THE CONCEPT OF THE BIOBANK INFORMATION SYSTEM AT *NICOLAE TESTEMITANU* STATE UNIVERSITY OF MEDICINE AND PHARMACY, REPUBLIC OF MOLDOVA

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Keywords: *Biospecimens, Biobank, research, database, donors.*

Introduction*. During the implementation of the Informational Record of Biospecimens within the Biobank project, the Register of Informational Record of Biospecimens within the Biobank software was developed and implemented.*

Material and methods. *A narrative synthesis on the informational aspect of bio-specimens within the Biobank at the international level was conducted. Sources were searched in public databases, and after identification and deduplication, 34 relevant sources were selected, out of which 15 were comprehensively analyzed. The Register of Informational Record of Biospecimens within the Biobank software fully captures the flow of information within the Biobank at the Nicolae Testemitanu State University of Medicine and Pharmacy and serves as a tool for managing the biospecimens stored in the Biobank. It offers various capabilities to ensure diverse and representative data regarding potential donors of biospecimens.*

Results. *The software enables rapid processing of biospecimens and their associated data, ensuring traceability with extensive management capabilities for diverse types of biospecimens at all stages throughout the Biobank circuit. The relevance of this data facilitates the improvement and acceleration of research and decision-making in the field of health, to the benefit of the donors. The software allows for the rapid registration and processing of biospecimens from donors in various research studies, adhering to the principles of research ethics and ensuring the anonymity of donors' personal data, as well as the biospecimen data and associated information.*

Conclusions. *The Register of Informational Record of Biospecimens within the Biobank software is relevant for initiating scientific research. Potential beneficiaries, including scientific researchers, collaborators in scientific laboratories, and the academic staff at Nicolae Testemitanu State University of Medicine and Pharmacy, will benefit from comprehensive informational support for biospecimen records within the Biobank and have opportunities to streamline research activities.*

Cuvinte-cheie: *biospecimene, biobancă, cercerare, bază de date, donatori.*

CONCEPTUL SISTEMULUI INFORMAȚIONAL AL BIOBĂNCII UNIVERSITĂȚII DE STAT DE MEDICINĂ ȘI FARMACIE „NICOLAE TESTEMIȚANU" DIN REPUBLICA MOLDOVA

Introducere. *În perioada realizării proiectului „Evidența informațională a biospecimenelor din cadrul Biobăncii" s-a elaborat și implementat softul „Registrul de evidență informațională a bio-specimenelor din cadrul Biobăncii".*

Material și metode. *Softul „Registrul de evidență informațională a biospecimenelor din cadrul Biobăncii" reflectă pe deplin mișcarea fluxului informațional din cadrul Biobăncii USMF „Nicolae Testemițanu" și servește ca instrument de gestionare a biospecimenelor stocate în Biobancă și are o serie de posibilități pentru a asigura date diversificate și reprezentative privind potențialii donatori de biospecimene.*

Rezultate. *Softul permite prelucrarea rapidă a biospecimenelor și a datelor asociate acestora, și asigură trasabilitatea cu posibilități vaste de gestionare a biospecimenelor de natură diferită la toate etapele circuitului în Biobancă. Relevanța acestor date facilitează îmbunătățirea și accelerarea cercetării și luării de decizii în domeniul sănătății în beneficiul donatorilor. Softul permite înregistrarea și prelucrarea rapidă a biospecimenelor de la donatori în diverse studii de cercetare, respectând principiile eticii cercetării, și asigură anonimatul datelor personale ale donatorilor, precum și a datelor biospecimenelor și a informațiilor adiacente acestora.*

Concluzii. *Software-ul „Registrul informațional al biospecimenelor din cadrul Biobăncii" este relevant în inițierea cercetării științifice. Beneficiari potențiali, cercetători științifici, colaboratori ai laboratoarelor științifice și personalul didactico-științific al USMF „Nicolae Testemitsanu", vor beneficia de un suport informațional cuprinzător pentru evidența biospecimenelor din cadrul Biobăncii și vor avea posibilități de eficientizare a activității de cercetare.*

INTRODUCTION

In the Republic of Moldova, the ongoing development of activities in the field of the human genome, technological innovations in cell processing, genetic research to study and describe the connections between genes, the physical and social environment, and people's lifestyles has led to the establishment of the national Biobank within the *Nicolae Testemitanu* State University of Medicine and Pharmacy (SMUPh), Republic of Moldova. Given the various types of Biobanks, it is essential to define the objectives of the Biobank at the outset of its formation.

