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# Formalization of the stages of diagnostic and therapeutic measures in decision support systems in medicine

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## ABSTRACT

The purpose of this study is to formalize the stages of diagnostic and therapeutic measures in the design of computer decision support systems in medicine. Functional, structural and mathematical models of diagnostic and treatment measures are developed with the aim of increasing the efficiency of medical services and minimizing the risks of medical errors. Analysis of diagnosed states in the space of medical actions allowed developing a method of hierarchical clustering of diagnoses in the space of medical actions and substantiating the threshold values of permissible uncertainties in the diagnostic decision rule.

**Keywords:** computer system, diagnostics, medical action, mathematical model, diagnostic feature, decision rule.

## 1. INTRODUCTION

The complex of diagnostic and therapeutic measures (DThM) consists of two interrelated stages: patient diagnosis and treatment of identified diseases with possible subsequent rehabilitation. The diagnosis is a difficult process of clarifying the diagnosis, which involves several doctors. The result of the diagnosis is a detailed diagnosis, which includes the main and associated diseases, at that after the diagnosis and prescription of treatment procedures, it is necessary to monitor the current state of the patient in order to assess the effectiveness of the treatment process and, if necessary, correct it. For the treatment of a disease, it is necessary to provide certain medical actions (MA) on the patient's body (surgical intervention, pharmacological, medical-therapeutic effects, rehabilitation measures) or a combination of these. At each of these stages, the doctor, as the decision-maker (DM), performs a management decision in the conditions of a lack of basic data and substantial a priori uncertainty, based on his qualifications, experience, and intuition. In this case, making the wrong decision (medical error) both at the stage of diagnosis and at the stage of treatment can have disastrous consequences for the health of the patient. The term "medical error" (ME) defines the wrong diagnosis of the disease or the wrong MA, which are caused by the doctor's sincere delusion. The cause of the diagnostic error is insufficient and/or insufficient formativeness of diagnostic data (use of outdated equipment or insufficient qualifications of the doctor who prescribed the set of examinations), or their incorrect interpretation (especially at a subjective analysis of qualitative features). The cause of the wrong MA with the correct diagnosis is insufficient consideration of the individual characteristics of the patient (allergic reactions to certain drugs, a set of diseases that the patient has already suffered, the taken medications, etc.). Currently, there is a wide range of computer diagnostic systems in various medical subject areas[1-3], which use various mathematical methods for decision-making support (deterministic logic[4], probabilistic approach[5,6], fuzzy logic[7], neural networks[8], etc.) and modern information technologies including telemedicine[9-11]. Since biomedical signals and images (BMS/I) contain a significant amount of diagnostic information, great attention is paid to methods of processing of them in order to improve the quality of visualization and morphological analysis of BMS/I (detection diagnostically significant structural elements on the background noise), as well as to methods of determining diagnostic features (DF)[12,13]. At the present stage, the informatization of recommendations on the selection and realization of MA is not so widely implemented and is limited to medical reference books, recommendations on the implementation of medical procedures[14], including in the form of information retrieval systems[15,16]. In modern computer decision support systems in medicine, the problems of diagnosis and MA are considered independently of each other, and when diagnosing, the risk of incorrect diagnosis is minimized without taking into account the stage of MA, therefore, the task of minimizing the risk of ME in the integrated assessment of all stages of DThM is relevant.

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## 2. AIM OF THE RESEARCH

The aim of the work is the task formalization and the information technology development for the integrated assessment of DThM stages to improve the efficiency of the provision of medical services and the ME risk minimize. To achieve the stated objective this work addresses the following tasks:

- to formalize the task of integrated assessment of the stages of DThM by developing a functional, structural and mathematical models;
- to develop a method for minimizing the risks of wrong decision making at the stage of diagnostics, taking into account their consequences at the stage of MA during the synthesis of a decision tree (DT), which is based on the transition from the traditional feature space to the space of MA;
- to develop a method for calculating the threshold values of allowable uncertainty intervals in the diagnostic decision rule.

