A System for Remote Monitoring of Pregnant Women's Health State and Pregnancy Complications Prediction

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Keywords: Remote Monitoring, Instrumental Methods, Complex of Biomedical Signals and Indicators, Assessment of the Current State, Dynamics Analysis, Short-Term Predicting, Pregnancy Complication.

Abstract: The development results of the system for remote monitoring of pregnant women's health state and pregnancy complications prediction are discussed. A set of diagnostically significant indicators has been substantiated and formed to assess the current state, monitoring and control of pregnant women health and prediction of pregnancy complications. Four groups of indicators showing the functioning of cardiovascular and endocrine systems of the body, biochemical urine indicators, and indicators taking into account subjective assessment of the pregnancy course have been identified. To assess these indicators, a set of biomedical signals is proposed, signal acquisition tools and an automated questionnaire of a pregnant woman was suggested according to experts' recommendations. A method for forming an integral assessment by groups of indicators, considering the risk of pregnancy complications and weight of a diagnostically significant indicator, and a method for short-term predicting of pregnancy complications based on the dynamics analysis of various groups of integral indicators are developed. An experimental sample of the system was developed and its individual functions were clinically tested in order to assess the correctness of the proposed solutions. The results of the approbation are discussed.

1 INTRODUCTION

The problem of remote health monitoring has become very important for pregnant women due to the negative impact of viral diseases on the course of pregnancy. Against the background of the risks of pregnancy complications due to existing chronic non-infectious diseases, such as hypertension, diabetes, chronic obstructive pulmonary diseases, in the context of the Covid-19 pandemic, the risks of pregnancy complications increase sharply (Villar et al, 2021). The combined impact of negative factors has caused increased maternal mortality in almost all countries of the world. This trend has especially intensified in countries with a high incidence of Covid-19. The WHO statistics show the increase in maternal mortality in a number of countries up to 30% (Yap et al, 2020). Under the current conditions, the most effective way to reduce maternal mortality is to use remote monitoring of pregnant women's health state outside a medical institution and prediction of pregnancy complications for emergency medical care (Ryu et al, 2021; Hema et al, 2020). The remote dynamics monitoring of a pregnant women's health state using instrumental methods and tools and an automated questionnaire designed to quantify the dynamics of subjective feelings of a pregnant woman about her state of health, allows identifying negative trends in the health state of a pregnant woman and predicting pregnancy complications in the short term.

The study objective is to develop instrumental methods and system structure for remote monitoring of a pregnant women's health state outside a medical institution in conditions of active life and predicting pregnancy complications.

The tasks of the study are as follows:

1. Justification and selection of a set of diagnostically significant indicators and signs

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showing the health state and the course of pregnancy;
2. Justification and selection of a complex of biomedical signals required for the assessment of diagnostically significant indicators, methods of their acquisition and registration in remote monitoring conditions outside the medical institution;
3. Development of a method for remote monitoring of pregnancy and complications predicting;
4. Justification and development of the structure of the remote monitoring system and prediction of pregnancy complications;
5. Clinical approbation of methods for recording signals outside a medical institution and predicting health state conditions using an experimental sample of the developed system.

Methods and materials of the study. To assess, monitor and control pregnant women's current health state, instrumental research methods were used with small-sized portable devices: a biochemical analyzer for evaluating 11 urine indicators, a device for assessing blood sugar levels, an automatic coagulometer, a blood pressure meter, a spirometer and a pulse oximeter. When monitoring and controlling the health state of a pregnant woman and predicting the risk of pregnancy complications, the assessment frequency of the current health state was determined based on the significant indicators dynamics. To ensure high accuracy of the short-term prognosis of pregnancy complications, the trend equations of indicators were determined, after each next stage of assessing the current state, the trend equation was corrected. The experimental approbation of the proposed methods and remote monitoring system was carried out under the supervision of doctors with the involvement of patients who were at risk of pregnancy complications.

