project's functionality; inadequate knowledge base ; system failure; system support;
2	"Home Doctor"		The initial definition of the disease nature	project's functionality; user's interface; inadequate knowledge base; system failure; system support;
3	MES Of differential diagnostics		Help to the physician in identifying a patient's diagnosis with symptoms and disease history	project's functionality; staff experience; inadequate knowledge base; system failure; system support;
4	MES DIOGEN		Diagnosis of hereditary diseases	project's functionality; inadequate knowledge base; system failure; system support;
5	MES DIN		Recognition the child's current condition during critical status in terms of one or more syndromes	project's functionality; staff experience; inadequate knowledge base; system failure; system support;

Conclusion

Thus, in the above-mentioned study, a qualitative analysis of the risks arising during the MES operation was carried out. For this purpose, first of all the concept of MES was defined and their main characteristics were also given, as well as examples of really functioning MES. In our paper the most common risk analysis methodologies were selected and reviewed: MSF; by Shafer D., Fatrell R., Shafer L.; Barry Boehm's methodology.

Thus, as a result of the comparative analysis, the most appropriate MSF classification was selected. The performed study showed that on the basis of MSF classification, risks in the MES are identified and their priority is determined.

It should be noted, that among the most important risks of MES exploitation, one can distinguish the functionality of the project, the experience of the personnel that uses them, the inadequate completeness of the knowledge base and also possible failures of the MES. Actually, it is very important to implement constant and timely maintenance of the system. This enables to non-stop replenish the knowledge base, if necessary. It should also be emphasized that in order to ensure system's reliability, it is quite necessary to add the mechanism of self-education in the MES to its functional.

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Аналіз ризиків експлуатації медичних експертних систем

Л. В. Мандрікова, В. А. Постернакова, І. Г. Красовська, Т. С. Симович

Анотація. Наведено характеристику медичних інформаційних і комп'ютерних систем. Окремо розглядаються медичні експертні системи як системи, що мають суттєві особливості, які пов'язані з діагностикою захворювань та підтримкою прийняття рішень щодо встановлення діагнозу пацієнту. Розглянуто актуальні медичні експертні системи як системи критичного призначення, особливо чутливі до виникнення ризиків і ризикових ситуацій. Завдання – виявити, ідентифікувати та ефективно боротись з наслідками ризиків, які можуть негативно вплинути на прийняття рішень при встановленні діагнозу. Наведено поширені підходи до аналізу ризиків при розробці і під час роботи програмного забезпечення. Наведені класифікації ризиків згідно відібраних методологій. Серед обраних класифікацій здійснено порівняльну характеристику класифікаційних ознак опрацювання цих систем. Для порівняння ризиків кожної з розглянутих медичних експертних систем та вилучення наслідків похибок в медичних експертних системах використано метод варіантних мереж. Відповідно до цього методу виконано оцінювання кожної системи, що наведено в статті. На основі аналізу методологій розробки медичних експертних систем визначено, що класифікацію ризиків за методологією MSF доцільно використовувати саме для медичних експертних систем.

Ключові слова: критичне ПЗ; аналіз ризиків; медичні експертні системи; методи класифікації МЕС; класифікація ризиків по MSF.

Анализ рисков эксплуатации медицинских экспертных систем

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Аннотация. Приведена характеристика медицинских информационных и компьютерных систем. Отдельно рассматриваются медицинские экспертные системы как системы, имеющие существенные особенности, связанные с диагностикой заболеваний и поддержкой принятия решений по установлению диагноза пациенту. Рассмотрены актуальные медицинские экспертные системы как системы критического назначения, особенно чувствительны к возникновению рисков и рисковых ситуаций. Задача - выявить, идентифицировать и эффективно бороться с последствиями рисков, которые могут негативно повлиять на принятие решений при установлении диагноза. Приведены распространенные подходы к анализу рисков при разработке и во время работы программного обеспечения. Приведенные классификации рисков по отобранным методологиям. Среди отобранных классификаций проведена сравнительная характеристика классификационных признаков обработки этих систем. Для сравнения рисков каждой из рассмотренных медицинских экспертных систем и извлечения последствий ошибок в медицинских экспертных системах использован метод вариантных сетей. Согласно этому методу выполнено оценивание каждой системы, приведенной в статье. На основе анализа методологий разработки медицинских экспертных систем определено, что классификацию рисков по методологии MSF целесообразно использовать именно для медицинских экспертных систем.

Ключевые слова: критическое ПО; анализ рисков; медицинские экспертные системы; методы классификации МЭС; классификация рисков по MSF.