## 3. METHOD AND BASIC ASSUMPTIONS

To achieve the objectives in the work there are used: IDEF0 functional modeling method for building a functional model; methods of morphological analysis for the detection of diagnostically significant structural elements (SE) of biomedical signals and images; clustering methods for the synthesis of hierarchical structures of diagnosed states (decision tree) and diagnostic features; methods of information theory for the synthesis of the structure of informative features; decision theory methods for synthesizing diagnostic decision rule; graph theory methods for building a structural model; set theory methods for building a mathematical model.

## 4. SOLUTION

Let us represent the process of diagnostic and therapeutic measures in the form of a generalized model $M_G = \{M_F, M_S, M_M\}$ where $M_F$, $M_S$, $M_M$ – functional, structural, mathematical models of DThM process.

*The development of the functional model of DThM* is carried out using the methodology IDEF0. The input of $M_F$ are sets of diagnosable states, analyzed BMS/I, diagnostic features, and diagnostic data that determine the patient's state. The output of $M_F$ is the necessary MA recommended by the system and confirmed or corrected by the doctor. The control is represented by various regulatory documents, as well as applicable optimization criteria. The main mechanisms in the context diagram are the patient, the medical staff and the decision support system in medicine (MDSS). For the decomposition of the contextual diagram, two main functional blocks (activities) are allocated that correspond to the stages of DThM: perform patient diagnostics; perform the necessary MA. Further decomposition of the activities 1 and 2 is performed. The activity 1 is divided into the activity 1.1 "Formation of a vector of diagnostic features" and the activity 1.2 "Diagnosis", after which they are decomposed (Fig. 1-3). The set of BMS/I which is set by the survey protocol is the input of the activity 1.1.1 (Fig. 1); a set of SE $\omega$ (in the system learning mode) is the output; an optimality criterion which is the minimum of the recognition error of SE is the control. The output of the activity 1.1.1 and a set of possible DF (a set of primary features) in a given subject domain of medicine, which are recorded directly with the patient, excluding BMS/I analysis, are the inputs of the activity 1.1.3; a formalized presentation of DF $X$ is the output. The activity 1.1.3 also implements algorithms for calculating secondary DF when analyzing the parameters of SE $\omega$. The vector $X^p$ of DF values after their preliminary processing (restoration of missing data, reduction to one scale, normalization, etc.) is the output. The set of possible states (diagnoses) in a given subject domain of medicine is the input of the activity 1.2.1 (Fig. 2); their formalized representation $D$ (in the system learning mode) is the output. The activities 1.2.2 and 1.2.3 are performed only in the system learning mode. The output of the activity 1.1.3 (Fig. 1) is the input of the activity 1.2.2 (Fig. 2); the hierarchical structure of informative DF consistent with the structure $S_D$ (see below) is the output; optimization criteria $Q_2$ which include the criterion of clustering and the criterion of information content are the control[17]. The hierarchical structure of diagnosed states $S_D$ (decision tree) is the output; an optimization criterion $Q_3$ in the form of a clustering criterion of states $D$ in the feature space $X$ is the control. The activity 1.2.4 (Fig. 2) in a formalized form is the task of classifying the patient's state $D^p$ when analyzing the DF vector $X^p$. The output of the activity 1.2.4 (Fig. 2) is the input of the activity 2.1 (Fig. 3); types of necessary MA (surgical intervention, pharmacological, therapeutic effects, rehabilitation measures, or their combination) are the outputs; regulatory documentation and the optimality criterion $Q_4$ which is used as an integral criterion in the problem of choosing alternatives are the controls. The implementation of the relevant MA taking into account the individual characteristics of the patient, contraindications to individual MA and the multi-criteria selection of analogs (when implementing pharmacological effects) are outputs. The proposed functional model of DThM is the basis for the development of structural and mathematical models, as well as the structure of MDSS.