2 SOLVING RESEARCH PROBLEMS

2.1 Justification and Selection of a Set of Diagnostically Significant Health State Indicators

To carry out remote monitoring of a pregnant women's health state and predict pregnancy complications, a number of diagnostically significant indicators of the state of vital body systems were selected, changes in which primarily signal the presence of pathological processes in the pregnant woman's body. These indicators were selected considering the opinion of practicing specialists in the field of obstetrics and gynecology.

After studying of a pregnant women's health state parameters which must be monitored during pregnancy, a set of diagnostically significant indicators was formed. They can be divided into four groups:

1. The first group includes information about the health of a pregnant woman, parameters of her body, information about bad habits, allergic reactions, past illnesses, family and obstetric and gynaecological history. This information is necessary in order the doctor has a general vision about the health of a pregnant woman and characteristics of her body. This knowledge will make it possible to conduct pregnancy more effectively, consider cause-and-effect relationships, as well as prescribe medications, considering all characteristics of the patient.
2. The second group includes the results of analytical studies. Conducting a biochemical blood test allows to detect health disorders at an early stage. The key indicators are the level of haemoglobin, platelets, leukocytes, glucose and the level of blood clotting. These indicators help to identify such common diseases in pregnant women as anaemia, thrombosis, and gestational diabetes mellitus. It is also extremely important to conduct a biochemical analysis of urine which allows determining the level of protein in the urine (Korneeva, 2021). Proteinuria is one of the symptoms of such a dangerous disease as preeclampsia, which is associated with high maternal and perinatal mortality. Also, the biochemical analysis of urine determines the level of glucose, bilirubin, leukocytes, and relative density of biological fluids. These indicators contribute to the early identification of other dangerous diseases and clarify (supplement) the results of a biochemical blood test.
3. The third group includes indicators obtained during instrumental studies of the functional state of the main body systems. First of all, it is necessary to monitor the dynamics of changes in the performance of the cardiovascular system. During pregnancy, significant changes occur in the cardiovascular system, its load increases significantly, therefore it is necessary to monitor the reaction of blood vessels and the heart, especially in the case of various cardiovascular diseases before pregnancy. Blood pressure and

heart rate measurements are used for daily monitoring, and if deviations are detected, extended ECG studies are performed to make a diagnosis (Semenova et al, 2020). Due to the increase in oxygen demand, the load on the respiratory system also increases; this justifies the need to monitor the dynamics of the respiratory system state, primarily the lungs vital capacity. Together with the study of functional state indicators of the respiratory system, it is necessary to register the oxygen level in the patient's blood, since its decrease is one of the main symptoms of an ongoing infectious disease. In addition, it is necessary to monitor the body temperature of a pregnant woman, since its increase is an adverse symptom that may indicate the onset of infection.

4. The fourth group includes indicators of a pregnant women's current health state, which cannot be quantified using medical devices. Monitoring of these indicators is necessary when the results of an instrumental examination do not reveal conditions that threaten life and health of a pregnant woman, although she draws the doctor's attention to a feeling of discomfort. To eliminate uncertainty in such situations, the doctor tries to assess the subjective feelings of the pregnant woman's condition. An example of such indicators is the degree of swelling, which may be a sign of thrombosis or preeclampsia, the severity of toxicosis and the presence of gynaecological discharge, which may be a symptom of miscarriage.

The selected set of diagnostically significant indicators and signs will be used for the integral assessment of a pregnant women's health state, it will help to identify the presence of diseases in the early stages and predict pregnancy complications.

2.2 Justification and Selection of a Complex of Biomedical Signals Necessary for the Assessment of Diagnostically Significant Indicators

To form a complex of diagnostically significant indicators characterizing a pregnant women's current health state, data from analytical and instrumental studies are required.

Analytical studies in the clinic include the assessment of the biochemical studies complex of the blood and urine of a pregnant woman. During the research, the presence of markers of various pregnancy complications is analyzed, as well as the risks are calculated. In the conditions of remote monitoring, it is possible to conduct express analysis of biochemical parameters, namely: general biochemical analysis of urine by dry chemistry, as well as analysis of blood glucose, analysis of blood clotting indicators based on coagulometry. Analytical studies are used primarily to assess metabolic processes in the body and to identify disorders at early stages.