The establishment of the Biobank requires accreditation and strict compliance with current quality standards. The Biobank at *Nicolae Testemitanu* SUMPh contains organized collections, storing human biological samples and associated data that are of great importance for research and personalized medicine. In other words, the Biobank serves as a repository of biological materials (biospecimens).

The purpose of the Biobank is to conduct the collection, reception, encoding/decoding, processing, storage, preservation, freezing, thawing, distribution, and/or destruction of biospecimens collected from patients involved in various research studies, along with their associated data, in order to support scientific investigations.

The individuals participating in the studies are assured of anonymity regarding their personal data after signing the consent form. Subsequently, samples are taken for the necessary biomaterial. The collected data are used exclusively for scientific and research purposes. During the biomaterial sampling and processing, personal data anonymization methods are employed, adhering to the limits established by the Personal Data Security Policy and the legal norms outlined in Law no. 133 of July 8, 2011, concerning the protection of personal data, as well as Law no. 71 of March 22, 2007, regarding registers. Ethical concerns surrounding biospecimens and the involvement of a number of people (operators) require special attention in information processing, with the incorporation of technological means. These factors constitute the critical components of the Biobank, with efforts made to ensure efficiency and safety in this aspect.

MATERIAL AND METHODS

A narrative synthesis was conducted on the informational subject of biospecimens within the Biobank at the international level. Simultaneously, data were systematized to fully reflect the movement of the information flow within the *Nicolae Testemitanu* SUMPh Biobank. Information sources were searched in PubMed, Google Scholar, and Hinari databases. The search strategies involved using keywords such as "biospecimens," "biobank," "database," "donors," and "data." The inclusion criteria for publications were articles published between January 2015 and January 2024. These publications were identified in databases such as Google Scholar, PubMed, HINARI, etc. After removing duplicate records and screening abstracts, 54 scientific sources were selected, of which 15 articles were fully reviewed.

The Biobank at *Nicolae Testemitanu* SUMPh features a specialized laboratory (scientific center) that enables the research, collection, processing, and storage of biospecimens obtained as a result of research projects. These biospecimens can be utilized in clinical trials or in prospective or retrospective studies (1). The increasing demand for tissues for translational studies is leading to a rise in the number of Biobanks (2).

RESULTS

The purpose of biobanks. To standardize the activities of the Biobank, it is necessary to implement standard operating procedures in all aspects, from acquisition, shipment, storage, and destruction to the safety of biospecimens (3). However, the development of these Biobank practices involves specialists to address potential ethical, legal, and social issues (4). The expanding field of biotechnology, which requires the establishment of an information system to monitor the collected biospecimens, highlights the increasing importance of financial support for Biobanks (5).

Biobanks serve as collections of biospecimens, which can later be used to elucidate medical diagnoses and personalized treatments (6). With this in mind, aliquoting will allow the use of biospecimens for both clinical and research purposes (7). To achieve this objective, the Biobank at *Nicolae Testemitanu* SUMPh collects, stores, and processes human biological materials, ensuring security in the collection of biospecimens intended for research or their use to guarantee a high level of

protection and promotion of human health. Various standard operating procedures and best practice protocols for biobanks are available, and the determination of which to use often depends on the specific needs of the clinic or study being conducted. The Best Practices for Operating Procedures, published by the Biospecimen Research Branch (NCI BBRB), can be accessed online (8).

Within the Biobank at *Nicolae Testemitanu* SUMPh, internationally standardized procedures, adjusted to the current legislation, have been implemented to assist researchers in making clinical decisions.

Screening the donor population can elucidate the specific alleles underlying a unique disease phenotype. By conducting such studies, it becomes possible to evaluate the environmental effects alongside the genetic ones, studying both monozygotic and dizygotic twins. This prospective approach can be employed in preventive medical programs and epidemiological studies (9).

The efficient management of biospecimens in the Biobank requires prompt and accurate collection, proper storage, and the recording of related information in an electronic system.

The information system allows for the accumulation and analysis of information related to biospecimens, including their storage in the Biobank and the monitoring of the flow of biospecimens from donors in various research studies. It ensures traceability with vast possibilities for managing biospecimens of different natures at all stages in the Biobank circuit.

The software contributes to the effectiveness and efficiency of personalized medicine processes, ensuring the qualitative management of information about research subjects. It serves as a strategic tool for the competitive clinical management of health services.

