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BIOBANKS, AN INTEGRAL PERSPECTIVE ON ITS IMPORTANCE IN BIOMEDICAL RESEARCH

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SUMMARY

The importance of biobanks in medicine is reviewed and challenges associated with their establishment and operation are discussed. The need for well-organized biobanks that store biological samples and clinical data to facilitate translational research and personalization of medical care is discussed. Likewise, the ethical, legal and technical aspects related to biobanks are reviewed, as well as the benefits and limitations of their use. Opportunities and challenges in biobank management are highlighted, such as obtaining informed consent, guaranteeing donor confidentiality and privacy, and implementing quality standards in sample collection, processing, and storage. Biobanks play a crucial role in biomedical research and precision medicine. These repositories of biological samples and clinical data allow advances in the knowledge of various diseases, facilitate the identification of biomarkers, support the development of more precise therapies and contribute to the personalization of medical care. Therefore, they are valuable resources for research and medicine, and their proper functioning requires the implementation of quality standards, ethical and legal considerations, as well as active collaboration between different institutions and biobanks.

KEYWORDS: Biobanks, store biological samples, biomedical research, precision medicine, legislation.

INTRODUCTION

Biobanks are organizations or institutions engaged in the collection, processing, storage, and distribution of human biological samples and associated data for use in scientific and medical research. These biological samples may include blood, tissues, body fluids, cells, DNA, RNA, among others.[1-10]

Biobanks play a crucial role in biomedical research, as they provide valuable resources for genetic, epidemiological and clinical studies. By collecting samples and data from a wide variety of individuals, biobanks allow researchers to conduct large-scale studies and discover associations between genetic data and disease risk factors, as well as identify new therapeutic targets.[6,11-15]

In addition to the function of storing and distributing samples, biobanks are also in charge of maintaining high standards of quality and confidentiality in data handling and guaranteeing the informed consent and privacy of biological sample donors.

It is important to highlight that biobanks must comply with rigorous ethical and legal regulations to ensure the protection of donor rights and the proper use of samples and data. These regulations include obtaining informed consent, donor anonymity, confidentiality of personal information, and compliance with privacy and data protection regulations.[1,8]

In summary, biobanks are infrastructures that allow the collection and storage of biological samples and associated data in an ethical manner.

Figure 1 summarizes the workflow of a biobank

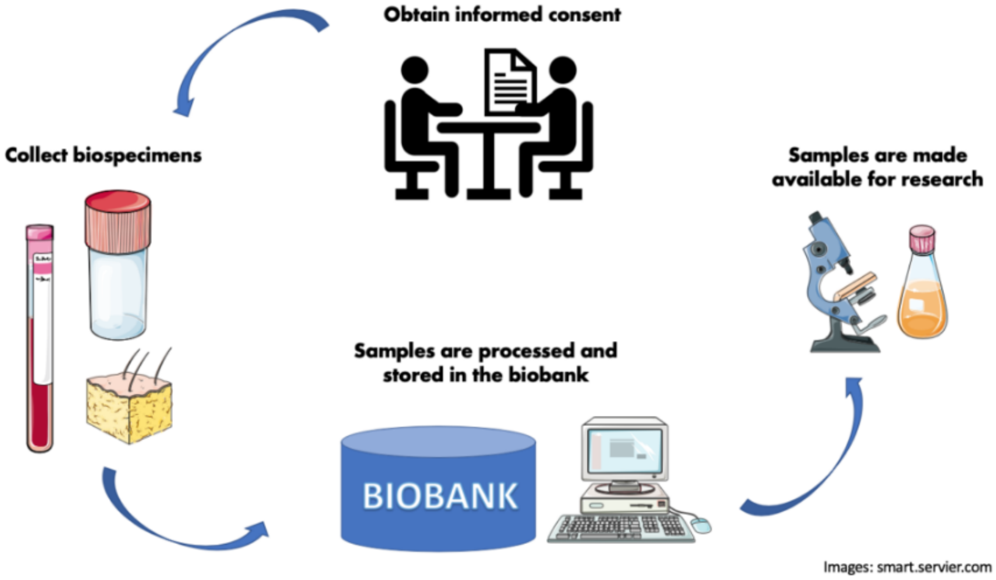

Figure 1: Typical workflow of a biobank

Figure 2 describes the summary representation of the processes carried out in a biobank.