Instrumental research methods are used to assess the functional state of the main body systems of a pregnant woman. To assess the functional state of the cardiovascular system, a multifunctional wearable heart monitor is used, which provides the acquisition and registration of the ECG signal, blood pressure monitoring. It is used to assess the heart rate and heart rate variability at different levels of physical activity, the dynamics of blood pressure. A portable spirometer and pulse oximeter are used to study the state of the respiratory system. They provide an assessment of characteristics of the respiratory cycle and the dynamics of blood oxygen saturation. The assessment of the endocrine system state is based on glucose levels in the blood and urine of a pregnant woman and their comparison with reference indicators.

An important condition when choosing measuring channels and technical means for implementation of measurements is their compliance with the standards to the equipment for the provision of medical services in the field of obstetrics and gynaecology, which are regulated by regulatory documents, the certificate availability of state registration of a medical device on the territory of the country.

In accordance with the requirements, the following medical devices are used in the measuring channels:

-portable biochemical urine analyzer;
-portable biochemical blood clotting analyzer;
-portable heart monitor with automatic tonometer;
-portable spirometer and pulse oximeter;
-portable blood glucose meter.

The listed devices together provide monitoring and control of a pregnant women's health state according to the indicators listed above.

2.3 Development of a Method for Remote Monitoring of Pregnancy and Complications Predicting

Remote monitoring and control of a pregnant women's health state is carried out by periodically taking and registering biomedical signals and data outside the

medical institution, assessing the current condition of a pregnant woman by groups of diagnostically significant indicators showing the state of cardiovascular, respiratory and endocrine systems, biochemical indicators and markers of specific complications of pregnancy. Additionally, the assessment of the health state dynamics of a pregnant woman is carried out using an automated questionnaire developed on the basis of the approved form of a pregnant woman examination recommended by medical experts (Kramar et al, 2021).

Monitoring of a pregnant women's health state is carried out using the adaptive sampling method. The method consists in changing the frequency of data collection and subsequent assessment of the condition, based on the dynamics analysis of a complex of diagnostically significant health indicators, as well as the combined manifestation of signs of pregnancy complications (Adaptive sampling. US patent US2011/0066053A1). As soon as any of the monitored indicators reaches the norm limit it must be carefully monitored and the time intervals between successive measurements should be shortened. This approach is used to correct the trend equation in a timely manner and ensure high accuracy in predicting pregnancy complications.

Algorithms for processing the received data and subsequent assessment of the current state and dynamics monitoring of the pregnant woman's condition are based on the use of distributed signal processing technology. The first part of calculations is performed on a pregnant woman's wearable computer (smartphone), which is an aggregator of biomedical signals recorded from the patient from various sources of acquisition and registration of biomedical signals and data. The pregnant woman's wearable computer structures information and transmits it to the server of a medical institution. The second part of calculations related to the assessment of the patient's current condition, monitoring and control of the health state, and predicting pregnancy complications is performed on the server of the medical institution, and the results are transmitted to the wearable computer of the doctor in charge.

To assess the current health state of a pregnant woman the significance of each indicator is preliminarily assessed according to a set of diagnostically significant indicators. To do this, the method of hierarchy analysis is used, which consists in a hierarchical representation of a group of indicators that determine the health state of a pregnant woman. The decomposition of each group of indicators into simpler components is performed, i.e. into point indicators, and further pairwise comparison of specific medical indicators by a specialist in obstetrics and gynaecology. As a result, the relative intensity of the indicators interaction in the hierarchy is expressed numerically, i.e. the influence of each indicator on general health of a pregnant woman is indicated. The chosen method has high universality, it is easy to use but it requires deep involvement of experts in solving the problem, which reduces the likelihood of errors when using this method.

