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INFORMATIONAL AND SOFTWARE MODULE "CLINASS" FOR REGISTRATION AND ABALYSIS OF CLINICAL DATA ABOUT THE PATIENT'S CONDITION

Introduction. Personalized medical care in clinical settings is an important factor for improving the provision of medical services. It is based on clinical indicators and the progression of the disease at the individual level, which makes it possible to get an idea of the dynamics of diseases and their treatment in different conditions of patients. The World Health Organization considers it necessary to use the methods and tools of digital medicine to implement the analysis of large data sets and calls for the use of digital technologies that make it possible to raise the level of medical care.

The purpose of the paper is to develop the information and software module "ClinAss" for registration and analysis of clinical data on the patient's condition based on formalized business processes of registration and analysis of data on the patient's health using classification models using Data Mining methods.

The results. To formalize the studied business processes, the definition of 1) participants in the process of accumulation and exchange of medical data in the infrastructure of digital medicine and 2) two types of sources of medical information about the patient are taken into account. Taking into account the characteristics of individual links of business processes and the sequence of processes of providing medical care, an information model for the implementation of business processes of registration and analysis of clinical data on the patient's condition in the infrastructure of digital medicine was formed.

According to the developed IT for classification of the patient's condition using a complex of filtering, clustering, and classification algorithms, rules for determining the stage of disease activity were formed. An appropriate classification algorithm was built according to these decisive rules, on the basis of which the "ClinAss" information and software module was developed for registration and analysis of clinical data about the patient's condition.

Conclusions. Formalized business processes for registration and analysis of patient health data define information flows for the optimal functioning of the medical data warehouse, to ensure their exchange between analytical specialists and doctors who use software modules and applications for the purpose of analyzing the health of patients.

The developed information and software module "ClinAss" is focused on the information interaction of different groups of users with the aim of analyzing the condition of patients during their treatment in clinical conditions using models of the severity of this condition, ensures the creation of a common information environment with the placement of a database about patients in a cloud storage.

Keywords: formalized business processes, medical data repositories, classification models, Data Mining methods, software module, clinical data analysis.

Introduction

Personalized medical care in clinical settings is an important factor for improving the providing medical services. It is based on the analysis of clinical indicators and the determination of the disease progression features at the individual level, which makes it possible to form an idea about the course of diseases and their treatment in different patients' conditions.

Digital revolution in personalized medicine and healthcare have seen recent years [1—5]. The World Health Organization considers it necessary to apply the methods and tools of digital medicine to implement the tasks of analyzing large data sets and calls on its member states to prioritize the development and use of digital technologies in the field of health care to promote universal coverage of medical care [6]. It is digital health, which is based on modern intelligent information technologies, will make it possible to raise the level of providing medical care to the population.

Modern directions of digital medicine are focused on the application of systems for multifunctional monitoring of patients' condition, the use of individual mobile health monitoring devices, but the problem of processing primary arrays of heterogeneous medical data for their analysis and interpretation is becoming even more relevant. One of the approaches to its solution is the development and application of information technologies using Data Mining methods.

Problem Statement

Traditional health assessments require visits to a clinic to have biosignals measured by professionals using special devices. However, it is often inconvenient and expensive to practice this among a wide population.

In turn, the developed digital devices are mobile (or portable) with fast data transmission wirelessly. This enables remote and non-invasive health assessments and encourages self-care for users.

The collection of a large number of medical parameters cannot be carried out without the use of mobile sensors, which automates the collection of large-scale data [7, 8], automatic de-identification of data, encryption and transmission makes it possible to compare personal data with population counterparts [9]. We emphasize that the automation of registration and collection of data on the health status of patients supports early disease detection, intervention and individualized treatment [10—12].

The need to combine various sources of clinical information (EHR, laboratory data, monitors, medical images) in the diagnostic process stimulates, on the one hand, data exchange technologies, and on the other hand, the application of data mining and machine learning methods to classify patients into risk groups and predict treatment results, mortality rate, disease stages, etc. [13-15]. The most common tools for intelligent data analysis (Data Mining) and IT development are such software products as: SAS Data Mining [16], Statistica Data Miner [17], WEKA [18], RapidMiner [19], Python programming environment, R, among which are available with open source. By its purpose, Data Mining is the process of identifying regularities in data arrays with subsequent use for health forecasting and decision-making [20].

