Biosensors as Emerging Market: Obstacles to Implement
Russian Case

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Abstract: We discuss the modern trend in high tech medicine connected with biosensors implementation. Though this technology being mature with a number of interesting technological and/or scientific solutions, the corresponding market has not been formed yet. In our work we try to summarize the obstacles for biosensors implementation using Russian Federation as an example of a country with strong governmental support for health care system. We argue that biosensors implementation should give rise for more proper monitoring and data handling, providing more correct choice of treatment, but should not be regarded as medical solutions.

1 INTRODUCTION

The modern pace of high technology development inevitably raises the question of its practical application, and medicine is one of the most promising areas. In particular, the general trend of devices miniaturization and progress in data handling have led to the possibility of developing biosensor systems used for the treatment and diagnosis of social diseases. Currently, the increasing worldwide attention is given to the prospects of usage of implantable sensors that register the parameters of human body.

In Russian Federation, the implementation of high-tech medicine service into reality is listed as government priorities, with special attention paid to the development of distant medicine. The need for such development is due to several reasons: first, an aging population and the associated rapid growth of health care costs, second - the growing shortage of qualified medical staff, third - the technical readiness for such devices production, and fourth - the defence needs.

We conducted a study of probable biosensors that could be implemented in Russia. The focus of our work was given to devices and approaches aimed at reducing mortality in the following areas: diseases of the cardiovascular system, control blood sugar levels, the disease of the gastrointestinal tract, and timely medication to the patient (drug delivery).

As a result of our work we formed a list of ready-to-produce devices that are in demand on the Russian market. This work is still under progress, and we are searching for new devices that could be implemented. Hereafter we present the results of our work as of 1 September 2013.

Totally about 150 companies were considered. It was found that following companies are the leading manufacturers and suppliers of implantable cardiac pacemakers and defibrillators: Medtronic, Boston Scientific, Biotronik and St. Jude Medical. Leading manufacturers and suppliers of implantable neurostimulators are Medtronic, and St. Jude Medical. These four companies account for 56 selected technical solutions while all other companies produce only 28 items.

Russian companies provide original solutions exclusively to the diagnosis and treatment of diseases of the cardiovascular system. Three main companies were identified - The Bakulev Center for Cardiovascular Surgery (Bakulev CCVS) of the Russian Academy of Medical Sciences (RAMS), Federal State Unitary Enterprise "IMZ" and "Kardioelektronika" Ltd. We also found several commercialized solutions for gastrointestinal tract diseases (particularly endocapsule "Lily of the Valley", developed by specialists of the Moscow

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Engineering Physics Institute). Though many Russian companies are said to operate in the field of high-tech medicine, we found that actually only 14 companies should be taken into account.

Major domestic results are still in the category of research, not many of them are ready for practical implementation. Thus, the analysis of 250 Russian projects under the Federal Target Program "Research and development on priority directions of scientific-technological complex of Russia for 2007-2013" revealed just 39 projects related to biosensors, and only 3 of them were proved to be ready for practical implementation.

Our short list of practical solutions contains 51 devices dealing with cardiovascular disease (market leaders - pacemakers, 43 items), 8 devices dealing with gastro-intestinal tract problems, 4 devices for blood sugar levels control, 10 neurostimulators (5 of them - at the stage of clinical trials, awaiting approve from FDA), and 11 other devices (typically - a targeted drug delivery system).

Comparative analysis of health care financing in the United States, Russia and other countries shows that the level of funding in Russia is about 20 times lower than in the U.S. The Russian market of mobile biosensors by 2015 will be about 1.5-2% of the world (with the prospect of up to 3%), i.e. will be largely a niche market with no significant export prospects (unless special measures are taken, such as production localization, building a cooperation research-production-implementation via governmental demand).

The expected growth in the Russian biosensors market is expected to be rather high, (about 10% in 2014-2017), with gradual decreasing (down to 5% after 2017). In this case, based on the market size of $ 300 million to date, by 2015 the expected volume will be 585 million, in 2020 - 845 million (18 and 26 billion roubles, respectively). Under certain conditions (first of all - managerial) distant market medicine in Russia in 2020 could amount to 70 billion roubles.

2 OBSTACLES TO IMPLEMENT

This forecast is however rather uncertain. Most analysts suppose the very problem is technological, and do not take into account obstacles that would arise after the device is ready for fabrication. During our study we encounter a number of obstacles that prevent biosensors to become the large-scale market in nearest future. This does not mean the impossibility to produce such devices, but rather refers to their usage and/or consequences that we suppose would be very different from ones expected now.

2.1 Technological Issues

First, let us consider problems derived from technological aspects. At present, modern advances in technology allow the design and implementation of very complex integrated microscale systems, including MEMS and labs-on-a-chip for biological applications. By a complex system we should understand a system that includes components from different physical domains and their behaviour is not obvious from the behaviour of their components. BioMEMS are true complex systems in this sense. They perform multiple functions and they combine elements from different physical domain. Therefore, there will be a number of difficulties in the fabrication and applications of BioMEMS that arise from their complexity and are typical for other MEMS devices. On the other hand, there will be specific issues related to the presence of biological agents and biological functions performed by BioMEMS.