The algorithm for calculating weight coefficients using the hierarchy analysis method consists of the following steps (Schmidt et al, 2015):

1. Formation of goals hierarchy. A hierarchy is formed, the top of which is the goal to be achieved, or the essence of the problem. In our case, the top of the hierarchy is the assessment of a pregnant women's health state. The following levels present criteria that directly affect the achievement of the goal, i.e. groups of diagnostically significant indicators and specific indicators included in these groups.
2. Pairwise comparison of indicators by importance. For comparison, a ten-level scale of relative importance of elements is used, with the help of which the expert alternately compares the significance of each indicator relative to the others.
3. Calculation of local priority vectors. At this stage of the calculation, a preliminary conclu-sion is made about which of indicators is the most significant for assessing the health state.
4. Checking the consistency of local priorities. At this stage, the consistency ratio (CR) is calculated. If $CR > 0.1$, it is stated that the expert's judgments, on the basis of which the comparison of indicators was carried out, are inconsistent, which means that the second comparison should be carried out. Otherwise, the expert's judgments are accepted and the weight coefficients obtained in paragraph 3 are used for further operation of the algorithm.

Thus, it is possible to calculate the weight coefficients of each diagnostically significant indicator and assess their impact on the current health state of a pregnant woman. The complex consisting of more than 30 diagnostically significant indicators is used for an integral assessment of the pregnant woman health state.

According to the described method, the weights of the first hierarchy level of diagnostically significant indicators were calculated, i.e. the influence of each group of daily monitored indicators on the health of a pregnant woman was evaluated (Table 1).

Table 1: Weight coefficients of the top level of the hierarchy.

Top level	Fetal movements	Physiological indicators	Painful syndrome	Nausea and vomiting	Pathological secretions	Weights
Fetal movements	1	3	1	3	1	0,27
Physiological indicators	1/3	1	1/3	3	1/3	0,12
Painful syndrome	1	3	1	5	1	0,29
Nausea and vomiting	1/3	1/3	1/5	1	1/3	0,06
Pathological secretions	1	3	1	3	1	0,26
CR = 0,02						

The obtained values of the weight coefficients are used in the automated questionnaire for the integral assessment of a pregnant women's health state.

To monitor the current health state of a pregnant woman, it is necessary to consistently compare the values of each monitored indicator with the norm level and, if the value of the controlled indicator exceeds the critical level, send an alarm signal to the doctor. A decision tree is used to form rules for comparing the values of diagnostically significant indicators with threshold levels. The decision tree is a decision support tool used to identify logical patterns in data. The rule by which the decision tree functions in the trivial case is represented as "If A, then B". If there is more than one condition in the rule, then it takes the following form:

"If <condition 1> ∩ <condition> ∩ <condition n>, then <objective function>"

Moving along the tree from the upper level to the lower one, it is possible to determine the logical rules of the system functioning. This method was chosen due to the simplicity of its use and interpretation, since making a decision using a decision tree repeats the logic of a doctor when making a diagnosis.

A fragment of the decision tree, which is used in the daily assessment of a pregnant women's health state is shown in Fig. 1.

If any indicator exceeds the value of the "norm", this indicator is classified as "pathology" (marked in red) and is included in the report on the current health state of a pregnant woman, which will be sent to the attending physician along with an alarm. If the indicator deviates slightly from the norm or the indicator value is found on the norm-pathology border, it is marked in yellow, a report on the current state of health is also sent to the attending physician. In this case, close monitoring of the health status of a pregnant woman is required, repeated verification of this indicator after a while and consultation with the attending physician via cellular communication. If all indicators correspond to normal values, a pregnant women's current health state is classified as "normal", the generated report with the current values of indicators is stored in the database and can be obtained by the attending physician upon request.

