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A descriptive review

The Principles of Creating and Maintaining Biobanks: A Thorough Analysis of the Global Literature

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Abstract

The increasing incidence of tumors in the human central nervous system has prompted the urgent need for a unified cryo-storage facility with a systematized database to aid in understanding brain cancer initiation, development, and progression. Biobanks have emerged as essential resources for collecting and preserving human tissue samples, particularly for studying tumor disorders.

The purpose of this review is to highlight the role of oncological biobanks in the era of personalized medicine, focusing on the importance of establishing a biobank dedicated to human brain tumor tissue. By collecting and storing high-quality tumor samples, researchers can gain insights into the molecular and biological mechanisms of tumor diseases and develop novel therapeutic strategies.

The review discusses the need for standardization in sample collection, processing, storage, and distribution, emphasizing the importance of accurate characterization and quality control to ensure reliable results. Additionally, it explores the significance of biobanks in identifying predictors of drug effectiveness, developing targeted therapies, and predicting clinical outcomes. The review also addresses the global challenges in establishing biobanks, such as fragmented sample collection and certification, lack of standardized protocols, and limited integration of patient data. Furthermore, it highlights the need for comprehensive electronic biobanks that facilitate the study of central nervous system tumors, personalized medicine, and advancements in neurosciences.

The review concludes by emphasizing the importance of biobanks as valuable resources for molecular and histopathological studies, biomarker discovery, and population-based research. The establishment and proper governance of biobanks are crucial for maintaining transparency, credibility, and scientific progress. Overall, oncological biobanks play a pivotal role in advancing cancer research, personalized medicine, and improving therapeutic outcomes in the field of oncology.

Key words: Biobank, neuro-oncology, cancer tissue, central nervous system, infrastructure.

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Introduction

Currently, there is a global trend of increasing incidence of tumors occurring in the human central nervous system. Despite numerous research efforts aimed at discovering novel therapies for this type of disorder, treatment of brain tumors remains unsuccessful in many cases. To address this issue, there is an urgent need to establish a unified cryo-storage facility with a systematized database that can aid in understanding the mechanisms of brain cancer initiation, development, and progression.

Over the past few decades, there has been a growing interest in the development of biobanks for collecting human tissues [1]. The first biobank for human samples, intended for transplantation purposes, was established in the United States in 1949 [2]. Subsequently, biobanks were developed to collect samples for studying various diseases.

The development of modern technologies, molecular biological methods, and sequencing has required tissue materials to obtain sufficient samples for scientists to obtain more reliable results. Specialized biobanks containing biological samples taken from patients with specific disorders have emerged, including biobanks focused on tumor disorders, which are particularly important.

The aim of these biobanks is to collect cancer tissues and make them accessible for a large number of specimens of cancer origin [3]. With the emergence of personalized medicine and the development of individual treatment protocols, understanding the individual mechanisms of tumor initiation and development has become critical for identifying novel targets and treatment strategies. Previously, research on human diseases was largely carried out in animals, as it was believed that animal tissue samples were more readily available. However, it was later shown that results of studies on animals cannot be fully applied to human diseases [4]. In recent years, the emphasis has shifted to the collection of human tissue materials as a source of information for studying gene expression, proteomics, and signaling pathways. Modern technologies require a large number of samples, which can only be obtained by developing biobanks [5].

Over the past 20 years, the need for the use of biobanks has increased several times, and this trend is expected to continue in the future [6]. However, the problem of establishing biobanks persists worldwide. In many cases, sample collection and certification are still fragmented, and there is often no connection between data on patient history and treatment or follow-up information, even within the same institution. The lack of standardization of sample collection leads to variability in the collected material, which reduces its value and the ability to obtain reliable results. Therefore, it is necessary to accurately characterize the material, describe its processing and storage, and ensure the quality and reliability of any studies that use such samples [7]. Establishing a biobank dedicated to human brain tumor tissue has been proposed as a solution to the challenge of providing researchers with sufficient and reliable high-quality tumor samples. In recent years, it has become clear that these requirements can only be met by biobanks created at clinics, hospitals, and other medical institutions that specialize in neurosurgery, particularly neuro-oncology. Ensuring the standardization of processes related to tissue biobanking is crucial. This involves implementing uniform and consistent protocols for the collection, processing, storage, and distribution of biological samples in biobanks.

