Journal of Diabetes & Metabolic Disorders
https://doi.org/10.1007/s40200-021-00781-8

COMMENTARY

Establishment of biobank facility at Endocrinology and Metabolism Research Institute of Iran: experiences, challenges, and future outlook

Somayeh Parichehreh-Dizaji[1] · Hilda Samimi[1] · Effat Asadolahpour[1] · Farzaneh Karimi-Birgani[1] · Vahid Haghpanah[1,2] · Bagher Larijani[3,4]

Received: 24 January 2021 / Accepted: 20 March 2021

Abstract

Biobanking as an emerging procedure referring to the development of sample storage technologies which provide essential structures for conducting research. This paper presents the experiences and challenges faced while establishing the non-communicable diseases (NCDs)-dedicated biobank at Endocrinology and Metabolism Research Institute (EMRI) in Iran, such as infrastructure, Laboratory Information Management System (LIMS), ethical and legal aspects, sample collection, preservation, and quality control (QC). NCDs are a major health problem around the world and in Iran, which is access to biological samples are required to understanding and planning to these diseases. The main objectives of the EMRI biobank is currently the collection and storage of biological samples such as blood, serum, plasma, urine and DNA from patients with NCDs including diabetes mellitus osteoporosis and elderly population based on cohort and cross-sectional studies. The biobank of EMRI aims to have a major impact on the NCDs by supplying biological samples for national and international research projects.

Keywords Biobank · Non-communicable diseases · Endocrinology and Metabolism Research Institute · Tehran University of Medical Sciences · Iran

Introduction

Since 1990 s, the creation of biobanks has been the subject of the scientific community [1]. In fact, pathology collections have been the primary biobanks for over hundred of years before modern biobanks were created [2]. The term "biobank" is used for the collection, storage, and maintaining a variety of plants, animals, bacterial, and human biological materials for applications such as research, clinical care, diagnostic purposes, and therapeutic treatment [3, 4]. Most biobanks store human specimens, along with clinical and demographic records, and environmental factors [1]. Moreover, biobanks provide researchers with immediate access to samples and speed up research projects [1] and so it seems to reduce common costs as associated with participants and sampling.

✉ Vahid Haghpanah
v.haghpanah@gmail.com; vhaghpanah@tums.ac.ir

✉ Bagher Larijani
emrc@sina.tums.ac.ir

Somayeh Parichehreh-Dizaji
parichehreh1365@gmail.com

Hilda Samimi
hilda_samimi@yahoo.com

Effat Asadolahpour
asadolahpour.1984@gmail.com

Farzaneh Karimi-Birgani
farzanehkarimi76@yahoo.com

[1] Endocrinology and Metabolism Research Center, Endocrinology and Metabolism Clinical Sciences Institute, Tehran University of Medical Sciences, Tehran, Iran

[2] Personalized Medicine Research Center, Endocrinology and Metabolism Clinical Sciences Institute, Tehran University of Medical Sciences, Tehran, Iran

[3] Osteoporosis Research Center, Endocrinology and Metabolism Clinical Sciences Institute, Tehran University of Medical Sciences, Tehran, Iran

[4] Diabetes Research Center, Endocrinology and Metabolism Clinical Sciences Institute, Tehran University of Medical Sciences, Tehran, Iran

Published online: 05 April 2021

The challenges typically associated with biobanks include ethical and legal issues as well as financial problems. Also, in biobank infrastructure various mechanisms concerning the organization, storage, operation as well as quality management system must be in accordance with the international standards [1]. There are many different types of biobanks such as disease-centric, population-based, genetics or DNA/RNA, organ/tissue-specific, project-driven, commercial and virtual biobanks [3]. In order to save labor and optimize quality and turnaround times, using automatized sample handling and storage procedures is recommended while handling large quantities of biospecimens in the setting of biobank facilities. Doing so could reduce the risk of temperature variations and thence is considered as an effective way to preserve sample quality in translational research [5].

Endocrinology and Metabolism Research Institute (EMRI) biobank

The biobank of EMRI has officially started its activity for accepting the samples since February 2018. After the allocation of a dedicated space in EMRI's main building, the equipment procurement has been performed according to the world standard protocols [6–8]. This biobank is committed to supporting and facilitating research projects that promote community health in the country and hopes to have an important influence on prevention, diagnosis, and treatment of non-communicable diseases (NCDs) by providing biological samples for national and international scale research projects. In this paper, we present the experiences and challenges we faced during the establishment of the NCDs-dedicated biobank at EMRI in Iran including infrastructure, Laboratory Information Management System (LIMS), ethical and legal aspects, sample collection, preservation and quality control (QC).