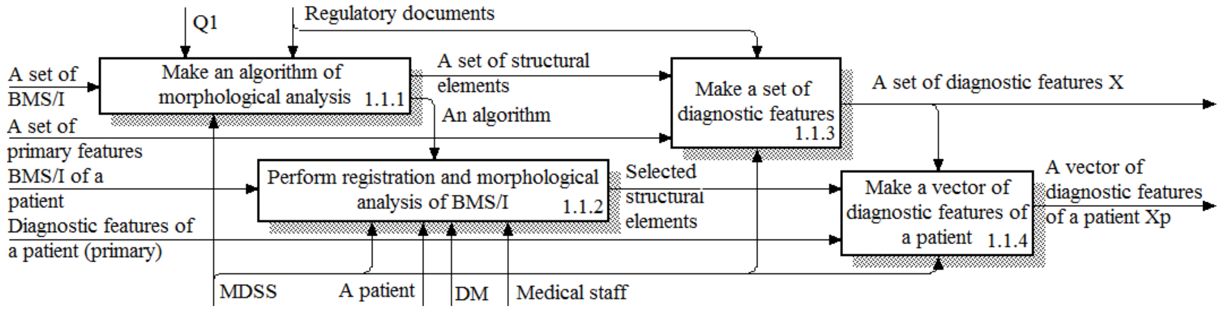


Figure 1. Decomposition of activity 1.1 “Formation of a vector of diagnostic features”.

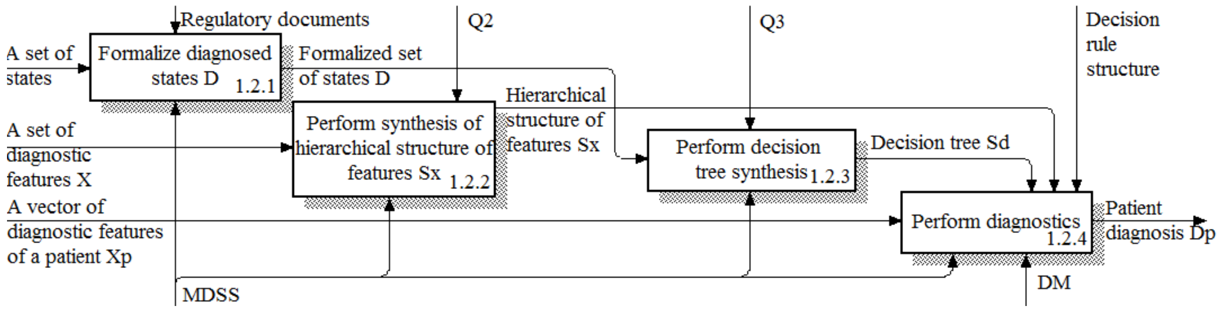


Figure 2. Decomposition of the activity 1.2 “Diagnosis”.

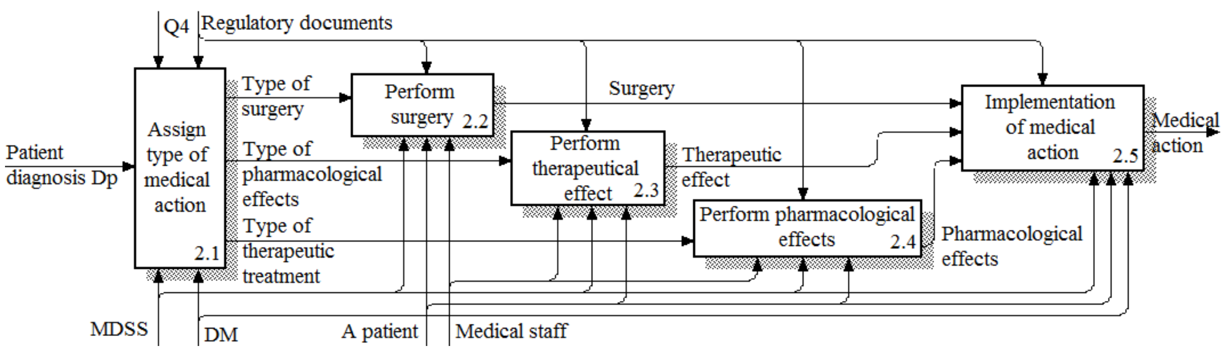


Figure 3. Decomposition of the activity 2 “Perform the necessary medical actions”.