The aim of this review is to emphasize the importance of establishing a unified biobank for human brain tumor tissues to improve our understanding of brain cancer mechanisms. It will address the current challenges and the need for standardized protocols in tissue collection and storage to ensure high-quality samples for advancing research and personalized treatment strategies.

Role of oncological biobanks

The development of oncological biobanks is becoming increasingly relevant in the era of personalized medicine. Despite advances in cancer treatment, rates of malignant neoplasm morbidity and mortality remain high worldwide. Many therapeutic issues are still unresolved. Unfortunately, 20-30% of cancer patients develop tumor resistance to previously effective molecular-targeted therapy, and the disease progresses. In addition, it is complicated to influence this process effectively due to insufficient knowledge of the molecular biological properties of a tumor. Therefore, the search for new predictors and drug targets is a priority task of modern oncology. Moreover, saving a sample of a primary tumor of a particular patient may be useful for developing personalized therapy at any stage of the disease course [8].

One of the important tasks of modern oncology is to search for laboratory diagnostic methods of predictors of a particular anticancer drug's effectiveness in treating malignant neoplasms. In this context, preserving biological tumor samples makes it possible to re-examine them retrospectively to create highly informative test systems. The experience of developing various targeted antitumor drugs and identifying biological targets highlights the importance of having access to tissue sample materials stored in biobanks throughout the study, from the stage of identifying subgroups of patients with different genotypes to the stage of testing diagnostic tests that identify patients with contraindications to the use of a drug [9-11]. Standard randomized clinical trials are not sufficient in these situations to obtain approval from national regulatory agencies, such as the US Food and Drug Administration.

Interestingly, the first attempt to create an independent unit with the purpose of storing biological samples was made in 1948 within the framework of the project to identify risk factors for cardiovascular disease based on the study of peripheral blood samples (Farmingham Heart Study). The research results of this bank were published only 20 years after the beginning of its formation [12].

Collections of biomaterials have been created for a long time, but not all of them can be considered as biobanks. Thus, in almost all pathological departments of large hospitals and medical centers, as well as in clinical diagnostic or equivalent laboratories, a certain number of samples of biological tissue of patients (e.g., blood serum, paraffin blocks, cytological preparations) are stored, but such collections are not considered as biobanks for several reasons. The samples are limited in terms of the possibility of manipulation since they are taken from a specific patient for specific purposes and tasks and cannot be used for research purposes.

In addition, diagnostic laboratories and departments do not have enough space and facilities to store samples of various types of tumor. All of the above were prerequisites for the formation of a new, special field of

activity in medicine and biology, designated as biobanking, and the structure itself was called a biobank.

Biobank activities include not only the storage of samples and personal information but also their study on the research platform of the biobank itself. As a result, each sample is accompanied by a number of additional biological characteristics. Information about the samples and their annotation information, while maintaining anonymity with respect to the personal data of a donor, should be widely available to the scientific community, facilitating a wide variety of research within the stored collections. Properly organized and functioning biobanks also provide detailed information about the acquisition, processing, and storage of each sample, such as the time and method of sampling, and delivery conditions as well. All definitions and technical aspects of maintaining a biobank are considered most fully in the article by M. Fransson et al. [13].

According to Aitkulova and Daulbayeva [14], biobanks have become common in many developed countries worldwide, including the Republic of Kazakhstan. The authors also noted an urgent need for increased scientific knowledge, innovation, and personalized medicine approaches in the country. To achieve this goal, it is essential to create a biobank that collects tumor samples of the central nervous system and venous blood components of neurooncological patients. By doing so, it will be possible to study the molecular and biological mechanisms of tumor initiation, development, and progression, as well as further develop immune-histochemical and molecular cytogenetic studies, novel therapeutic methods (e.g. targeted therapy, pharmacogenomics), and neurosciences. Creating an electronic biobank for central nervous system tumors is particularly important in the era of personalized medicine since it aims to develop neurosciences [15].

The primary objective of human biosample biobanking is to preserve the samples for future research tasks such as genetic, proteomic, and metabolomic studies, as well as routine practical tasks like transplantation and reproduction [16, 17]. In oncology, biobanking focuses on searching for biomarkers that predict the onset and prognosis of the clinical behavior of tumors, developing new methods of prevention and treatment, and predicting their effectiveness and safety [18, 19].