Among the general difficulties from the first group, we should mention the following:

- The lack of tools for the complete modelling and design of BioMEMS. In addition, we still need to develop the understanding of their behaviour on the system level. This will become an issue in the next years since the modern technology allows the fabrication and integration of extremely complex and multi-function systems;
- Issues related to the reliability, lifetime and long-term stability of used materials and the dependence of their properties on the environment;
- The reliability and lifetime issues can be expanded specifically to BioMEMS. BioMEMS are particularly sensitive to short-term and long-term material stability issues. The materials used for BioMEMS as reacting agents must be biocompatible and highly selective. (i.e. the material must accurately quantify a selected bio-agent in the environment where many other bio-agents can also be found). The materials used for BioMEMS structure and wafers must also be biologically stable and compatible and resistant to oxidation;
- The lifetime of material/devices is also a very sensitive point. Particularly for implanted

bioMEMS when there is no possibility to replace the device too often;

- Since we mentioned implanted BioMEMS (which are impossible to access too often to replace batteries), effective power supply is another problem;
- It is widely argued if the device could operate independently or if it should be controlled by an operator. At any case this issue requires a stable connection and/or synchronization with PC.

It is important to understand that due to the complexity of such systems, designers have to address numerous issues: packaging, material selection, energy efficiency, signals acquiring and processing, biocompatibility and etc. There are many researchers that tackle these issues at different levels. For instance, material reliability/selection is solved by introducing new materials. Lifetime and power consumption is solved on the engineering side by introducing low-power efficient control circuitry and energy harvesting from human/environment motion. Signal processing – by improving the algorithms that allows to analyse sparse or distorted signals. Finally modelling and design is a multi-disciplinary area addressed by researches in the area of physics, engineering biology and mathematics.

2.2 Data Handling

Most biosensors work with numerous data obtained from human body and handling it is a great challenge.

First, by now most biosensors work as devices individually adjusted in any chosen case. That means the necessity of individual data handling. Second, it is still not clear what data is sufficient. How much information should be collected? And if we gather all possible information, is it possible to transmit and analyse it? What part of data could be lost without serious consequences? Third, if a biosensor is supposed not to only monitor, but also to act as a therapeutic tool, the question is what algorithms should be used to take the decision? And to what extent could we transfer this option from a man to the computer?

All these issues are not new, and most of them have been successfully solved in other areas (decision making, data processing, etc.), but in case of biosensors one should take into account that most information is private or can be supposed to be private, that restricts its usage.

2.3 Ethical Aspects of Biosensor Implementation

In our opinion, in Russia in the near future two problems with moral and ethical aspects of the use of biosensors will manifest: on the one hand - populist and unexamined, but vibrant domestic "threats", and on the other - articulated long-term questions from abroad (where this problem has been studied for a much longer time). The first will be as permanent bursts, in which interest will be warmed up by certain quarters for their own purposes (political or financial), the second - will be the limiting factor in a number of research, development and implementation for the Russian market.

Let us list a number of basic problems of moral and ethical plan, relevant in Russia:

First, it is a threat to establish total control over the person from the state or medical services. In the Russian emphasis it is the suppression of the individual, while in the West the problem is considered from the point of view of the loss of human autonomy and the loss of personality.

Secondly, the problem “end justifies the means”. This problem is always neglected in Russia, but is a key issue for Western professionals: what is to improve a man? Where man ends and a machine starts, if any? It continues to the general concept of life and death in the concept of modified human. Is it ethical to interfere in the future?

Third, issues related to information security (that is very closely connected with data handling problems). What information collected by biosensors, is ethical? What information can and should be collected? Should we limit the collection of information? There is no doubt that the widespread adoption and use of biosensors will lead to a correction of the relevant laws.

Fourth, the issue of equality and accessibility of services in the field of bio-sensing technology. Who could use biosensor technology and why? What are the limits? Price? Religious beliefs? We note a great concern of probable inequality that could derive from biosensor implementation in nearest future.

Fifth, what would be the overall effect of high tech implementation in medicine on the society? On the socio-political structure, the economics, etc.? We have not found any detailed study yet. Let us just mention a survey on high-tech medicine conducted in Russia in 2012 that reveals the following. Just 16% are familiar with this issue, 68% see no need of high-tech implementation, the average amount of subsidy from the government was about 4000 USD, 83% got the information from their physician, the

main drawback mentioned by people were quotas for high–tech medicine implementation. Thus we see that people just do not understand what biosenors mean and if they can be used in their everyday life.

2.4 Institutional Aspects of Biosensor Market Formation in Russia

The formation of the market of high-technology medical care in Russian Federation today is hindered by a number of institutional factors that need to be addressed.