The advantages of using Data Mining methods (in particular, decision trees) for the analysis of clinical data are due to the absence of requirements for the distribution of data and their type, as well as the possibility of interpreting the results, displaying the model in the form of a tree, the structure of which is determined by logical rules as the basis for the formation of decision rules for classification and diagnosis the state of human health.

The purpose of the paper is to develop the information and software module "ClinAss" for registration and analysis of clinical data on the patient's condition based on formalized business processes of registration and analysis of data on the patient's health using classification models using Data Mining methods.

Formalized Business Processes of Registration and 1Analysis of Patient Health Data

Accumulation and exchange of medical data in the infrastructure of digital medicine. For the optimal functioning of the medical data warehouse, to ensure their exchange between the data analysis specialist and the physicians who use the software applications for the analysis and forecasting of the

health status of patients, the first stage should be the accumulation of various medical data about the patient.

At this stage, in order to formalize the studied business processes, we identified the participants in the process of accumulating and exchanging medical data in the infrastructure of digital medicine, which require personal medical repositories [21] and identified two basic types of sources of medical information about the patient [22]:

1. the results of diagnostic studies, which were performed in any health care fasilities and verified by an authorized medical worker;

2. data and measurements received by the patient himself using mobile devices.

Taking into account the characteristics of individual links of business processes and the sequence of providing medical care, an information model of this technological business processes in the infrastructure of digital medicine was formed (Fig. 1).

We will provide a description of business processes for the accumulation and processing of medical data.

Stage 1. Collection of clinical data − indicators of the patient's condition according to a certain diagnosis. Acquisition of data from many patients (from 100 to 500 patients) in digital format from diagnostic devices. The data is depersonalized.

Stage 2. Formation of a database of patient health indicators:

▪ database integrity check;

▪ checking of log files and elimination of identified problems, if any;

▪ create/edit/delete users and manage access rights.

Stage 3. Registration of patients; entering and saving the results of examinations, patient studies.

Stage 4. Passing the authorization procedure; entry of doctor's notes; local protocol input.

Stage 5. Performing data analysis and forecasting based on Data Mining models. Comparison of prediction results with clinical data of a specific patient.

Stage 6. Receiving the results of the analysis to the doctor. The doctor's correction of treatment measures for a specific patient with the introduction of certain changes to local protocols.

Stage 7. To check the effectiveness of the results of treatment and rehabilitation measures, an analysis of clinical indicators is carried out.

Stage 8. Entering data into the database of medical records of patients, validated by a medical specialist.

Basic functions and requirements for the implementation of the accumulation algorithm. An algorithm for the personal medical data accumulation has been developed, which takes into account a set of functional capabilities of users, depending on the role of a specific participant. The main functions and requirements for the implementation of the algorithm for the digital medical data accumulation are based on the features of receiving medical information from various sources and the choice of targeting a certain group of users. Traditionally, healthcare, and especially the digital product development industry, has been focused on the healthcare provider. Taking into account modern challenges, it is necessary to change this orientation, switching attention to another group of users − to the patient. Such a patient-oriented principle has to begin to operate from the moment when the patient needs to use medical care. And first of all, patients need to have easy access to their own digitized medical records regardless of the environment they work in (low-tech or high-tech).