Understanding the genetic, signaling, and metabolic nature of tumor diseases opens up new avenues for personalized medicine [20]. Comparing the results of molecular genetic studies with radiological imaging of pathological foci in vivo has applied value. For instance, it can help personalize drug selection and treatment regimens, target monitoring foci during the treatment process, and predict "responders" and "non-responders" for treatment [21].

Most biobanks store samples of different types, such as biological fluids (blood serum, saliva, urine), normal or pathological tissues, cell cultures, strains of bacteria, viruses, and nucleic acids. However, the need to compare a vast amount of data has led to creating various types of biobanks according to the objectives and ultimate goal of the study [22].

Historically, oncological biobanks were mainly tissue biobanks or tumor biobanks, aiming to compare the characteristics of tumor and healthy tissues. This approach allowed for an in-depth study of the molecular and biological basis of the disease, searching for diagnostic markers and new therapeutic targets. However, the modern oncological biobank is more than just a collection of tumor tissue. Other biological fluids and tissues such as blood and serum are essential for oncology research. Additionally, some projects require the isolation and preservation of nucleic acids [23, 24]. Therefore, oncological patient sample biobanks can not only be attributed to nosological ones but are also population biobanks due to the scale and importance of the tasks they solve [25-27].

Population biobanks provide an invaluable source of samples for many studies, enabling the scaling up of research [28-30]. Despite the importance of using pathomorphological samples in research, digital archives of pathological specimens are practically non-existent. Each pathomorphological department in the country stores tissue samples fixed in paraffin and histological preparations for at least 25 years after sampling. The collected pathomorphological samples are mainly used for clinical tasks and are not utilized for scientific research due to a lack of appropriate informed consent and associated information, sample quality, and processing standardization. The involvement of pathology archives in the activities of biobanks is low due to established traditions and workflows in clinical laboratories, a lack of interest of pathology departments in promoting scientific research, and current pathology laboratory equipment not meeting the high requirements of biobanking.

The worldwide cancer biobanks

Cancer biobanks around the world, as a variety of disease based biobanks, are vital for studying fundamental mechanisms of cancer initiation, progression and development. These cancer specimens' repositories store data on biomaterials with the accent on good quality management, results on molecular and histopatological studies.

General principles of biobanking

The process of formation of a biobank begins with the definition of a goal of the project, which should not be narrowly focused. The set target will determine the type of samples. The sample collection process begins with the signing of the patient's informed consent, which must be approved by the local ethical committee of an organization.

The functions of the body regulating the work of biobanks are carried out by the international organization International Society for Biological and Environmental Repositories (ISBER) and its branch European and Middle Eastern and African Society for Biopreservation and Biobanking (ESBB). The functions of ISBER are quite wide - the development of biobanking and the international network of biobanks, the accumulation of international experience relating to all aspects of biobanking and its stages, and the development of recommendations as well.

In addition to ISBER, which develops international recommendations for the organization of biobanks, there are international and European standardization organizations that develop standards for the organization of biobanks, as well as pre-analytical procedures. In August 2018, the International Organization for Standardization ISO published the biobanking standard ISO 20387:2018 [31].

Strict observance of all necessary ethical requirements is of great importance in the field of biobanking. Issues related to the establishment of the Biobank, as well as the approval and introduction into circulation of various documents regulating its activities were considered by the Ethics Committee of the Center. Moreover, the issues controlled by the Ethics Committee include: - compliance with ethical obligations; – voluntary provision of biological samples by patients and donors; – the safety of the procedures used for obtaining biological material; – the safety of personal data of patients and donors, through the implementation of data depersonalization algorithms; - completeness of information provided to donors of biological samples on the scientific goals of biobanking. The most important issue resolved by the Ethics Committee is the consideration and approval of the "Informed Consent of a Patient for Biobanking" and "Information for Patients" forms, which have been developed on the basis of ISBER recommendations [32].

The collection of blood samples and other fluids for biobanking is usually carried out during the initial diagnostic phase of the disease, either in the outpatient setting or in the 24-hour inpatient setting. In the case of tissue sampling for research purposes, the need and importance of a complete diagnosis should be the primary consideration. Tissue samples will only be deposited in a biobank if the necessary amount of material for all stages of diagnosis of the disease has been obtained. The involvement of a pathomorphologist, who must confirm the quality of the sample, is absolutely essential.