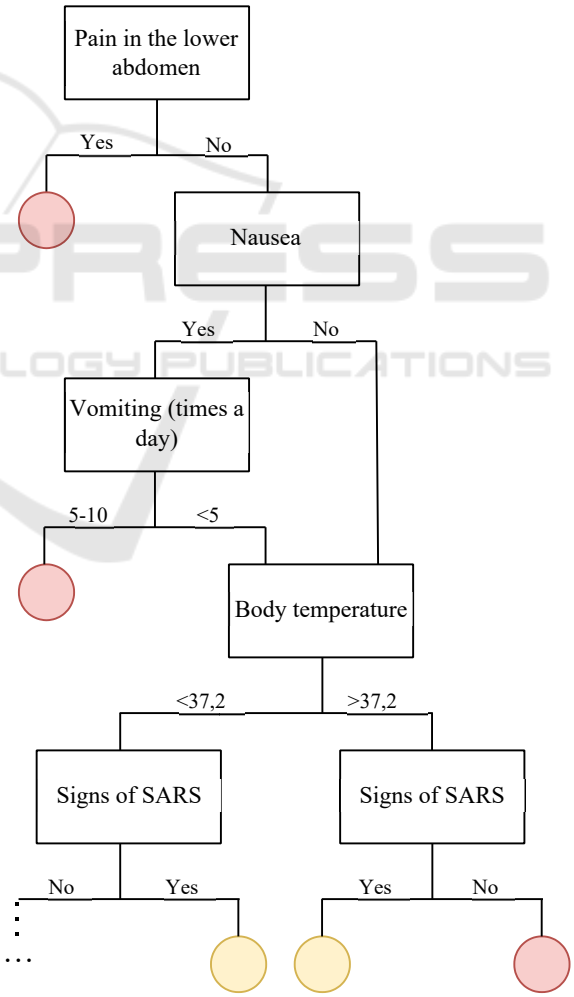

Figure 1: Part of the decision tree used in the daily assessment of a pregnant women's health state.

To predict the dynamics of a pregnant women's health state, the method of analyzing a time series of states based on the construction of a trend equation is used. Predicting is based on the assumption that the development pattern observed in the past will continue in the predicted future. At the same time, the level of the time series is formed under the influence of many factors, but the influence of each of them is not singled out separately. In this case, the development trend is not related to the factor, but to the time period. Predicting is carried out by groups of indicators. Before you start predicting, you need to make sure that the data are normalized. Next, an extrapolation procedure is carried out, that is, an extension for the future of the trend observed in the past. Further, by substituting the prediction period into the trend equation, a point estimation of the prediction is obtained at a specific time in the future, and the boundaries of a possible change in the prediction indicator are determined. The prediction result is also sent to the doctor, in addition to the main report on the patient's current condition.

2.4 Justification and Development of the Structure of the Remote Monitoring System and Prediction of Pregnancy Complications

For remote monitoring of a pregnant woman's health state and prediction of pregnancy complications, the system presented in Figure 2 is proposed.

The structure of the system consists of several levels (Yuldashev et al, 2017). At the first level, biomedical signals and data are collected and recorded outside the medical institution, providing a comprehensive assessment of the current state of the body on the principles of systemic medicine. At the same time, data is collected on more than 30 indicators, including indicators of the functioning of various body systems, such as the cardiovascular and endocrine systems, the respiratory system, as well as data from biochemical studies showing the dynamics of biochemical parameters of urine and blood clotting. At this stage, it becomes possible to identify individual features of the functioning of the body at all stages of pregnancy with the combined manifestation of various chronic diseases and exposure to external pathogens.

At the second level, information about the current health state of a pregnant woman is structured, considering the degree of diagnostic significance of indicators, correction of individual norm indicators, considering the combined manifestation of several factors of exacerbation of the disease, and a formalized description of a pregnant women's health state is compiled based on a set of diagnostically significant indicators. If necessary, biomedical signals received from measuring channels are pre-processed. The complex of diagnostically significant indicators is divided into groups according to the level of importance.

Structuring of information at the second level of the system is carried out in order to present it to the doctor in a form convenient for subsequent analysis and to reduce the level of medical error. Using of the automated questionnaire allows to quantify the dynamics of the pregnant woman's condition. The data of the automated survey of a pregnant woman consist of both rank variables showing her feelings about the signs of pregnancy, which cannot be quantified, and quantitative variables obtained using instrumental means. In the process of processing the results of an automated survey, rank variables are converted into quantitative ones using methods of qualimetry, and an integral self-assessment of the state is formed (Mabikwa et al, 2017).