Analysis of Medical Data Based on Data Mining Models

For the analysis of medical data, for prediction and comparison of prediction results with the clinical data of a specific patient (see stage 5), the information technology (IT) of classification of the patient's condition was used [22]. The developed information technology for the classification of the patient's condition is based on the used Data Mining methods based on the processing of digital medical data (ECG, Echo-CG, laboratory data, doctors' records). A hybrid approach was used to develop models for determining the patient's condition (disease activity): a complex of filter-
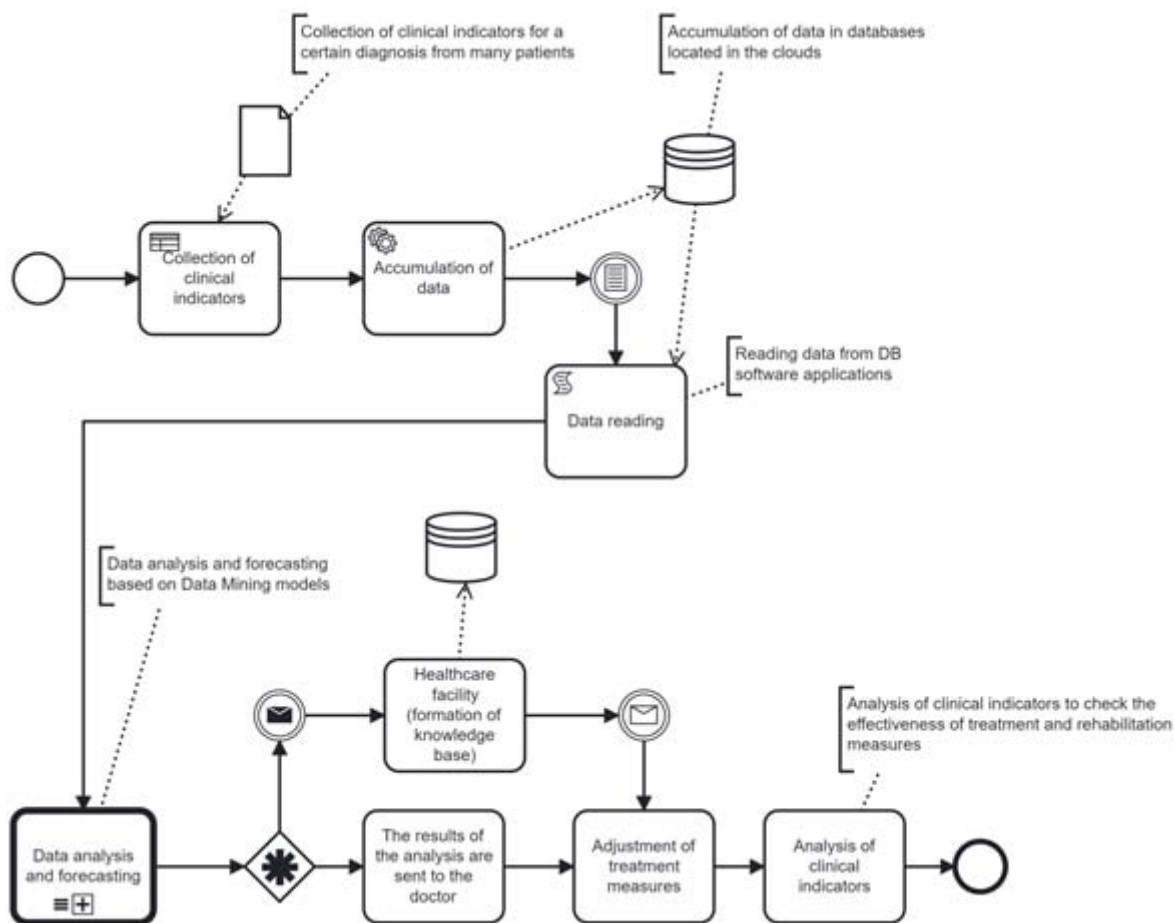
Fig. 1. An information model for the implementation of business processes of accumulation and analysis of medical data in the infrastructure of digital medicine

ing, clustering, and classification algorithms. The models were developed based on the integration of clinical databases into the STATISTICA Data Miner data mining environment. In the future, it is possible to use other platforms: SAS Data Mining, WEKA, RapidMiner, KNIME, Python programming environment, etc.

With the help of the developed IT, a set of informative ECG indicators was determined for evaluating changes in the patients` functional state. ECG and echocardiogram indicators − markers of cardiovascular disorders and classification signs of the patients' condition − were determined. For children with manifestations of inflammation of the connective tissue, the limit values of the condi-tion severity indicators, which are not included in the standard determining the activity of the disease JADAS (Juvenile Arthritis Disease Activity Score), have been determined. The rules for classifying the patients` condition (decision rules) were developed in the form of "if, then" based on a set of diagnostic indicators of ECG and Echo-CG.