All necessary conditions (time, temperature, etc.) must be observed when transporting a sample. Once a sample arrives at a biobank, it is anonymised, labelled and processed. At this stage, the crucial step is sample aliquoting. Aliquoting is the process of dividing either the native sample or isolated fraction (plasma, serum) into samples to improve freezing and storage conditions and to create replicates of a sample, allowing it to be tested several times from the same patient without compromising its quality.

Biobanks presently represent a unique research infrastructure in need of adequate flexible governance mechanisms, which do not impede scientific progress. Governance tools for the biobanking industry are designed to maintain a balance between the needs of the scientific community and donors of biological material, with a focus on transparency and credibility at all stages of work [33].

Summarizing the long-term experience of a number of institutions and projects involving the resource of biobank, we can conclude that the correct operation of a biobank consists of several components (Figure 1):

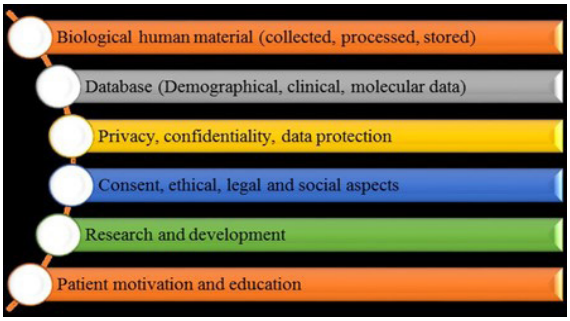

Figure 1 - Components of the biobank

• collection and storage of biological material in combination with medical and epidemiological data;

• dynamic development of a biobank – continuous collection of samples in the long term;

• connection of a biobank with current research projects;

• maintaining the anonymity of donors (patients who provided samples);

• use of uniform standards and management procedures.

Conclusion

Biobanks are essential tools for solving therapeutic issues in oncology, including studying risk factors for developing malignant tumors, searching for predictors of therapy response, and identifying new targets for targeted therapy. Today, biobanks are considered a unique research resource and a form of biological life insurance, not just for humans but for all species. Some authors even argue that biobanks play a crucial role in a country's biological security.

The creation of large-scale bioresource collections is not new, and it is gaining popularity worldwide. Developing oncobiobanks is crucial for conducting both fundamental research in molecular biology and clinical research into the search for new anticancer drugs, methods of detecting their effectiveness, and possible risk factors for tumor development. Currently, all targeted and immuno-oncological drugs and modern molecular genetic diagnostics have resulted from the use of biological samples taken from biobanks. The success in diagnosing, treating, and preventing cancer in recent decades is also due to the creation and development of a network of biobanks as the most important infrastructural element in this field.

The primary goal of biobanks is to provide a constant flow of biological samples for various studies. Biomaterials of various types are collected legally and ethically, and everyone who needs sample preparation, laboratory processing, and storage participates fully.

The samples are characterized fully and associated with the maximum possible volume of clinical and laboratory information.

The biobank of tumors of the central nervous system in Kazakhstan will contribute to the development of various areas of neuroscience, personalized and translational medicine. Translational medicine will allow for the rapid transfer of fundamental research results, mainly in the field of molecular cytogenetics and biochemistry, into clinical practice. The created biobank will expand and develop

personalized medicine and scientific activity, which will give a powerful impetus to the industry to meet the standards of developed countries.

Biobanking in Kazakhstan is still in its early stages, and developing a national network based on close cooperation between biobanks and medical institutions seems most relevant at this stage. This will provide the necessary basis for conducting our own fundamental and applied research in all areas of biomedicine, including oncology. It will also create a network of biobanks of central nervous system tumors among countries in Central Asia.

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Түйіндеме

Орталық жүйке жүйесі ісіктерінің өсіп келе жатқан аурулары ми ісіктерінің пайда болу, даму және прогрессия механизмдерін зерттеу үшін жүйеленген дерекқоры бар бірыңғай криосақтау орталығын құруды талап етеді. Биобанктер адам тіндерінің үлгілерін жинау және сақтау үшін, әсіресе ісік ауруларын зерттеу үшін маңызды ресурстарға айналды.