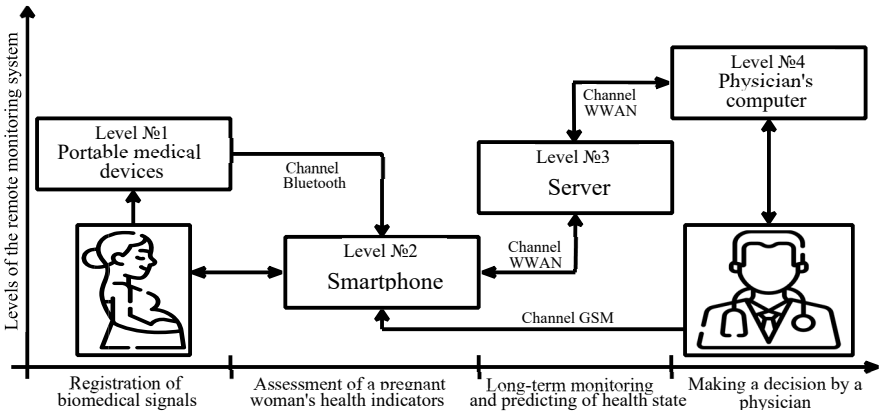

Figure 2: Generalized structure of the system for remote monitoring of pregnant women's health state.

This quantitative assessment is necessary solely to reflect the dynamics of the health status of a pregnant woman in some metric scale. The answers obtained allow the doctor to assess the subjective state of the pregnant woman, which is an important diagnostic sign of a number of diseases, since in some cases it is impossible to fix the presence of pathology with the help of available tools.

To predict the dynamics of the condition and the possible development of pregnancy complications, a trend line is preliminarily constructed, which allows predicting the borderline state and the state of complications of pregnancy, considering the combination of the influence of factors aggravating the complication of its course. Predicting is performed by groups of diagnostically significant indicators with a frequency sufficient to obtain sufficient results.

It is known that for the state of the physiological norm, biomedical indicators showing the processes occurring in the human body describe oscillatory processes (daily, weekly, monthly) within the individual norm. It is characterized by lower and upper boundaries. These processes can be described by a set of harmonic functions, each of which will describe the dynamics of indicators during the day, week, month. When exposed to any factor that causes a complication of the course of pregnancy, there will be a trend in the dynamics of the indicator. It will show the transition from the state of an individual norm to a qualitatively new state. In the first approximation, this trend can be described either by an exponential dependence, in which the time constant of the exponent will show the duration of the transition process, or by a Taylor series describing the trend dynamics function of a significant indicator. The prognosis of complications of pregnancy is the likely achievement of an undesirable state of health, characterized by a set of indicators, for a certain period of time. It is obvious that improving the accuracy of the predict, if an undesirable trend of significant indicators is detected, it is necessary to reduce the time between the intervals of evaluating the indicators of the current state. It will allow us to estimate discrete values of trend dynamics and derivatives of the Taylor series with greater accuracy. When solving the problem under consideration, of course, we are talking about a short-term predict for several days, a maximum of a week. As the predict time increases, the probability of reaching the threshold values of the indicators will decrease.

2.5 Clinical Approbation of Experimental Sample of the Developed System

For experimental testing, a measuring channel was selected that collects data on the dynamics of biochemical parameters of urine. There are many portable biochemical analyzers on the market that allow you to conduct a general urine analysis at home. For testing and subsequent inclusion in the hardware and software complex, a portable analyzer was selected that allows assessing the patient's health status based on a set of 11 indicators:

1) glucose (GLU);
2) bilirubin (BIL);
3) relative density (SG);
4) pH;
5) ketone bodies (KET);
6) hidden blood (BLD);
7) protein (PRO);
8) urobilinogen (URO);
9) nitrites (NIT);
10) leukocytes (LEU);
11) ascorbic acid (VC).

