The features of cord blood banking bioeconomy in Ukraine and abroad

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ABSTRACT
The paper highlights the features of cord blood stem cells banking worldwide, modern trends of development of this biomedical industry, problems and prospects. The role of the sector of public and family cord blood banks in shaping the market of storage of human cells and tissue is considered. The data of sociological surveys in Ukraine and abroad, to evaluate the level of awareness of future parents and medical community about the value and possibilities of storage of cord blood is presented. The study revealed favorable preconditions and emphasized the social importance of creating a public cord blood bank in Ukraine in the perspective of its integration with international registries of hematopoietic stem cells.

KEYWORDS: umbilical cord blood; stem cells; cord blood bank; bioeconomy

In recent years the umbilical cord blood as the source of various populations of stem cells and a unique biological material for the production of certain immunobiological drugs (artificial tears, platelet gel, enriched with growth factors plasma) attracts increasing attention of the scientists, physicians, businessmen [1-4]. The umbilical cord blood stem cells are actually used in the treatment of about 80 diseases [5] and officially were announced as bone marrow alternative by the European Group for Blood and Marrow Transplantation (EBMT) [3].

From the moment of the first cord blood application in 1988 more than 35,000 transplantations of cord blood derived stem cells were performed worldwide for the treatment of cancer and regenerative therapy of other diseases in children and adults [2]. In USA the Office of Cellular, Tissue and Gene Therapies (OCTGT), Food and Drug Administration (FDA) approved several cord blood stem cells based drugs, such as AlloCord, Hemacord, Ducord [6, 7]. In 2012, in Canada the first cellular drug Prochymal for the treatment of graft-versus-host disease was approved and the efficacy of this medication is also being studied for the therapy of diabetes mellitus type 1 [7]. In Belarus 17 cellular technologies based on the use of autologous transplant of mesenchymal and hematopoietic stem cells were registered, in particular for the treatment of pharmacotherapy-resistant multiple sclerosis, also for the plastics of large defects of the front abdominal wall, treatment of graft-versus-host disease, diabetes mellitus, hypoparathyreosis and others [8]. Ukrainian scientists also have significant achievements in the field of manufacturing of immunobiological drugs, containing cord blood stem cells [3, 14]. Thus, in 2012 the Ministry of Health of Ukraine officially approved the methods of treatment of critical lower limbs ischemia and panceonecrosis using cord blood stem cells, developed by the Institute of Cell Therapy (Kyiv) [3, 9]. Hence, wide application of the umbilical cord blood drugs in clinical practice and significant financing of studies on their therapeutic potential in the developed world mediates the importance of cord blood banking and facilitates the development of the entire biotechnological industry [2, 3, 7].

The world’s first cord blood bank was created in 1991 at the New York Blood Centre in USA [10]. Actually cord blood banks are actively functioning both in the countries with high social standards and developing countries [11]. The world market of cord blood banking in 2012 was evaluated for $12.4 billion and due to specialists’ prognoses will make $15.23 billion till 2019, having reached from 2013 to 2019 annual index of growth on the level of 5.6 % [11].

The umbilical cord blood banking may be public and private (family, autologous) [1, 3, 10, 12]. Public banks of cord blood predominantly are created at the transplant centers and are operated using state financing or funds of the charity organizations [3]. Public banking of cord blood is based on the free of charge donation of cord blood sample by the women after childbirth [1, 10]. Information on cord blood samples, stored in public banks, is introduced in the international registries of the donors of hematopoietic stem cells and upon request the transplant of the certain phenotype is transferred to the relevant transplantation center inside the country or abroad [7]. Private cord blood banks offer willing parents the opportunity to preserve the umbilical cord blood collected at childbirth for the own needs of the family in the case of a disease due to the agreement signed with the bank [3]. Autologous cord blood banking is considered as a kind of biological insurance and cord blood storage is the most popular service in the field of banking of human cells and tissues [5, 7].

Controversial is the issue on the exact number of cord blood banks, functioning actually in the world, since the practice when a certain biobank offers its services through numerous daughter companies in different countries is very common [13]. Thus, due to the data of Parent’s Guide to Cord Blood Foundation at least 434 cord blood banks of a family type (together with daughter companies) offer their services to expectant parents but only 214 from them are true banks (with laboratories) [13].

In 2003, the Parent’s Guide to Cord Blood Foundation counted that the number of cord blood samples, stored in the banks of a family type in USA...
The development of cord blood banking in these countries is largely due to the government policy that supports this industry. Thus, the leading positions of the North America on the arena of cord blood banking are mediated by the support of their activity by the governmental organizations and wide use of the methods of cell therapy in clinical practice in USA and Canada [7, 11]. The high awareness of the US and Canada population on the value of cord blood and covering of the expenses for its storage by the insuring companies also favoured the boost of this industry in the Northern America [11].