Бұл шолудың мақсаты - ми ісіктерінің тіндеріне арналған биобанк құрудың маңыздылығына назар аудара отырып, жекелендірілген медицина дәуіріндегі онкологиялық биобанктердің рөлін атап өту. Ісіктердің сапалы үлгілерін жинау және сақтау зерттеушілерге ісік ауруларының молекулалық және биологиялық механизмдері туралы түсінік алуға және жаңа терапиялық стратегияларды әзірлеуге мүмкіндік береді.

Шолуда үлгілерді жинау, өңдеу, сақтау және таратуды стандарттау қажеттілігі талқыланады, нәтижелердің сенімділігін қамтамасыз ету үшін дәл сипаттау мен сапаны бақылаудың маңыздылығына назар аударылады. Биобанктердің дәрі-дәрмектің тиімділігін болжаушыларды анықтаудағы, мақсатты терапияны дамытудағы және клиникалық нәтижелерді болжаудағы маңыздылығы да қарастырылады. Шолу үлгілерді жинау мен сертификаттаудың үзінділері, стандарттalған хаттамалардың болмауы және пациенттер туралы деректердің шектеулі интеграциясы сияқты биобанктерді құрудағы жаһандық мәселелерді қарастырады. Сонымен қатар, орталық жүйке жүйесінің ісіктерін, жекелендірілген медицинаны және нейрогылымдардың жетістіктерін зерттеу үшін кешенді электронды биобанктердің қажеттілігі атап өтіледі.

Қорытындылай келе, биобанктердің молекулалық және гистопатологиялық зерттеулер, биомаркерлерді ашу және популяцияны зерттеу үшін құнды ресурстар ретіндегі маңыздылығы атап өтіледі. Биобанктерді құру және дұрыс басқару ашықтықты, сенімділікті және ғылыми прогресті қамтамасыз етудің кілті болып табылады. Жалпы, онкологиялық биобанктер қатерлі ісік зерттеулерін дамытуда, жекелендірілген медицинада және онкологиядағы терапевтік нәтижелерді жақсартуда маңызды рөл атқарады.

Түйін сөздер: Биобанк, нейроонкология, ісік тіндері, орталық жүйке жүйесі, инфрақұрылым.

Принципы создания и поддержания биобанков: Анализ литературы

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Резюме

Растущая заболеваемость опухолями центральной нервной системы требует создания единого центра криохранения с систематизированной базой данных для изучения механизмов возникновения, развития и прогрессирования опухолей мозга. Биобанки стали важными ресурсами для сбора и хранения образцов тканей человека, особенно для изучения опухолевых заболеваний.

Цель данного обзора — подчеркнуть роль онкологических биобанков в эпоху персонализированной медицины, сосредоточив внимание на важности создания биобанка, посвященного тканям опухолей мозга. Сбор и хранение качественных образцов опухолей позволит исследователям получить представление о молекулярных и биологических механизмах опухолевых заболеваний и разрабатывать новые терапевтические стратегии.

В обзоре обсуждается необходимость стандартизации сбора, обработки, хранения и распределения образцов, акцентируется внимание на важности точной характеристики и контроля качества для обеспечения надежности результатов. Также рассматривается значимость биобанков в выявлении предсказателей эффективности лекарств, разработке целевых терапий и предсказании клинических исходов. Обзор затрагивает глобальные проблемы в создании биобанков, такие как фрагментарность сбора и сертификации образцов, отсутствие стандартизированных протоколов и ограниченная интеграция данных о пациентах. Более того, подчеркивается необходимость комплексных электронных биобанков для изучения опухолей центральной нервной системы, персонализированной медицины и достижений в области нейронаук.

В заключение, акцентируется важность биобанков как ценных ресурсов для молекулярных и гистопатологических исследований, открытия биомаркеров и популяционных исследований. Создание и надлежащее управление биобанками имеют ключевое значение для обеспечения прозрачности, достоверности и научного прогресса. В целом, онкологические биобанки играют важную роль в развитии исследований рака, персонализированной медицины и улучшении терапевтических результатов в области онкологии.

Ключевые слова: биобанк, нейроонкология, опухолевая ткань, центральная нервная система, инфраструктура.