The information received from the medical institutions participating in the research projects is stored in the biospecimen record system using a standardized recording form. The data transmission procedure is outlined in a standardized instruction. The form encompasses primary patient data from various research studies, including passport information, epidemiological data, clinical details, paraclinical data, and more. These details are then presented to the operator responsible for records within the Biobank.

The Biobank operator accumulates and stores data in the *Register of Informational Record of Biospecimens within the Biobank* software, developed as part of the *Informational Record of Biospecimens within the Biobank* project, number 21.70086.37ŞD.

Collecting pertinent data on researched patients enables the assessment of management potential, efficiency options, and effectiveness in enhancing patients' quality of life while minimizing the impact on the health system.

Following the processing of all the data obtained at the Biobank level, information is obtained about the patients included in the research, with the elaboration of reports on the state of health regarding various medical conditions as well as their genealogy.

Donors' personal data, including biomaterial coding, are accessible to a limited number of people. Confidentiality regarding their identity and background is maintained throughout and after the completion of their studies.

Software requirements. Accreditation of a Biobank ensures that the laboratory (scientific center) controls and optimizes the use of biospecimens in accordance with good professional practice, as defined by internationally established standards. Accreditation requirements include the implementation of an operational quality management system and continuous control of the methods used for diagnostic purposes (10). Consequently, the Biobank is recognized for maintaining high-quality processes that produce reliable results. The accreditation process provides the Biobank with acknowledgment by ensuring consistency and standardization of practices.

Clinical research involving the Biobank requires approval from the Medical Ethics Committee (11). The cornerstone of bioethics is informed consent, which mandates providing patients and/or subjects with an overview of the study, a discussion of the protocol specifics, and disclosure of potential benefits and risks.

Equally important to a Biobank's role in acquiring and processing biospecimens is the management of clinical and research data relevant to each of those biospecimens. The *Nicolae Testemitanu* SUMPh Biobank's information record software has important capabilities that are recommended

in the practice guidelines and provides a secure environment that protects the data, includes a unique and unchangeable identifier for all biological samples, and the ability to continuously monitor the location and status of the evidence. The software system, with its implemented encryption component, operates 24/7, has a resilient infrastructure, and can effectively handle disasters and downtime. Moreover, it has the capability to recover stored data from regular backups using hard drives, external hard drives, USB sticks, and other portable memories, all properly encrypted to meet the latest information technology standards.

The biospecimen information record software within the Biobank satisfies the complete structure of the medical information of donors' samples. This adherence is in accordance with the sample collection form developed by the work team and provided to the Biobank at *Nicolae Testemitanu* SUMPh. It fully meets the needs for storage, processing, and validation of the obtained data. The software encompasses instruments enabling the accumulation and storage of information about the collected samples in the Biobank. It includes processing elements for primary donor data, diagnostic data, bio-specimen type, and more. It allows access to information about biospecimen donors from medical institutions, both separately by institution and in full, including donor data. The software facilitates the storage of sample information about donors through the software component created for the *Nicolae Testemitanu* SUMPh Biobank, which owns the database. Moreover, it grants access to collaborators at *Nicolae Testemitanu* SUMPh who are authorized to work with the IT system in question. The software enables the processing and analysis of results, such as the selection of samples based on criteria like nosology and those related to a specific period, on an institutional level. Additionally, it offers the capability to create reports through graphical representation and the use of statistical formulas. It is equipped with functionalities to analyze correlations between the data stored in the software from all medical institutions as a whole.

The software is equipped with interactive subsystems tailored to facilitate the tasks of operators. One group of operators focuses on collecting information from various medical institutions, while another operator, situated within the Biobank at *Nicolae Testemitanu* SUMPh, processes the gathered data. Hence, the software, referred to as the *Register of Informational Record of Biospecimens within the Biobank*, is organized into modules, each comprising two primary components. The first component is designed to input information about donors and the details acquired during the collection of their samples from medical institutions. The second component is integrated within the Biobank at *Nicolae Testemitanu* SUMPh, and its role is to manage the collection and preservation of human biological material for scientific purposes.

Each system component encompasses functions such as input-output, data validation and control, and performing relevant calculations to ensure the provision of information flows based on various parameters (grouping criteria). This shared functionality across different system services enhances the efficiency and quality of information related to the collection of donor sample data.