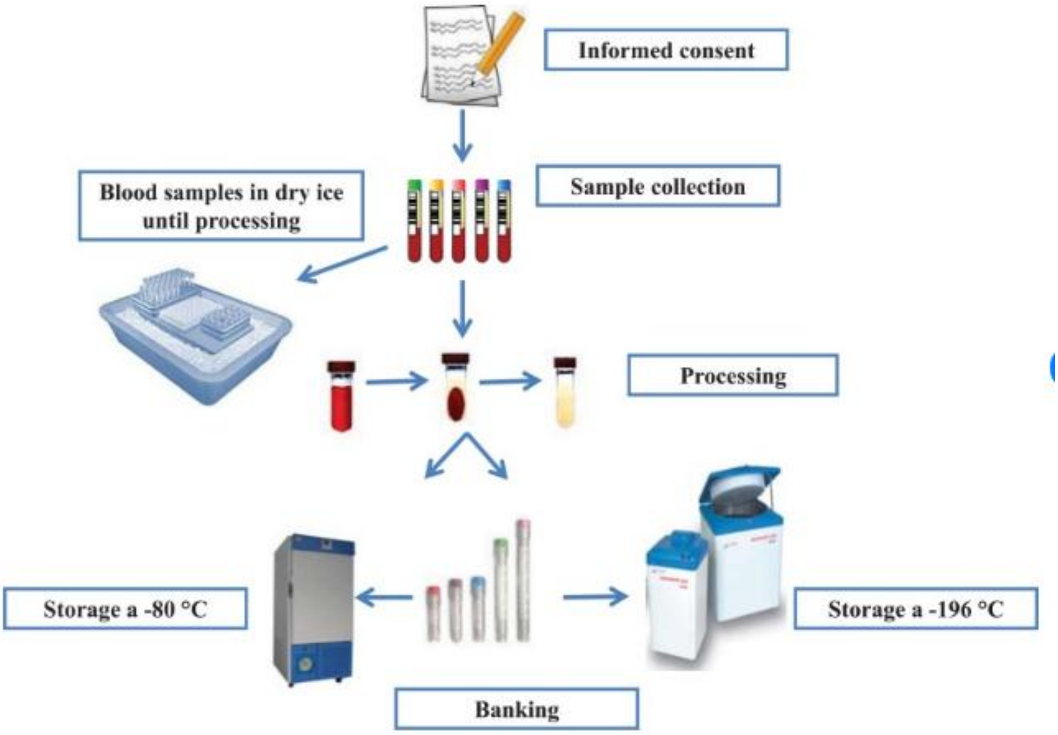

Figure 2: Different processes carried out in a biobank.

Classification of Biobanks

Biobanks can be classified into different types based on their focus and purpose. Some examples are.[16-19]

Population biobanks: These biobanks focus on collecting samples and data from a specific population, such as a country, region, or ethnic group. These biobanks enable large-scale epidemiological and genetic investigations to better understand diseases and risk factors in a given population.

Clinical biobanks: They focus on collecting samples from patients with specific diseases or who have undergone certain medical treatments. These biobanks are valuable for translational research, which seeks to bring scientific discoveries from the laboratory to clinical practice.

Rare disease biobanks: These biobanks focus on collecting samples from patients with rare and uncommon diseases. Since these diseases often have a genetic basis, rare disease biobanks allow for genetic studies and research to better understand these conditions and develop more effective therapies.

Cancer biobanks: These biobanks specialize in collecting tumor samples and related tissues from cancer patients. These biobanks are crucial for cancer research, since they allow the study of the genetic and molecular profiles of cancer, which can lead to advances in the diagnosis and treatment of this disease.