Preliminary processing of the studied data includes their arrangement and structuring, filtering and determination of informative features.

Clustering algorithms based on sets of informative features are applied (to exclude non-representative learning). In the next step, the clustering results (identified subgroups) are used as training samples to develop classification models. Algo-

rithms of cluster analysis (k-means clustering, Fuzzy clustering), Hierarchical clustering were applied.

According to the developed IT [23], the ensemble of classification methods can include: logistic regression, SVM, decision trees (CART, Random Forest, Boosted decision trees), neural networks (ANN). In this study, the method of building a decision tree (CART, Random Forest, Boosted decision trees) was used.

Coordination and comparison of classification models was carried out according to classification efficiency indicators (Accuracy, F-score). Indicators of sensitivity, specificity, and predictive accuracy were calculated for each class. The number and composition of sets of classification features selected by different models were compared. The overall classification accuracy of different models (error) was compared, as well as the quality indicators for each class. The optimal model was selected based on the criterion of the highest classification quality and the smallest number of features. In case of unsatisfactory quality, it is possible to return to the previous stages using other methods of selecting subsets of features or selecting model parameters. The final result is the formulation, generalization and optimal composition of the found rules in the form of logical expressions.

The study is based on the results of laboratory and clinical examination of children with manifestations of connective tissue inflammation, expert values of disease activity were determined according to the Juvenile Arthritis Activity Scale (JADAS) [24] and compared with the analysis of informative ECG indicators detected by models: heart rhythm disorders, T amplitude in the II lead (Ampl. T wave amplitude (lead II)), integral indicator of the form of STT in lead II (Integral indicator of the form of STT (lead II)), QRS angle in the frontal plane (QRS alpha angle), T wave symmetry index (T wave symmetry ratio).

The target variable disease activity, had three gradations: 1 initial stage of activity (D1), 2 (D2), 3 (D3) subsequent stages of connective tissue inflammation.

The following decisive rules for the classification of the severity of the condition were formed:

• High disease activity level D3 =3:

if Sim T(I) > 0,57 and Ind STT ≤ 49,5 or Ind STT > 49 then D3=3.

• Middle disease activity level D2 =2:

Amp T(II) > 160,5 and QRS > 75,5 or Simm T(I) > 0,57) then D2=2.

• Low disease activity level D1:

if (SimT(I) ≤ 0,57 and Amp T(II) > 160 and QRS ≤ 75,5 or Amp T(II) ≤ 160,5) D1 = 1.

Therefore, the final result is classification rules based on an informative set of ECG indicators that determine the severity of the patient's condition. The procedures of the Data Miner module of the STATISTICA 10 package were used during development.

Implementation of the "ClinAss" Software Nodule

The "ClinAss" module are built taking into account the main functions that are implemented during the exchange of information and data between various participants of this process, as it is taken into account in the information model of the medical data exchange in the infrastructure of digital medicine created by us (see Fig. 1).

The structure of the "ClinAss" module in a generalized form consists of three main levels:

▪ central virtual storage (virtual data center that provides implementation of specified functions);

▪ remote administration segment (technical support and administration network);

▪ user segment (mobile devices and user-patient and doctor applications).

The remote administration segment includes administrators' workstations that ensure the work of administrative staff.

The above servers can function both on physical servers and in a virtual environment under the virtualization system control. In the first case, each server with corresponding functions works on a separate physical server, in the second case, a virtual environment is created on a physical server/ server cluster, in which, in turn, corresponding virtual servers are created. Also, in the case of building a system in a virtual environment, servers for creat-

ing and managing the virtual environment or separate management mechanisms must be provided

"ClinAss" Module Software

The "ClinAss" software module is a client-server application that operates with data in conjunction with a database management system.

The following server technologies are used:
- main programming language: PHP 8.0;
- server software: Apache 2.4.23 or Nginx 1.5.13;
- database management system: MySQL 8.0.17;
- additional package of functions: NET_HL7 1.0.1;

and client technologies:
- main programming language: JavaScript;
- the main markup language of the project: HTML 5;
- the main design language of the project: CSS 3 or CSS 4;
- additional libraries: jQuery 3.3.1, Bootstrap 4.0.

