Status of creation of hardware-software complex of automatic control of the insulin delivery

P.I. Tutubalin[1], S.V. Novikova[1], V.V. Mokshin[1]

[1]Kazan National Research Technical University named after A.N. Tupolev – KAI, K. Marx street 10, Kazan, Russia, 420111

Abstract. The article discusses issues related to the prospects for the implementation of the idea of creating a hardware-software complex for automated regulation of insulin delivery. Today, there are drugs that allow people to live relatively comfortably even with the most severe types of diabetes. The main difficulty of insulin therapy is that it is necessary to constantly (at any time, day or night) to carry out the procedure of control and regulation of the introduction of the drug into the patient's body. Unfortunately, not all patients are able to perform it properly. The ideal solution could be a system that performs all these actions automatically, without the participation of the patient. Therefore, the implementation of the idea of creating a hardware and software system for automatic regulation of insulin delivery using the program-adaptive control scheme is relevant. The article forms the general requirements for an approach capable of providing safe medical care for people with type 1 diabetes. The requirements to which the hardware-software complexes of automatic regulation of insulin delivery must correspond are formulated, their block diagram is presented.

1. Introduction

Today, there are more than 34 million people in the world suffering from insulin-dependent diabetes mellitus (type 1 diabetes). More than 1 million patients live in Russia, of which more than 10 thousand in Tatarstan. According to the Diabetes Institute "Endocrinological Research Center" of the Ministry of Health of the Russian Federation, this figure increases annually by 6% [1].

The most physiological method of administering insulin for diabetics is the insulin pump (insulin pump), however, the delivery of insulin is manually controlled by the patient himself, and it is almost impossible to achieve perfect compensation. According to a study on diabetes mellitus compensation in adolescents [2], only 13% of patients are fully compensated (stable maintenance of blood glucose level, as close as possible to normal values), 16% are in a subcompensation state (intermediate state between compensation and decompensation). The overwhelming number of patients - 71% - are decompensated (a condition in which the blood sugar level is not amenable to correction with drugs, as a result of which severe lesions of many systems and organs of the patient develop).

One of the temporary solutions to this problem is to create a system that simulates the algorithm of a healthy pancreas. Such a system should, on the basis of data on the level of blood sugar and physiological features of a particular patient, automatically calculate the required dose of insulin and inject it into the patient's body. At the same time, it makes sense to design and develop such a system as a subsystem of a comprehensive automated system for collecting, storing, processing information and adaptive management.

Separately, we note that an artificial intelligence (AI) block, which is responsible for various aspects of control, can be included in such an ambient system, but due to the lack of stable and, above all, safe AI samples, we still offer purposefully and deliberately limited to AI, and software-adaptive control ("intelligent" unit).

Let us formulate the requirements for such a system as a whole and for a possible hardware and software complex for the automatic regulation of insulin delivery in particular.

2. Requirements for the binding system of hardware-software complexes for automatic regulation of insulin delivery

We formulate the basic requirements for the binder system:

1) Minimum risk for the patient, provided by relying on modern standardized and optimized algorithms for specialized medical care for diabetics.

2) Convenience of targeted use (preservation of the patient’s state of compensation for an arbitrarily long period of time while observing and fulfilling a certain list of requirements).

3) Availability (in the sense of acquiring or receiving by quota, that is, if the personal hardware-software complex for automatic regulation of insulin delivery is too expensive or too difficult to manufacture, then it will become practically useless and the binding system will be idle without need).

4) The possibility of interfacing with modern means of communication (mobile devices, computers, etc.).

5) The ability to provide viewing and collecting data on the patient's condition (patients) directly from the patient's personal device and indirectly remotely. It should be noted the need to ensure high reliability and efficiency of such data, which can be achieved using appropriate models, methods and approaches [4].

6) Availability of the necessary interfaces for viewing the collected data and the possibility of their on-line processing, analysis and provision of the processing results to interested persons who have the appropriate permission for this with the use of modern computing tools [4]

7) Ensuring the required level of information security [3].

In general, a huge number of current existing automated systems for collecting, storing and processing information fall within these requirements, but the medical specificity of the problem under consideration introduces its own characteristics in the design and development of such a system, or rather, in the design and development of an automated feed control software insulin (especially its interfaces to the ambient system).

First, we will present a sketch of the structural diagram of such a cohesive system of complexes, Figure 1.

In Figure 1, the following notation:

CQS - communication and query server;

P_1, ..., P_N - patients with insulin-dependent diabetes mellitus (type 1 diabetes);

PCD_1, ..., PCD_i, ..., PCD_N - a personal compensation device, that is, ensuring stable maintenance of the level of glucose in the blood, which corresponds most to the normal values for a particular patient;

M_1, ..., M_R - medical workers who, either remotely or in direct personal contact with the patient, monitor and possibly change the settings of the onions of one or several patients;

DPS_1, ..., DPS_S - patient data processing servers;

DB_1, ..., DB_Z - databases that store patient data;

L_1, ..., L_V, ..., L_U - persons who have the necessary and sufficient resolution, as well as access to relevant interfaces to view the collected patient data, the possibility of their prompt processing, analysis and obtaining the results of this processing. The circle of such persons may include attending medical workers, researchers of new treatment algorithms and their testers, as well as ordinary patients, but only in exceptional cases.