To study the effectiveness of the device, as well as to assess the accuracy of the results obtained (in comparison with laboratory analysis) and the feasibility of including the device in a remote monitoring system, daily urine tests of a healthy person were conducted for a month. Figure 3 shows a summary graph of changes in the studied part of indicators during the month.

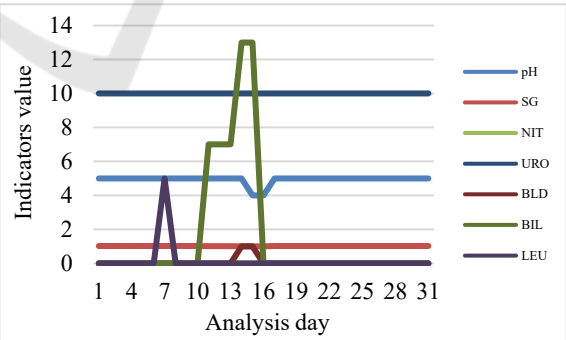

Figure 3: Changes in the biochemical parameters of urine.

Based on the summary data, it is possible to identify some patterns in the patient's health state. For example, it can be seen that the levels of indicators such as urobilinogen (URO), ketones (KET), glucose (GLU), ascorbic acid (VC) and nitrates (NIT) remained close to zero throughout the study. At the

same time, the graph shows a jump in indicators such as latent blood (BLD), protein (PRO), relative urine density (SG) and urine pH. Outliers are observed for five days, which corresponds to the period of critical days in the subject. After the end of this period, the indicators return to normal limits until the end of the study. There is also a one-day outlier in the number of white blood cells (LEU), which corresponds to the recovery period after the introduction of the tested vaccine against COVID-19 a day earlier.

In order to understand the degree of accuracy of a separate study, a urine analysis of the subject was conducted in parallel in the laboratory. Comparative data of the analysis are given in Table 2.

Table 2: Comparative analysis of biochemical parameters of urine.

Urine indicators	Data from the portable analyzer	Data from the laboratory analyzer
Urobilinogen	<16 mkmol/l	10.7 mkmol/l
Hidden blood	Negative	Negative
Bilirubin	Negative	Negative
Ketone bodies	0 mmol/l	0.35 mmol/l
Leukocytes	0	1
Glucose	Negative	Negative
Protein	Negative	Negative
pH	5	4.9
Nitrites	Negative	Negative
Relative density	1.020	1.012
Ascorbic acid	Negative	Negative

Comparison of the results obtained using a portable analyzer and a stationary analyzer in the laboratory service allows us to identify minor differences in three indicators: urobilinogen, leukocytes and ketones. However, the differences in them are insignificant and do not affect the overall interpretation of the analysis results. Therefore, diagnostics with the help of the analyzer under study provides accuracy comparable to laboratory analysis.

3 CONCLUSIONS

The problem of remote monitoring of people's health has become especially actual at the present time due to many factors, including the spread of dangerous viral diseases. Especially the changed living conditions and the provision of medical care affected pregnant women, greatly increasing the mortality rate among the latter. The result of the study is a generalized structure of the system that will allow monitoring the condition of a pregnant woman remotely, without reducing the quality of observation and medical care using instrumental research methods and an automated questionnaire. The development of an experimental sample of a remote monitoring system using certified portable devices and medical systems has been carried out. Clinical testing of measuring channels of the remote monitoring system was carried out, its effectiveness in remote monitoring conditions was proved. The results obtained allow us to conclude that in the conditions of isolation, self-isolation of a pregnant woman, remote monitoring of a pregnant women's health state and prediction of pregnancy complications can solve the problem of monitoring the health status of a pregnant woman and avoid pregnancy complications. Certainly, such monitoring and monitoring of a pregnant women's health state is inferior in effectiveness if the patient were observed in a clinic. There is no other alternative outside of clinical conditions, and remote monitoring technology should be further developed in the direction of improving the quality of predicting complications. The results of the study allow us to summarize the experience of developing and using remote monitoring systems for further development of the technology.

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