Biobanks must also comply with quality standards and good practices in the collection, processing, and storage of biological samples. This implies the implementation of appropriate preservation and storage techniques, as well as the cataloging and management of associated data in an accurate and reliable manner.[20,21]

Regarding legislation and regulations, biobanks must comply with the ethical and legal requirements established in each country. These requirements include obtaining informed consent from donors, protecting the privacy and confidentiality of personal data, and complying with data protection and bioethics regulations.[22-25]

They are entities specialized in the collection and storage of biological samples and associated data, with the aim of promoting scientific and medical research. Its importance lies in providing resources for large-scale studies, facilitating research in different areas, and contributing to the advancement of knowledge and the development of more effective treatments for various diseases.[26-28]

Biobanks can also be classified into different types based on their focus and purpose. Some examples are[6,8,17,24]

1. Population Biobanks, are a specific form of biobanks that focus on the collection and storage of biological samples and data from a given population. These biobanks have as main objective to understand the genetic variability and risk factors associated with diseases within a specific population.

By focusing on a particular population, population biobanks allow researchers to analyze and compare samples and data from a homogeneous group of individuals. This can be especially useful in the study of diseases that have genetic variations or specific risk factors in certain ethnic groups or geographic regions.

Some examples of population biobanks include[10,11,15,23]

National Biobanks: These biobanks are established at the country level and seek to collect samples and data representative of the genetic diversity of the national population. These biobanks often involve the collaboration of multiple institutions and research centers across the country.

Ethnic or regional biobanks: These biobanks focus on specific populations with a shared ethnic heritage or on specific geographic regions. These biobanks make it possible to investigate genetic differences and disease rates in ethnic groups or populations that share common geographic features.

Birth Cohort Biobanks: These biobanks are established by collecting samples and data from a cohort of individuals from birth to adulthood. This allows for long-term longitudinal studies to investigate the influence of genetic and environmental factors on disease development over time.

Population biobanks are valuable for epidemiological research, as they provide a large number of samples and data from a given population. This allows for genomic wide association studies (GWAS) and other genetic analyzes to identify genetic variants associated with specific diseases or traits within that population[3,6,14]

In addition, population biobanks can be used to address public health challenges, such as the study of endemic diseases, the analysis of modifiable risk factors, and the identification of biomarkers for the diagnosis and treatment of specific diseases in a given population.

In summary, population biobanks focus on the collection and storage of biological samples and data from a specific population. These biobanks are powerful tools for investigating genetic variability and disease-associated risk factors within a population, which can contribute to personalized medicine, public health, and the advancement of scientific knowledge[14,17]

2. Clinical Biobanks. are biobanks that focus on the collection and storage of biological samples from patients with specific diseases or who have undergone particular medical treatments. These biobanks are closely linked to clinical settings and hospitals, allowing them access to patient clinical data and samples.

The main purpose of clinical biobanks is to facilitate translational research, which seeks to bring scientific advances from the laboratory to clinical practice. By collecting samples from patients with a specific disease, clinical biobanks provide researchers with a valuable source of biological materials to study disease, identify biomarkers, develop more effective therapies, and improve patient diagnosis and prognosis.

Some characteristics and applications of clinical biobanks are[5,11,14,16,18]

Collection of clinical samples: Clinical biobanks collect a variety of biological samples, such as tumor tissue, blood samples, body fluids, DNA or RNA samples, among others. These samples are obtained through medical procedures, surgery, biopsies, or other clinical methods.

Associated clinical data: In addition to biological samples, clinical biobanks collect relevant clinical information from patients, such as medical histories, diagnoses, treatments received, laboratory test results, and long-term follow-up. These clinical data are essential to contextualize biological samples and perform more complete analyses.

Disease and therapy research: Clinical biobanks allow researchers to conduct in-depth studies on specific diseases. For example, they can investigate the molecular and genetic characteristics of a type of cancer, identify risk factors, determine the response to a specific treatment or search for new therapeutic targets.