In these theses, we will limit ourselves for the time being only to the fact that we will proceed to the formulation of requirements for personal compensation devices (PCD), which are essentially hardware-software complexes for automatic control of insulin delivery to a particular patient, in the presence of specialized input and output interfaces. information through them and from (to) them.

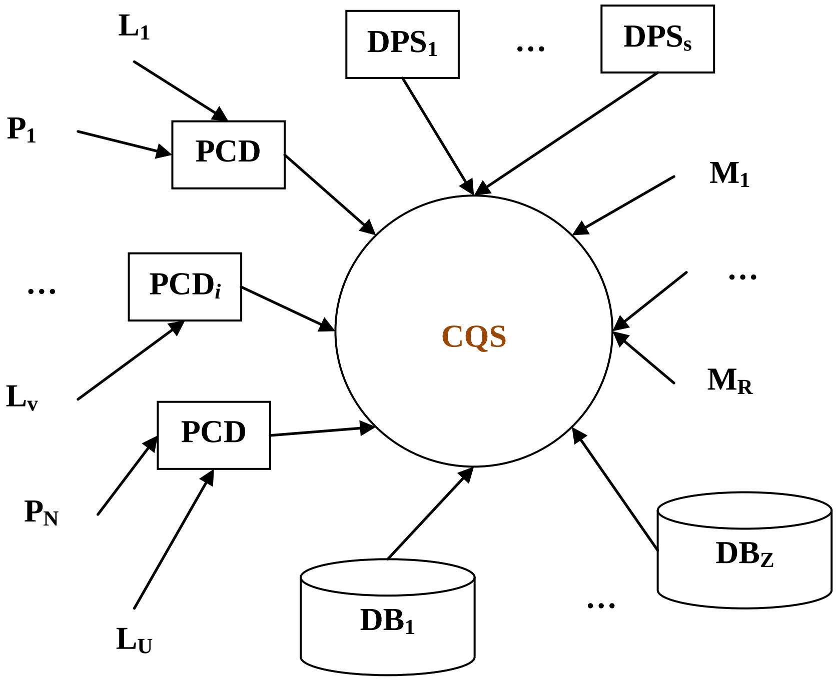

Figure 1. Block diagram of the connecting system of hardware-software complexes for automatic regulation of insulin delivery.

3. Hardware-software complex for automatic regulation of insulin delivery

Specify requirements for PCD.

1) the subsystem should be executed from blocks with clearly defined functionality;
2) each unit of the subsystem must have the ability to function autonomously;
3) component parts of the blocks should be produced in series;
4) the component parts must be of domestic production;
5) all components of the units must be obtained state certificates for the possibility of their use for medical purposes.

We will offer one of the layout options for the PCD, the hardware-software complex of automatic regulation of insulin delivery can consist of three main blocks:

1) a sensor measuring the patient's blood glucose level;
2) an insulin pump that provides continuous administration of the drug subcutaneously through a catheter;
3) an “intelligent” block linking all components into a single closed loop system.

The “intelligent” block noted in the third item of the list should receive data from the sensor, calculate the required dose, taking into account the physiological data of the particular patient entered into it, and generate a control signal for the insulin pump to administer the calculated dose.

The first two components - the sensor and the insulin pump - are usually serial standard medical products, and are freely sold or provided to diabetics in the Russian Federation, which ensures that requirements one and two of the above list are met.

There is a problem associated with the design and development of an "intelligent" unit, such a unit is called the " Artificial Pancreas System" (APS).

The hardware part of the “intelligent” unit can be assembled from standard components based on a microcomputer and a radio card transmitting a radio signal.

Here, the "intelligent" block is understood only as a software-adaptive control scheme, which in reality does not allow for the provision of an intelligent control scheme. But in view of the fact that in the future this block may actually be endowed with intelligence, we are already using the phrase “intellectual” block. ”

We present a block diagram of the hardware-software complex of automatic regulation of the supply of insulin (PCD), Figure 2.