The computer system can manage information collected at the time of receiving biospecimens, as well as details about previously stored samples (both current and stored over time). The software is equipped with a service and maintenance tool for the database. The system includes essential components for reporting statistical data (a set of standardized reports) about donor samples stored in the database. Diagnoses are recorded according to the international codes of ICD revision X.

The computer system, named *Register of Informational Record of Biospecimens within the Biobank*, implemented within the Biobank at *Nicolae Testemitanu* SUMPh, can group, adjust, and process information within an individual medical institution, as well as across all medical institutions whose donor samples are included in the register. It also has the capability to process data from any period within the stored records.

Taking into account the potential dangers that may arise when collecting donors' personal data as well as the real risks when storing and processing them, the software provides the possibility of anonymizing and encrypting personal data.

Within the computerized system of informational record of biospecimens within the Biobank, technical and organizational measures will be imple-

mented to prevent the destruction or unauthorized modification, processing, and access to the data in the system. The primary and traditional measure for protecting personal data is the obligation of the staff engaged in using the IT system to maintain the confidentiality of patients' medical data. Given the various potential biosecurity hazards involved in working with bio-specimens, it is crucial for all staff members to adopt appropriate security measures. The relevant Biobank staff will regularly review biosafety information documents for all materials used. These documents include Material Safety Data Sheets, providing information on health hazards associated with chemicals and infectious agents, as well as guidelines on how to use biosafety items (12).

To ensure the confidentiality of donor sample data and medical institutions, the software should restrict access to unauthorized individuals. Depending on the size, various types of staff may be required for proper Biobank operation (13, 14, 15). Therefore, when hiring staff for a Biobank, factors such as professional training, work ethic, promptness, intellectual capacity, teamwork, and communication skills must be taken into consideration. Additionally, employees should be enrolled in educational programs to obtain the required certifications. Biobank staff may have a range of responsibilities such as purchasing, processing, storing, and maintaining the database.

DISCUSSIONS

The system's integrity is assured by the proper functioning of the developed tools. Data processing for scientific medical research and statistical purposes must adhere to suitable safe guards. The computer system will provide regular backups of data. The Biobank oversees the management and storage of data and generates electronic registers based on information authenticated and validated according to pre-established criteria.

The software developed for the Biobank provides data that will describe the biological material, its origin, and outcome. It facilitates information exchange with medical institutions through network traffic established between the Biobank and these institutions. Electronic records are created online, and the system encompasses various functionalities:

- Sample Collection Register - activates a screen with a table containing all the recorded samples;
- Project Log - opens a screen with a table containing all existing projects in the platform and related information;
- Donor register - opens a screen with a table containing the data of all the donors registered in the Biobank platform who have developed analyses, according to their agreement, for different scientific researches and projects;
- Results register - opens a screen with a table containing all the results of samples registered in the platform;
- Archived samples register - opens a screen with a table containing all the samples that have been destroyed, removed from research or have completed their research cycle.

The software implemented in the Biobank of the *Nicolae Testemitanu* SUMPh has an archiving system for sample records.

CONCLUSIONS

1. The development of the Biobank at *Nicolae Testemitanu* SUMPh adheres to the same requirements as other Biobanks for research. Emphasizing ethical considerations and respecting personal data through encryption are primary elements of the software development. This Biobank has the potential to offer unique research-based services to the scientific and medical community. Biospecimens are essential resources for research focused on human diseases. It is crucial for funding agencies, governments, and private entities to continue recognizing the importance of Biobanks in the ongoing development of human genome activities and genetic research.
2. Scientific researchers, collaborators of scientific laboratories, teaching and scientific staff at *Nicolae Testemitanu* SUMPh benefit from comprehensive informational support for recording biospecimens within the Biobank at *Nicolae Testemitanu* SUMPh, and they have the opportunity to enhance the efficiency of their research activities.

CONFIRMATION

This work was developed at *Nicolae Testemitanu* State University of Medicine and Pharmacy as part of the research project *Informational Evidence of Biospecimens within the Biobank* during the years 2021-2023, under the strategic direction of *Information Technology and Digital Development*. The project is registered in the State Register of projects in the field of science and innovation under the number 21.70105.37ŞD.

CONFLICT OF INTEREST

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

ETHICAL APPROVAL

The study was conducted and approved by the Ethics Committee no. 35/03.05.2022 of *Nicolae Testemitanu* State University of Medicine and Pharmacy of the Republic of Moldova.

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