*Development of a structural model.* As a structural model $M_S$ of DThM, an oriented graph is proposed that reflects the basic states of this process and their interactions (Fig. 4). It is assumed that the entire learning process of the system is completed, i.e. the hierarchical structures of DF $S_X$ and the diagnosable states $S_D$, noted earlier in $M_F$, are formed and the structure of the diagnostic decision rule is defined. Also using $M_S$, the causes of ME are determined in order to formalize it and develop methods to minimize it. In a directed graph, the transition from the state $S_i$ to the state $S_j$ is possible only in the case when $i<j$, $p_{ij}\in[0;1]$ $\forall i=\overline{0;7}$ – the transition probabilities between states. Since the states $S_0$ – $S_7$ determine the order of DThM, the probabilities of transitions between them are equal to 1. The probability of the transition $p_{78}$ determines the probability of ME, because only after the realization of the wrong MA or if the necessary MA is not fulfilled, the negative consequences of ME are manifested. However, the causes of the appearance of ME are contained in all previous states (except $S_0$). Let us consider in detail this statement. In each of the states $S_i$, it is possible to occur an error $\gamma_i=\alpha_i+\beta_i$ where $\alpha_i$, $\beta_i$ – types I and II errors. In the state $S_1$, the occurrence of an error $\gamma_1$ leads to a distortion of the values of the primary DF vector. In the state $S_2$, an error $\alpha_2$ corresponds to a false identification of a SE, and an error $\beta_2$ corresponds to the omission of a true SE, which ultimately leads to a distortion of the values of the

secondary DF vector, therefore, in the state $S_3$, errors are determined by the expressions $\alpha_3 = f(\alpha_2) + \alpha_3'$, $\beta_3 = f(\beta_2) + \beta_3'$ where $f(\cdot)$ – some dependence, which is determined by the algorithm for calculating secondary features in the analysis of SE parameters; $\alpha_3'$, $\beta_3'$ – errors that appear in the state $S_3$. Since in the state $S_4$, a DF vector is formed, the components of which are the outputs of the states $S_1$ and $S_3$, the errors are determined as $\alpha_4 = \max(\alpha_1, \alpha_3)$, $\beta_4 = \max(\beta_1, \beta_3)$. In the previously considered states, the causes of errors in the formation of the DF vector and their probability are determined. The obtained expressions can be used to calculate the maximum permissible errors in the states $S_1$ – $S_3$ when specifying the corresponding values at the last stage ($S_4$). In the state $S_5$, classification error $\gamma_5$ is determined by the location of the scattering ellipsoids of classified objects of the training sample (diagnosable states *D*) in the feature space *X* without taking into account their impact on the stage of selecting the required MA and their subsequent implementation. When implementing a probabilistic DR in the form of a refinement diagnosis (see below), a binary DT $S_D$ is used, the root of which is the full set of diagnoses $\{D_i\}_n$ in a given subject domain, diagnosis clusters are located in the branches, and separate diagnoses are leaves. In this case, the optimal distribution of the error $\gamma_5$ in the tree nodes is performed, since the optimal DT is constructed by the criterion of hierarchical clustering of objects in the feature space. The meaning of this distribution is that the error at each node of the tree is minimized, starting from the root. It should be noted that in each *k*-th node there are uses its own set of features or its own set of diagnostically significant intervals of the same-name features that are sufficiently informative to perform the task of classification into two branches at the specified node, and the values of classification errors are determined by the location of the scattering ellipsoids of two clusters each of which corresponds to the branches of the *k*-th node in the space of a subset of features of the *k*-th node.

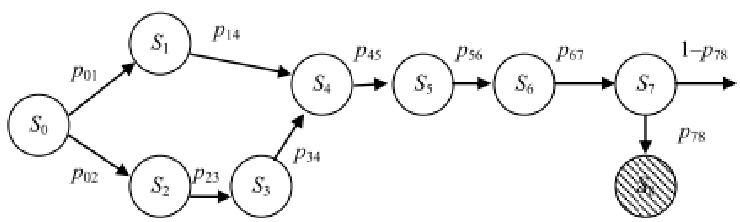


Figure 4. The structural model $M_S$ of DThM: $S_0$ – the initial state of the *i*-th patient; $S_1$ – determination of primary diagnostic features; $S_2$ – morphological analysis of BMS/I; $S_3$ – calculation of secondary DF; $S_4$ – formation of a full vector of diagnostic features $X^p$; $S_5$ – formation of a detailed diagnosis; $S_6$ – determining the type of needed MA; $S_7$ – determination of the implementation of MA; $S_8$ – condition of ME.