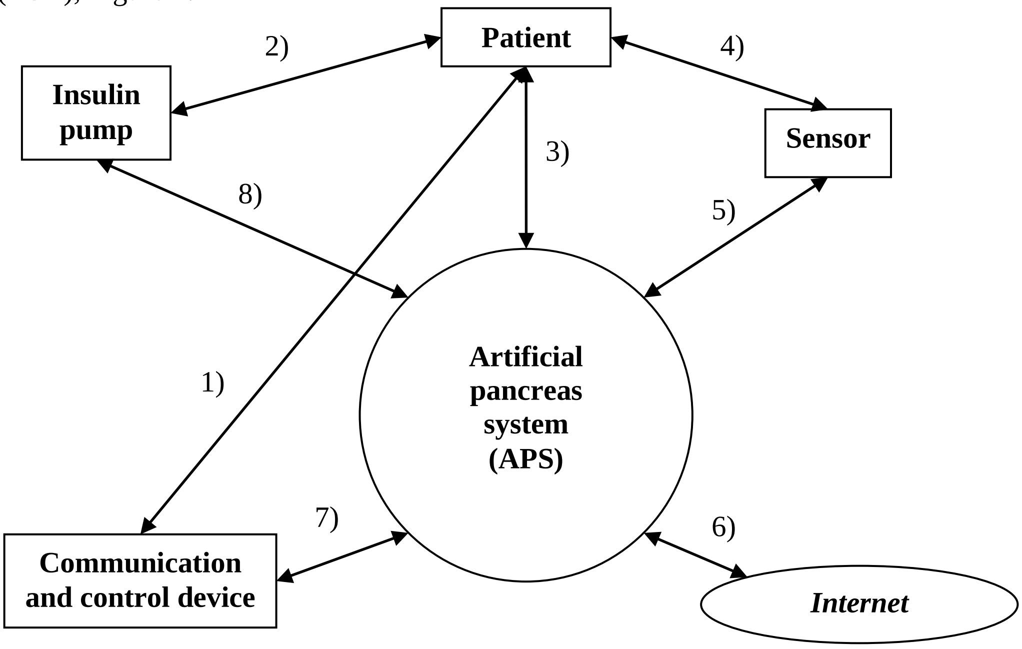

Figure 2. Block diagram of the hardware-software complex for automatic regulation of insulin delivery (PCD).

Let us briefly explain the figures in Figure 2 - a term that has not previously been encountered in the article, and arrows marked with numbers:

communication and control device - a mobile device of the patient, either a health worker or a researcher with the ability to access the Internet, use wireless networks, Bluetooth data transmission channels, which is equipped with an interface to the APS for control (which also provides for the analysis of the patient’s state over time, any reports related to the data collected on the patient's condition and on the functioning of the APS) to her directly and with the insulin pump indirectly through the APS; A personal computer can also act as such a device, which can additionally allow using the interface to the APS via a twisted pair wired network;

arrow 1) - the ability of the patient through the communication and control device to obtain the necessary permissible and secure access to the APS through one of the available communication channels with him;

arrow 2) - the ability of the patient through the interface of an insulin pump to influence its mode of operation, as well as, if necessary, change it to any other;

arrow 3) - reflects the possibility of a direct (through some physical port) connection of the patient to the APS for service purposes if he has the appropriate qualifications and admission in exceptional cases;

arrow 4) - shows the physical process of measuring the patient's blood sugar level by the sensor;

arrow 5) - shows the process of transmitting information about the level of sugar in the patient's blood received by the sensor in the APS;

arrow 6) - shows the ability of the APS to connect to the Internet or some other computer network, it’s natural that in this case the modules and blocks for ensuring the required level of information security of the PCD as a whole should be introduced into the APS software;

arrow 7) - indicates the presence of a physical channel for the exchange of data and commands between the ICG and the communication and control device;

arrow 8) - indicates the presence of a physical channel for the exchange of data and commands between the ICH and the insulin pump.

Summarizing the intermediate result, it can be stated that the software of the APS and the communication and control devices should provide a number of the following general functions:

1) Control functions:

a) Remote control of an insulin pump in real time in automatic and manual modes from a communication and control device.

b) Managing the parameters and modes of operation of the ICH from a remote communication and control device (via the Internet).

2) Monitoring functions.

a) Viewing data about the patient's blood sugar level in real-time in dynamics on a remote communication and control device (via the Internet).

b) Viewing data on the status and parameters of the insulin pump on the communication and control devices.

4. Conclusions

The article formulates an approach to the development of a hardware-software complex for the automatic regulation of the supply of insulin into the body of a patient with type 1 diabetes. The lists of requirements for the system of a set of such devices (complexes), for the complexes themselves, for their software were determined, the main functions of the software of these complexes were also determined.

5. References

[1] Dedov, I.I. Epidemiology of diabetes mellitus in the Russian Federation: clinical and statistical report for 2016 according to the federal diabetes registry / I.I. Dedov, M.V. Shestakova, O.K. Vikulova // Diabetes Mellitus. – 2017. – Vol. 20(1). – P. 13-41.

[2] Hirsch, Ya.V. Mother and Child in Kuzbass. – 2005. – Vol. 2. – P. 40-42.

[3] Tutubalin, P.I. The Evaluation of the cryptographic strength of asymmetric encryption algorithms / P.I. Tutubalin, V.V. Mokshin // Second Russia and Pacific Conference on Computer Technology and Applications (RPC), 2017. – P. 180-183. DOI: 10.1109/ RPC.2017.8168094.

[4] Yakimov, I. The comparison of structured modeling and simulation modeling of queueing systems / I. Yakimov, A. Kirpichnikov, V. Mokshin, Z. Yakhina, R. Gainullin // Communications in Computer and Information Science (CCIS). – 2017. – Vol. 800. DOI: 10.1007/978-3-319-68069-9_21.