Pharmacogenomics studies: Clinical biobanks are also used to investigate pharmacogenomics, which studies how genes influence an individual's response to drugs. By analyzing samples and data from patients who have been treated with certain drugs, genetic markers can be identified that predict the effectiveness or side effects of drugs.

Precision medicine: Clinical biobanks are an important tool in precision medicine, which seeks to adapt medical treatments to the genetic and molecular characteristics of each patient. By having a wide range of biological samples and clinical data, clinical biobanks contribute to the identification of biomarkers and the personalization of medical treatments.

It is essential to highlight that clinical biobanks must comply with high ethical and confidentiality standards to guarantee the privacy and informed consent of patients.

3. Rare Disease Biobanks, are specialized biobanks that focus on the collection and storage of biological samples from patients affected by rare or infrequent diseases. These diseases are characterized by affecting a small number of people compared to more common diseases.

These biobanks are of vital importance due to the rarity and complexity of these diseases. Being rare diseases, it can be difficult for researchers to obtain enough samples and clinical data to conduct meaningful studies. However, rare disease biobanks are dedicated to collecting, preserving, and making available to researchers the biological samples necessary to advance the understanding and treatment of these diseases.

Here are some points to keep in mind about rare disease biobanks[2,13,22,23]

Specialized sample collection: Rare disease biobanks focus on the collection of specific biological samples from patients with rare diseases. This may include samples of tissue, blood, DNA, RNA, or other bodily fluids relevant to the disease in question.

Diversity of diseases: These biobanks cover a wide range of rare diseases, which may be of genetic, congenital or acquired origin. Examples of rare diseases include hereditary metabolic diseases, neuromuscular diseases, rare genetic disorders, and rare diseases of the immune system.

International collaboration: Since rare diseases can be extremely rare and geographically dispersed, rare disease biobanks often work in collaboration with other biobanks and international networks. This allows the exchange of samples, data and knowledge to expand the database and maximize research in rare diseases.

Genetic research: Biobanks of rare diseases facilitate genetic research in search of genetic mutations and rare genetic variants that may be associated with these diseases. Genetic analysis of samples can help identify genes responsible for rare diseases and provide crucial information for diagnosis and development of therapies.

Development of therapies: Biobanks of rare diseases play an important role in the development of specific therapies for these diseases. Biological samples from affected patients allow the investigation of therapeutic targets, the development of disease models, the evaluation of the efficacy of therapies and the identification of useful biomarkers for the diagnosis and monitoring of the disease.

Support to patients and families: In addition to their role in research, rare disease biobanks can also provide support to patients and their families. By storing patient samples and data, these biobanks can help establish contacts between patients with similar illnesses, facilitate access to clinical studies, and offer resources and guidance for disease management.

Rare disease biobanks play an essential role in research and advancing the understanding and treatment of rare diseases. By collecting and storing biological samples from affected patients, these biobanks enable genetic research, the development of personalized therapies, and the connection of patients and families in the fight against these rare diseases.

4. Cancer Biobanks, are specialized biobanks that focus on the collection and storage of biological samples from cancer patients. These biobanks play a crucial role in cancer research by providing a valuable source of biological material for the study of this complex disease.

Here is more information about cancer biobanks[2,5,22]

Types of samples: Cancer biobanks collect a wide variety of biological samples related to cancer. This includes tumor tissue, blood samples, body fluid samples (such as urine or saliva), as well as DNA, RNA, and protein samples. These samples allow researchers to analyze and understand the molecular and genetic characteristics of cancer, as well as its interactions with the tumor microenvironment and the immune system.

Associated clinical data: In addition to biological samples, cancer biobanks collect detailed clinical information from patients, such as the type of cancer, the stage of the disease, the treatments received, the results of laboratory tests and long-term follow-up. term. These associated clinical data are essential to contextualize biological samples and perform more complete analyses.