In the process of diagnosing the *i*-th patient with a known vector $X_i^p$, the movement takes place on DT, in each *k*-th node of which differential diagnosis of the states $D_q$ and $D_l$ is performed by calculating the DR and making a decision in favor of $D_q$ or $D_l$. The method of clarifying the diagnosis is a modification of the method of sequential analysis (Wald method) and it is based on the analysis of the interaction of the hierarchical structures of the diagnostic features $S_X$ and the diagnosed states $S_D$. At each *i*-th stage of DR, with differential diagnostics between two states $D_q$ and $D_l$, the next symptom $x_j$ is analyzed and the likelihood ratio is calculated

$$\Theta = \prod_j \frac{P(x_{jk}/D_q)}{P(x_{jk}/D_l)}, \tag{1}$$

which is compared with thresholds $\Theta > A$, $\Theta < B$ where *A* and *B* are upper and lower bounds of uncertainty necessary for decision making. When one of the conditions is fulfilled, the decision on the diagnosis $D_q$ or $D_l$ is made and the transition to a lower level of the hierarchy of diagnoses is carried out in order to clarify the diagnosis. If both inequalities are not fulfilled, the next ($i+1$)-th feature is added and the procedure is repeated. The features in (1) are ranked in descending order of their informativeness with respect to the states $D_q$ and $D_l$, and when the list is exhausted and the decision is not made, further refinement of the diagnosis ceases (a “weak” decision is obtained), about which the MDSS informs the DM for making a final decision (possibly, re-examination, additional examination, etc.).

In a sequential analysis, the decision making boundaries $A$ and $B$ are related with the classification errors $\alpha$ and $\beta$:

$$A=\frac{1-\beta}{\alpha}\ ;\ B=\frac{\beta}{1-\alpha}\ . \tag{2}$$

Any classification error in the $k$-th node ($\alpha_{5k}$ or $\beta_{5k}$) leads to the fact that further diagnosis refinement (except for the case when the nodes $D_q$ and $D_l$ are leaves of the tree) is carried out along the "wrong" branches of the tree, in which features are analyzed that are not very informative for specifying classification, which increases the likelihood of a "weak" solution. With such an organization specifying the diagnosis, the total classification error is significantly reduced, which is obtained with classifying tree leaves by increasing the likelihood of "weak" solutions of MDSS that are subjectively controlled by DM, which ultimately improves the quality of diagnosis. For example, prescribing a therapeutic effect or carrying out rehabilitation measures practically does not lead to the appearance of ME.

In the state $S_6$, the selection error $\gamma_6$ of MA type is determined differently depending on the specific situation. On the other hand, the appointment of a surgical intervention is controlled by regulatory documents and in most cases is carried out by a council of doctors. In the case of the appointment of combinations of MA, the situation is even more complicated. Therefore, the paper considers the most common case of prescribing pharmacological effects $F$, the choice of which is conventionally considered to be infallible $\gamma_6=0$, and errors are considered at the next stage of realization of this effect. In the state $S_7$ for the established patient state $D^p$, a subset of the necessary pharmacological effects $F_D=\{f_i\}_D$ is formed, after which their realization is determined in the form of prescribing a complex of drugs taking into account the patient's individual characteristics, contraindications to certain $f_i$ and multi-criteria selection of analogs. The complex of drugs is the result of MA. The prescription $F$ in the case of a known diagnosis $D^p$ is performed according to regulatory documents in various subject domains of medicine (for example[11]). The cause of the error $\gamma_7$ is the insufficient consideration of the individual characteristics of the patient (individual constraints $\Omega^p$ on the subset $\{f_i\}_D$). Let us determine the likelihood of ME, taking into account the fact that events $\gamma_5$ and $\gamma_7$ are independent:

$$p_{78}=1-(1-\gamma_5)(1-\gamma_7)=\gamma_5+\gamma_7-\gamma_5\gamma_7\ . \tag{3}$$

The consequence of ME in case of erroneous diagnosis ($D_q^p$ instead of $D_l^p$) and the correct medicinal purposes $F_D$ ($\gamma_5\neq 0$, $\gamma_7=0$) is that $F_{D_l}$ is prescribed instead of $F_{D_q}$ whose components do not match, i.e. the necessary $f_i$ may be missing, but "extra" $f_i$ may be present. Limitations $\Omega^p$ are violated in the case of error-free diagnosis and error in the medicinal purposes $F_D$ ($\gamma_5=0$, $\gamma_7\neq 0$). Both components are a consequence of ME in the presence of errors in both stages ($\gamma_5\neq 0$, $\gamma_7\neq 0$). In[18] there is developed a method for analyzing diagnoses in the space of MA $f_i$ (transition from traditional feature space $X$ to space $f_i$) which allowed minimizing the classification error $\gamma_5$ taking into account its consequences at the stage of MA during the synthesis of the decision tree, developing a method for calculating threshold values (2) in the decisive rule (3), which ultimately reduces the risk of medical errors.