The information and software module "ClinAss" offered by us is built using the international standard HL7 CDA, is based on an electronic medical document, which structurally corresponds to the accounting form F.003.o "Medical card of an in-patient."

The application of the HL7 CDA standard makes it possible to formalize electronic medical records using RIM (Reference Information Model), which can be used to "pull up" the necessary directories and classifiers when creating medical records and documents.

The database structure ensures the formation of data for their further processing and exchange between different users and enables several users to work with this data in parallel. This database was created using SQL and is located on a virtual cloud. The architecture of the entire information and software module corresponds to SOA (service-oriented architecture), which enables the use of various applications at the same time.

Conclusions

Formalized business processes for registration and analysis of patient health data define information flows for the optimal functioning of the medical data warehouse, to ensure their exchange between analytical specialists and doctors who use software modules and applications for the analyzing the patients` health.

The developed information and software module "ClinAss" is focused on the information interaction of different groups of users with the aim of analyzing the patients` condition during their treatment in clinics using models of the severity of this condition, ensures the creation of a common information environment with the placement of a database about patients in a cloud storage.

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ІНФОРМАЦІЙНО-ПРОГРАМНИЙ МОДУЛЬ "CLINASS" ДЛЯ РЕЄСТРАЦІЇ ТА АНАЛІЗУ КЛІНІЧНИХ ДАНИХ ПРО СТАН ПАЦІЄНТА

Вступ. Персоналізована медична допомога в клінічних умовах є важливим фактором для поліпшення процесу надання медичних послуг. Вона базується на клінічних показниках і прогресуванні захворювання на індивідуальному рівні, що дає можливість скласти уявлення про перебіг захворювань та лікування за різних станів пацієнтів. Всесвітня організація охорони здоров'я вважає за необхідне застосовувати методи та засоби цифрової медицини для реалізації завдань з аналізу великих масивів даних і закликає використовувати цифрові технології, що дасть можливість підняти рівень надання медичної допомоги населенню.

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Метою статті було розроблення інформаційно-програмного модулю "ClinAss" для реєстрації та аналізу клінічних даних про стан пацієнта на основі формалізованих бізнес-процесів реєстрації та аналізу даних про стан здоров'я пацієнтів з використання класифікаційних моделей за методами Data Mining.

Результати. Для формалізації досліджуваних бізнес-процесів враховано визначення 1) учасників процесу акумулювання та обміну медичними даними в інфраструктурі цифрової медицини та 2) два типи джерел медичної інформації про пацієнта. З урахуванням характеристик окремих ланок бізнес-процесів та послідовності процесів надання медичної допомоги сформовано інформаційну модель реалізації бізнес процесів реєстрації та аналізу клінічних даних про стан пацієнта в інфраструктурі цифрової медицини.

За розробленою ІТ класифікації стану пацієнта з використанням комплексу алгоритмів фільтрації, кластеризації, класифікації сформовано віршувальні правила для визначення стадії активності захворювання. Побудовано відповідний алгоритм класифікації за цими вирішувальними правилами, на основі якого розроблено інформаційно-програмний модуль "ClinAss" для реєстрації та аналізу клінічних даних про стан пацієнта.

Висновки. Формалізовані бізнес-процеси реєстрації та аналізу даних про стан здоров'я пацієнтів визначають інформаційні потоки для оптимального функціонування сховища медичних даних, для забезпечення обміну ними між фахівцями-аналітиками та лікарями, які використовують програмні модулі та застосунки з метою аналізу стану здоров'я пацієнтів.

Розроблений інформаційно-програмний модуль "ClinAss" орієнтовано на інформаційну взаємодію різних груп користувачів з метою аналізу стану пацієнтів підчас його лікування в клінічних умовах за використання моделей тяжкості цього стану, забезпечує створення загального інформаційного середовища з розміщенням бази даних про пацієнтів у хмарному сховищі.

Ключові слова: *формалізовані бізнес-процеси, сховища медичних даних, класифікаційні моделі, методи Data Mining, програмний модуль, аналіз клінічних даних.*