First of all, it is the lack of institutionalization of the actors of the market - the economic and technological agents that form stable types of behaviour in the market, both in the short and in the long term. Institutionally, the market of high-technology medical care in Russia, as in many other countries, is not a classic, i.e. the consumer of health services, as it was not veiled insurance mechanisms, not the taxpayer, which determines the range of the market. That is the government, and precisely – the main actor is the Ministry of Health of Russia that forms the demand in high-tech care in Russian Federation, as well as put the standards for them. That is easily understood in term of price and money needed: the only source for a large-scale financing is governmental budget.

However, Russian Ministry of Health constitutes its viewpoint based on medical issues, i.e. is inclined to current medical practice, not assuming innovative proposals that the market could offer today and/or in the future. The only actors, able to properly move the aspects in the formation of the nomenclature of the market towards the introduction of the achievements of biosensor technologies are experts' community. One of them is the technological platform "Medicine of the Future", that brings together specialists from different fields and organizations in solving the general problem of the development of new high-tech face of the Russian medicine - the task set and maintained by the state. Biosensors are distinguished as a special trend within the Technology Platform. Among the organizations that might have a major influence on the direction of development of high-tech medicine, it is necessary to highlight the National Research Centre "Kurchatov Institute" - a fundamentally interdisciplinary leading research and technology centre in the country with the functions of the organization and promotion of technologies in various sectors of the Russian Federation.

Thus we conclude that nowadays the position of experts' community is crucial: they can attract more attention to biosensors, influencing the authorities to bring innovative ideas into practice.

Another important issue is financing the biosensor technology implementation. By now it is supposed to be financed via the Fund of obligatory medical insurance. However expensive medical treatment (or rather long one) could not be afforded and the idea is to develop a voluntary medical insurances company. Scientific research is funded through highly specialized grants systems (Russian Foundation for Basic Research, Bortnik Fund, etc.). Commercialization is supposed to be supported by Vnesheconombank program (public-private partnership for the development of distant medical services). There are some signs of big mobile operators' interest to this issue. In 2012 Beeline (one of three largest mobile companies in Russia) conducted a test of mobile medicine usage in Moscow region that has rather promising results.

Thirdly, the very important issue is the question of standards. Data collecting (what exactly, with which preciseness, etc.), parameters of the devices (size, weight, electrical circuits inside, etc.), parameters of the resulted information (what is "out"?). If those standards refer to medicine? Technical devices? Information processing? This question has not been solved yet, and biosensors can be considered differently: there is no precise rule. Practically, he, who establishes the standards, will control the market. Russian Federation strives to strictly protect its independence, and do not adopt foreign standards. European Union, as can be concluded from plans of Horizon 2020, will not supervise it, and European standards are supposed to follow ones proposed by the US. This means that for Europe the United States will form the biosensors market, and demand will be defined by US needs and preferences.

3 CONCLUSIONS

The problems of biosensors implementation are not limited to the obstacles listed above, and for sure there are a lot of other issues that would arise while developing the biosensor market. Our work is still continuing, and we are currently updating the lists of technical solutions appropriate for Russian market, as well as lists of challenges.

We stress, however, the hope that biosensor could solve all medical problems and distant medicine would substitute the old one is useless.

So what could be "Dream Biosensor"? To answer this question we conduct a short survey of

specialists in the field of medicine and biotechnology. By the end of 2013 we received more than 100 filled questionnaires. Experts stress that the device should be small (light weight), should deal preferably with cardiovascular decease, and should have some new (re)charging mechanisms. The last peculiarity seems to be the most important.

An ideal "Dream Biosensor" could be described as passive universal implantable medical device that measures and transmits to mobile devices and/or personal computers a number of selected indicators (such as temperature, pulse, blood pressure, the content sugar in the blood). The collected data are used for 2 purposes: first, the government has the precise statistics about national health, and can modify its politics in accordance with real situation; and second it can be used for better medical treatment. This should be performed either by the patient himself advised by a physician (likely after the case of alert), or by specialist who interprets the data distantly. The decision making procedure could never be fully automatized, and human control proves to be necessary.

One can hope that in this case the biosensor would not be too "individual" with high price, and could be produced in a large numbers in different areas of the country.

Thus, to our viewpoint biosensors should be considered as a tool to optimize the decision concerning health issues. And those decisions could be both medical and managerial: what treatment would be better? What politics should be followed?

As the government is the main customer of high-tech medicine in Russia, its position will be decisive. At the same time, as of today the market in Russia has not formed yet, the purpose of all stakeholders (both Russian organizations and foreign manufacturers) is to form the market, to identify key trends and to offer a wide range of devices for different price range which could be introduced in Russia.

Thus, we see three essential steps for biosensor market development in Russia. First, to form the consolidated viewpoint of experts' community. Second, to influence the government, to convince the authorities to support distant medicine implementation. And third, to arrange the production of the devices. We note that similar model attracting the most promising and profitable solutions for their implementation under the governmental control, could then be replicated in other countries with strong state influence on the health system.

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