*Development of a mathematical model.* Based on the previously reviewed functional model, the following mathematical model $M_M$ is proposed: $M_M=\langle SP, SP^p X, X^p, D, D^p, S_D, S_X, M_a, M_a^p, T, Q_t\rangle$ where $SP=\{sp_i[\cdot]\}$ – the set of digital BMS/I; $SP^p=\{sp_i^p[\cdot]\}$ – the set of BMS/I which are recorded with the patient; $X=\{x_i\in X^{(A)}\cup X^{(SP)}\}$ – the set of DF; $X^{(A)}$, $X^{(SP)}$ – the subsets of primary and secondary (obtained by processing BMS/I) DF; $X^p=\{x_i^p\}$ – the set of DF which are measured with the patient; $D=\{d_k\}$ – the set of possible diagnostic states in a given subject domain; $D^p=\{D_i^p\}$ – the set of diagnostic conclusions of the patient; $S_X$, $S_D$ – the hierarchical structures of DF and diagnosable conditions; $M_a=\{m_{a_k}\}$ – the set of possible MA; $M_a^p=\{m_{a_k}^p\}$ – the set of MA that are assigned to the patient; $T=\{t_{SPX}, t_{SP^pX^p}, t_{X^pD^p}, t_{DM_a}, t_{D^pM_a^p}\}$ – the set of correspondences between the sets; $Q_t$ – the set of criteria of correspondences $t$. The $t_{SPX}$ sets the algorithm, and the $t_{SP^pX^p}$ implements the procedure of morphological analysis of

BMS/I[19-21] and forms a vector of secondary DF. The $t_{X^p D^p}$ implements diagnostic DR under control of hierarchical structures $S_X$ and $S_D$ [22]. The $t_{DM_a}$ sets the algorithm, and the $t_{D^p M_a^p}$ implements the procedure for prescribing MA to a patient with an established diagnosis[23]. Thus, the mathematical model of the patient's DThM is developed, with the help of which the formalization of knowledge formed as a result of all stages of processing is completed.

## 5. RESULTS AND DISCUSSION

The previously developed functional, structural and mathematical models are the basis for the development of the structure of the MDSS for the conduct of DThM[24]. The structural scheme of the MDSS is presented in Fig. 5.