In 2005, the Institute of Medicine (IOM) in the USA issued so called broad report on the banking of the umbilical cord blood, containing accurate recommendations for the medical personnel on the provision of all expecting parents the objective information on the possibilities of cord blood preservation before childbirth [7, 16]. The Department of Health and Human Resources in its turn founded the National Cord Blood Inventory (NCBI) Program, supporting cord blood banking for the treatment of patients as well as scientific investigations [17]. Stored cord blood stem cells are available for physicians and patients for unrelated stem cells transplants within the C. W. Bill Young Cell Transplantation Program [7, 16]. Actually in USA 28 states legalized the educational programs on cord blood, that cover 76% of all childbirths [16]. The majority of states in the USA follow the IOM recommendations and several states are on different stages of the development of legislative procedures on the necessity to inform expectant parents on the possibilities of cord blood storage [7, 16].

In recent years the quick development of cord blood banking was marked in China and India [1, 2, 11]. Densely populated countries of the Pacific region, due to experts’ prognoses, will mediate a significant increase of the market of cord blood banks in the period between 2015 and 2022 [11]. This will be enhanced by significant investments in the industry by the main market players, support of the government as well as rise of the level of health care in these countries [2, 11]. The economics of the developing countries is also characterized by the huge potential for the expansion of cord blood banking industry [11]. In recent years, cord blood banking is actively developing both in the countries of the Arabic world [17]. Family cord blood banks occupied the largest part on the industry market in 2014 [2, 11]. Although due to prognoses, the support of public banks by the government as well as free storage of cord blood will favor the increase of their number on the world market in the period of 2015-2022 [11]. According to experts’ prognoses, the increase of awareness of expectant parents on the importance of cell therapy definitely will favor the development of cord blood banking in several coming years. Indeed, due to the data of sociological surveys as of today the expectant parents in different world countries are not well informed about the relevance of cord blood preservation for the benefit of their families [3, 11, 12, 18]. Thus, the study, published in 2006 in the Journal of Reproductive Medicine showed that one third of expectant parents does not know about the possibility of cord blood preservation and the rest respondents called themselves minimally informed [11]. This study also showed that 84% parents expected that obstetrician-gynecologists, who took care of them during pregnancy, will provide them information on cord blood storage but only 14% respondents received expected answers from the physicians or nurses [11]. And sociological survey, conducted in the January 2014 by the agency BioInformant Worldwide LLC (600+ answers from expectant parents or individuals, who became parents recently) showed that actually the index of awareness of expectant parents on the value of cord blood and possibilities of its storage did not change significantly, despite the efforts on the popularization of cord blood banking, that are made in different countries of the world [11].

In Ukraine the results of sociological studies conducted in 2015 and in 2010 showed that about 90% respondents aged 19-65 knew the terms «stem cells» and «cell therapy», what is 20% higher than the indices of the same survey of 2006 [18]. Also due to the results of the sociological survey of 2015 the number of persons with positive attitude to cell therapy increased for 13.5% compared to the relevant index of 2010 [3, 12]. Maybe this is due to the active highlighting of the advances of regenerative medicine in mass media during recent several years in Ukraine, in particular the announcements on the official approval of cell therapy treatments, developed by the Ukrainian scientists by the Ministry of Health in Ukraine in 2012 and the Nobel Prize of 2012, awarded for the discovery of the induced pluripotent stem cells [3]. Half of the respondents both in 2010 and in 2015 in Ukraine answered that they knew that the umbilical cord blood was the source of stem cells what is 10% higher than the relevant index of 2006 [3, 19]. However, if in 2010 every second respondent confirmed their readiness to preserve the umbilical cord blood after childbirth as a biological insurance, as of 2015 this option of answer was chosen only by 30% surveyd residents of the different regions of Ukraine [3, 12]. Also the number of respondents, whose decision on cord blood storage will depend on the cost of this service in 2015 increased almost for 30% compared to the data of sociological survey conducted in Ukraine in 2010 [3, 12]. These indices may be explained by the significant economic crisis in Ukraine, that is noted in 2014-2017.

The results of survey of pregnant women in Ukraine showed that 97% of them heard about stem cells and more than 80% knew that the umbilical cord blood is the rich source of them [3]. About 50% of surveyed pregnant women had positive attitude to cell therapy but only 1.3% respondents were going to sign a treaty on cord blood storage with one of the biobanks after childbirth [3]. According to the results of survey, the cost of services of cord blood cryostorage is too high for 87.1% of surveyed pregnant women, other 5.7% respondents noted that they did not trust cord blood banks [3]. Obtained data as of 2015 are equivalent with the relevant study, conducted in 2010 [3, 12]. As the results of the sociological survey of 2015 showed, only 8.4% obstetrician-gynecologists recommend cord blood storage to their patients, however as due to the data of survey of 2010 and 2015, nobody of the surveyed physicians discourages pregnant women from such a decision [3, 12].

The results of the mentioned studies show high awareness of the population of modern Ukraine of the different sociological categories on the up-to-date stem cell based technologies as well as the positive attitude both from the side of the expectant parents and medical community to the cord blood preservation, what is the consequence of the active educational and marketing activity of the national family cord blood banks in Ukraine. Taking into account the high number of deliveries in Ukraine, compared with the other countries of Europe, peculiarities of the HLA-phenotype and high migration activity of the population
REFERENCES


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