Genomic and molecular research: Cancer biobanks allow genomic and molecular research in the field of cancer. This involves analysis of genetic alterations, somatic mutations, gene expression profiles, and molecular features of cancer. These studies help identify biomarkers, therapeutic targets, and molecular patterns associated with different types of cancer, which in turn may facilitate the development of more precise and personalized therapies.

Epidemiological and prognostic studies: Cancer biobanks are also used to carry out epidemiological and prognostic studies in relation to cancer. These studies involve analyzing the demographic and clinical characteristics of patients, identifying risk factors, evaluating the efficacy of treatments, and predicting the course of the disease. Data and samples from cancer biobanks are valuable for conducting these studies and providing relevant information for the prevention, early detection, and treatment of cancer.

Therapies development and precision medicine: Cancer biobanks play an important role in the development of targeted therapies and precision medicine for cancer. The samples and data collected allow the identification of molecular markers that can guide the choice of treatment and predict the patient's response to specific therapies. This is especially relevant in the context of targeted therapy and immunotherapy, where the identification of biomarkers is crucial for the selection of suitable patients for specific treatments.

Collaboration and exchange of samples: Many cancer biobanks participate in international networks and collaborations to facilitate the exchange of samples and data. This expands the availability of samples and allows researchers to access a diversity of data and resources to carry out larger and more representative studies.

Cancer biobanks play an essential role in researching and advancing the understanding of cancer, as well as in developing more precise and effective therapeutic approaches. By storing biological samples and clinical data, these biobanks contribute to the development of prevention strategies, early diagnosis and personalized treatment for cancer.[5,22]

Figure 3 represents the most common types of biobanks.

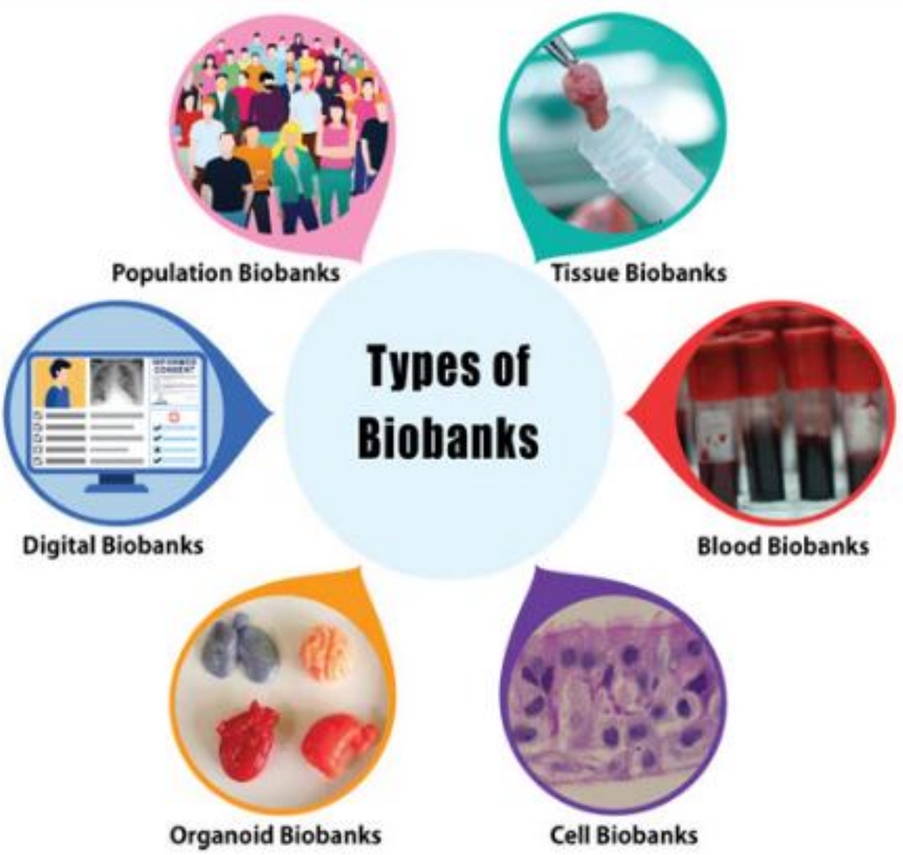

Figure 3: Most common types of biobanks.