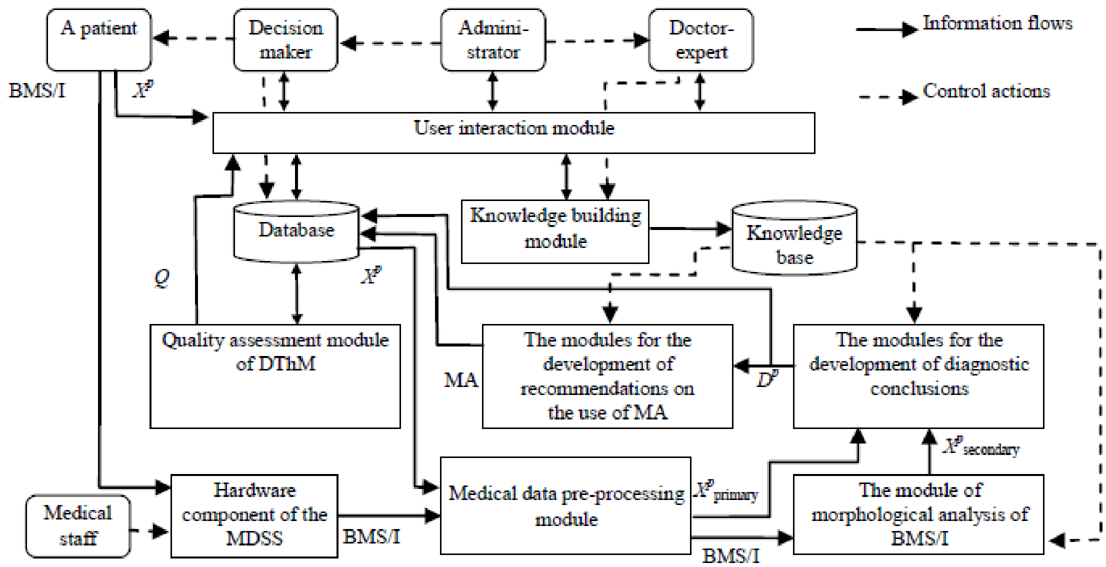


Figure 5. The structural scheme of the MDSS.

The database (DB) stores information about the patient and the results of his examinations, diagnostics, and prescription of MA, obtained BMS/I, various reference information (regulatory documents, forms of protocols, ICD-10 disease classifiers, etc.) and other information necessary for the functioning of the MDSS. Methods and rules for the transformation of information, including the morphological analysis of BMS/I, the formalization of input information, the development of diagnostic solutions and recommendations for the prescription of MA are stored in the knowledge base. The knowledge building module is responsible for the formation of knowledge frames represented by methods of morphological analysis of BMS/I, hierarchical structures $S_X$ and $S_D$, DR parameters, sets $f_{di}$, descriptions of drugs, and expert assessments regarding local and global priorities for analogous drugs. The medical data pre-processing module is designed to ensure the operation of the hardware component of the MDSS, input and storage of medical data, it performs standard processing methods, such as formalization of heterogeneous medical data, filtering BMS/I and so on, it performs the maintenance of the medical record of the patient, the formation and printing of diagnostic conclusions and recommendations on the use of MA. The user interaction module is represented by a graphical user interface and allows for the collection of examination data, BMS/I input, visualization of work results, data administration, and also the input of expert data that are used in generating knowledge of the system. The following types of users are defined: administrator, doctor-expert and decision maker (doctor-user). The administrator determines what powers to assign to other users, but does not have the ability to independently make changes in the DB and knowledge base, as well as to verify the system solution, since he is not a doctor. The greatest authority is owned by a doctor-expert. It has the ability to not only revise, but also correct the database, make changes in the knowledge base, and also correct the system solution. However, the main task of the expert is the formation of the knowledge base. The doctor-user has the opportunity only to revise the DB and, having entered individual patient data, to obtain a solution of the system regarding the diagnosis and the list of recommended MA. In addition, he is given the opportunity to make changes to the solution obtained by completing his verification. In the morphological analysis module, specialized methods of BMS/I analysis are implemented, as a result of which a vector of secondary DF is formed. The modules for the development of diagnostic conclusions and recommendations on the use of MA are designed to form the recommendations of decision makers and their arguments. The decision maker confirms or corrects the system decisions. In the quality assessment module various criteria for evaluating the performance of individual modules can be implemented.

## 6. CONCLUSIONS

There is developed an information technology of decision support when conducting DThM based on the formalization of stages and the development of a functional, structural and mathematical models of the diagnostic process and medical actions during their integrated assessment, which allows minimizing the risks of medical errors and increasing the reliability and validity of decisions. The transition from the traditional space of DF into the space of MA is carried out for a comprehensive assessment of the stages of the diagnostic and therapeutic process in order to minimize the risks of medical errors. Analysis of diagnoses in the space of MA allowed to solve the following tasks: to minimize the risks of incorrect decision making at the stage of diagnosis, taking into account their consequences at the stage of MA during the synthesis of the decision tree; to develop a method for calculating the threshold values of acceptable uncertainty intervals in the decision rule. The proposed functional, structural, and mathematical models made it possible to develop a generalized structural scheme of the MDSS of the DThM process. The modular principle of the system development allows not only to easily upgrade existing modules but also to add new modules necessary to integrate specialized software into existing systems and complexes. Further research is aimed at using a more complex presentation of MA, including, if necessary, ranking and numerical components, forming an appropriate space for the implementation of other types of medicinal actions (surgical intervention, medical-therapeutic effect, rehabilitation measures).

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