Figure 4 schematically shows a representation of the classification of biobanks.

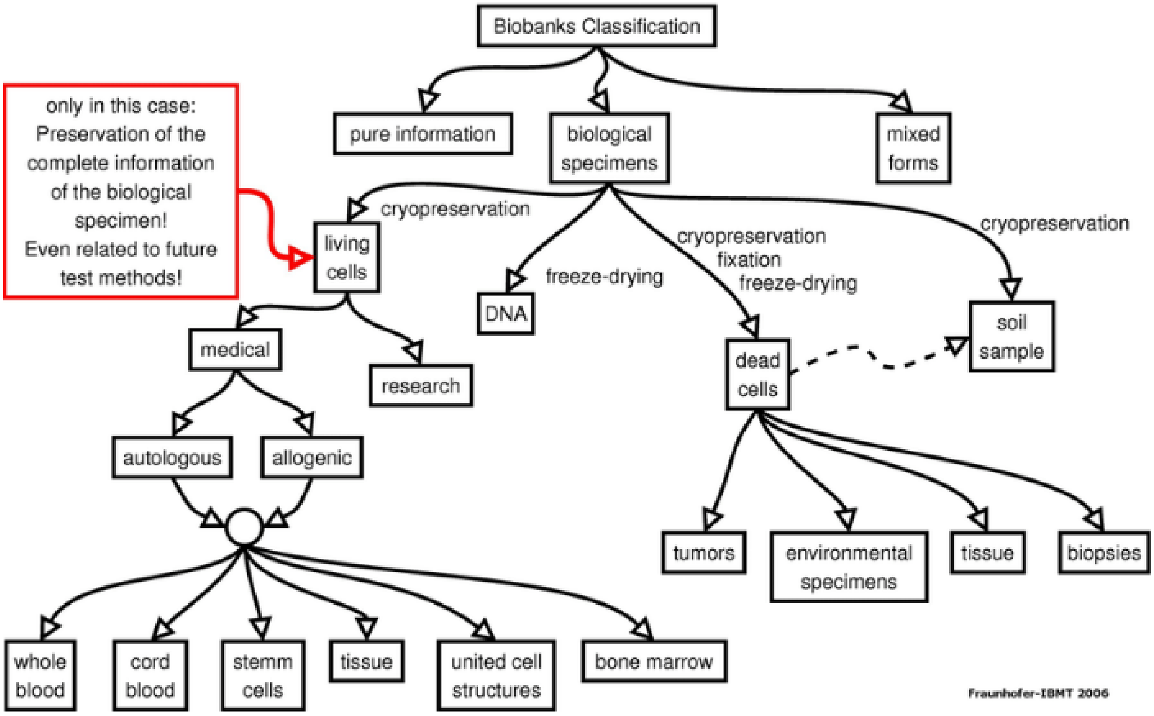

Figure 4: Classification of biobanks.

Example of the DxConnect Virtual Biobank (https://www.finddx.org/biobank-services/vbd/), which acts as a clearinghouse for clinical samples, connecting researchers with institutions around the world that have clinical samples available for the development and validation of new diagnostic tests (Fig. 5).

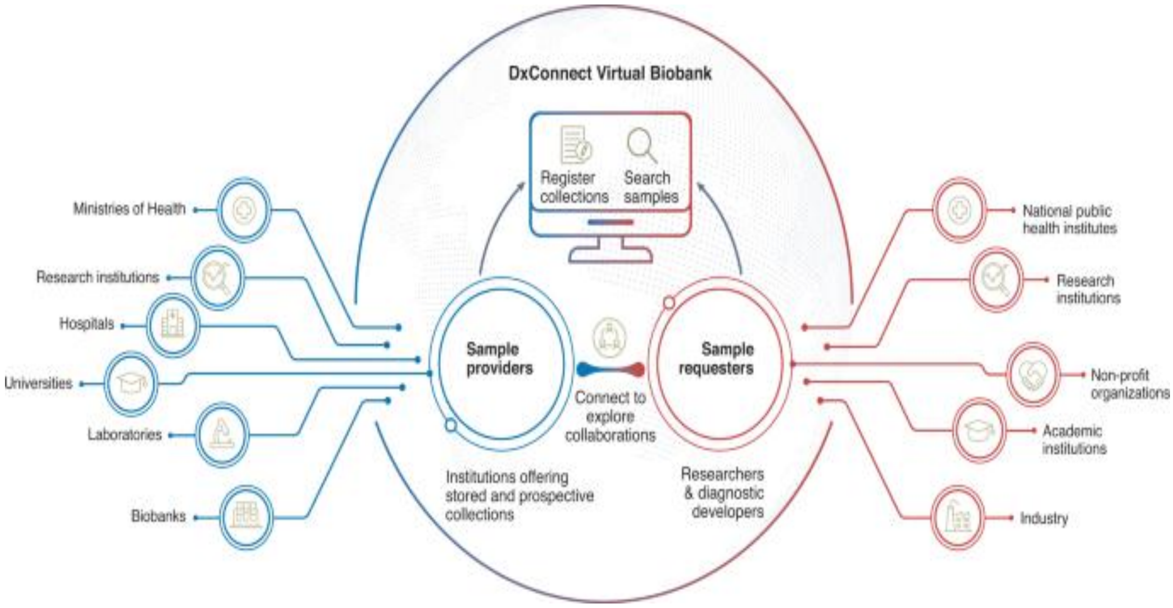

Figure 5: DxConnect Virtual Biobank, which would be an open access resource.

Legislation

Legislation and regulations related to biobanks vary by country and jurisdiction. However, in general, there are several key issues that are often addressed in legislation and regulations related to biobanks. Here is an expansion of these aspects.[4,19,25]

Informed consent: Most regulations require that informed consent be obtained from donors of biological samples and clinical data stored in a biobank. Informed consent must be voluntary, understandable, and based on complete information provided to the donor, including the purpose of the biobank, the type of samples and data to be collected, and how they will be used in research.

Privacy and confidentiality: Biobanking regulations often include provisions to protect the privacy and confidentiality of donors and their data. This may include security measures to protect the identity of donors, as well as safeguards to prevent unauthorized disclosure of personal information or medical data.

Ethical use and approval of research: Regulations usually require that research projects that use samples and data from a biobank be reviewed and approved by ethical or institutional committees. These committees evaluate the scientific and ethical relevance of the proposed research, as well as the protection of the rights and well-being of donors.

Ownership and access to samples and data: Regulations can address issues of ownership and access to samples and data stored in a biobank. This may include defining the ownership of samples and data, as well as the conditions for their use by researchers, academic institutions, or private companies. Some regulations may also establish requirements for equal access and sharing of samples and data between different biobanks and researchers.

International transfer of samples and data: In the case of biobanks that participate in international collaborations or that carry out transfers of samples and data internationally, there may be specific regulations to address the ethical and legal aspects of such transfers. This may include specific consent requirements, sample and data sharing agreements, and compliance with relevant data protection laws in the countries involved.

Supervision and regulation of biobanks: Regulations often establish requirements for the supervision and regulation of biobanks. This may include the need to obtain licenses or authorizations to operate as a biobank, conduct regular audits or inspections, and apply sanctions in case of non-compliance with regulations.

It is important to note that specific laws and regulations may vary by country or region, so it is crucial to consult local laws and regulations to fully understand the legal requirements applicable to biobanks in a specific jurisdiction.

Regulation and Good Practices

Quality standards and good practices in the collection, processing and storage of biological samples are essential to guarantee the integrity and reliability of the data obtained from these samples. Here are some key aspects that are addressed in these standards.[11,15,17]

Informed consent and ethics: Quality standards emphasize the importance of obtaining adequate informed consent from donors of biological samples, ensuring that the purpose of sample collection and use is fully understood. Emphasis is also placed on the need to follow ethical principles, respecting the autonomy and confidentiality of donors.

Collection methods: The standards establish guidelines for the collection methods of biological samples in order to minimize variability and preserve the quality of the samples. This includes adequate training of the personnel in charge of sample collection, the use of standardized techniques, and the implementation of quality controls during the collection process.

Labeling and recording: It is essential to correctly label each biological sample and keep a complete record of its origin, date of collection, method of collection and any other relevant data. This facilitates sample traceability and avoids confusion or loss of important information.

Proper transport and storage: Quality standards establish specific guidelines for the transport and storage of biological samples. This includes the use of adequate packaging, controlled temperature conditions, monitoring of the cold chain and the implementation of protocols for long-term storage, including the use of freezing or cryopreservation systems.

Quality control and quality assurance: The standards promote the implementation of quality control measures to guarantee the integrity and quality of biological samples. This may include carrying out quality tests and contamination controls, regular monitoring of storage conditions and participation in external quality assessment programmes.

Documentation and traceability: The standards emphasize the need to maintain complete and accurate records of all activities related to biological samples, including documentation of the chain of custody, changes in the state of the samples and any relevant events that may affect the quality or use thereof.

Regulatory and legal compliance: Quality standards are also aligned with relevant regulations and laws regarding the collection, processing and storage of biological samples. This includes compliance with privacy and data protection requirements, as well as specific regulations related to research and the use of human samples.

By following these quality standards and good practices, the reliability and integrity of biological samples can be guaranteed, which in turn contributes to the quality of the research and the results obtained. Various organizations and regulatory agencies, such as the International Organization for Standardization (ISO) and the National Institutes of Health (NIH), have developed specific guidelines and standards that detail the quality standards in the management of biological samples.[11,17,21,22,27]

The importance of collaboration between biobanks and the need to establish biobank networks to promote research and improve medical care must be highlighted.[9,19,22]

CONCLUSIONS

Biobanks are a fundamental piece of biomedical research and precision medicine. Through the proper collection, processing, and storage of biological samples and clinical data, biobanks provide valuable resources for epidemiological studies, biomarker discovery, development of personalized therapies, and advances in disease understanding.

We can highlight the following points:
Advancement of research: Biobanks allow researchers to access a large amount of samples and data, which drives scientific research in areas such as genetics, oncology, rare diseases and many others. This leads to new discoveries and advances in disease diagnosis, treatment, and prevention.

Validation of biomarkers: Biobanks play a crucial role in the validation of biomarkers, since they allow the comparison and validation of results in large cohorts of patients. This is essential to identify accurate biomarkers that can be used in early diagnosis, patient stratification, and treatment response monitoring.

Personalization of medicine: Biobanks facilitate precision medicine by allowing the identification of specific genetic and molecular profiles of patients. This makes it possible to personalize medical care, allowing more effective treatments and reducing adverse effects.

International collaboration: Biobanks offer opportunities for collaboration and exchange of samples and data between institutions and countries. This encourages global research and access to more diverse resources, which broadens scientific perspectives and increases the validity and applicability of the results obtained.

Challenges and ethical considerations: Despite the benefits, biobanks also face ethical and legal challenges, such as privacy and confidentiality of donor data, obtaining informed consent, and managing sensitive data. It is essential to address these challenges with adequate policies and regulations to guarantee the protection of the rights and dignity of donors.

In summary, biobanks are valuable resources in research and medicine, and their successful implementation requires adherence to quality standards, sound ethical considerations, and collaboration among researchers, institutions, and communities. By leveraging the diversity of samples and data stored in biobanks, scientific innovation can be driven and healthcare improved for the benefit of society at large.

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