Infrastructure, equipment

When setting up this biobank, the best practice recommendations developed by the International Agency for Cancer Research (IARC) and the International Society for Biological and Environmental Repositories (ISBER) were used to standardize the biobank-related processes [6–8]. All preparations in the floor and Wall Finishes were done in accordance with international standards in the field of the biobanking [6–8]. The biobank space is divided into two sections. We process the samples in one section and preserve them in another separate section. The alarming system for alterations in freezers temperature as well as the ambient CO, O_2 and CO_2 of the preservation area are available. A powerful cooling system is also designed to protect against the hot climate and to maintain the temperature of the area at around 20 °C. Additionally, the protection of specimens and data stored therein are assured via security cameras and door entry sensors. Moreover, CO_2 backup systems and Emergency Power Supply Systems (EPSS) are prepared for possible power outages. Besides, automatic voltage stabilizers are used to act efficiently to damp the electromechanical oscillations in the interconnected power systems.

Laboratory Information Management System (LIMS)

Electronic management and tracking of samples as well as associated clinical data are performed by LIMS system. Choosing a LIMS for biobanking purposes should be based on certain features such as the cost-effectiveness, customization and flexibility, the regular updating of the software, ease of implementation, maintenance, security, support, availability to technical support services, supporting barcode design and printing, as well as handling of large amounts of sample information [9–11]. The LIMS elaborated in the biobank is the biobank Sample-Tracker software developed by "BATAB Tajhiz Parsin" company located in Iran, that provides biobank efficiency and control services. This software is a web- and window-based operating system and is designed for a variety of display equipment such as tablets, laptops, personal computers, etc. This software manages and displays sample location in freezers and also the sample life cycle from collection to distribution and all transfers that each sample has had in its life cycle. In order to identify a sample correctly, and to avoid human errors, the related operations are carried out manually using a barcode reader. The biobank Sample-Tracker software has the ability to define and manage plans and phases. Also, biobank Sample- Tracker software manages the user access through allowing only registered users to provide maximum security. The biobank Sample-Tracker software can also provide reports in PDF, excel and other formats compatible with comprehensive Hospital Information System (HIS) software. These reports include the status of samples, user performance reports, transactions performed on the sample, such as deletion, transfer, consumption or registration of samples, defined boxes, racks, etc.

Ethical-legal aspects

Ethical considerations observed in this biobank facility consist of obtaining explicit and informed consent from patients as an essential aspect of research, privacy and anonymity of participants' identities as well as the protection of personal information. Moreover, we are committed to observe the ethical considerations in accordance with the international ethical guidelines with regard to the delivery of results to participants,

commercialization process, exchange of information and sample ownership.

In our biobank facility, we receive a broad informed-consent from each participant which permits the researchers to use participants' samples and data in the future for unrelated research studies other than that reported in the document. The consent form, presented in an easily comprehensible manner, is accessible for each participant. Privacy and confidentiality in accordance with the international biological ethics guidelines are important issues for this biobank. Protecting patient privacy will create mutual trust between the patients and researchers/biobankers. To address this, we make sure the samples are coded and deidentified. According to the international ethical regulations, we remove the sample and accompanying clinical data upon participant withdrawal. In our biobank, the protocol of human specimens and wide-spread data sharing, both in the national and international context, are in accordance with the practical guidelines, protocols and standards in the field of biobanking [7, 8].

Collection, preservation, and QC of samples

The IARC and ISBER guidelines have established generic benchmarks in biorepository science for internationally accepted best practices [6–8]. To ensure proper preservation and protection of valuable biospecimens, we have designed a well-developed and reliable infrastructure that adheres to international guidelines by IARC and ISBER best practices [6–8]. Also, Standard Operating Procedures (SOPs) are used for the management of biological samples in all steps including collection, handling, processing, storage and analysis of biomarkers, in accordance with best-practice guidelines. Samples are stored in barcoded cryovials. The relevant information are scanned accurately and saved in LIMS software dedicated to the project. As a matter of course, the quality of samples is affected by pre-analytical variables during the handling of the samples. Therefore, the QC process in this biobank is considered from the pre-analytical period until the sample repository. In this biobank, QC is performed yearly in 2 % of the frozen samples randomly.

Non-communicable diseases biobank at EMRI

NCDs such as diabetes, osteoporosis, alzheimer's disease, cardiovascular diseases and cancers are one of the challenges of the 21st century [12]. According to the latest statistics reported by World Health Organization (WHO) in 2018, the mortality rate of NCDs was 71 % of all cause death in the world [12]. The prevalence of NCDs was increased and now it is the main causes of morbidity and mortality among Iranian population. The mortality rate due to NCDs in Iran has increased from 57 % to 1990 to 76 % in 2010 [13], and it has reached to 82 % in 2016 [14]. In several developing countries, similar trends were observed [13].

Given the high prevalence of NCDs in Iran, the establishment of a biobank at EMRI, as a scientific hub in Iran, could significantly improve the quality of biological and biomedical research in the areas of NCDs in the country. This NCDs dedicated biobank is deemed to have an important influence on prevention, diagnosis, and treatment of NCDs by providing biological samples for national and international research projects. Currently, the main goal of this biobank is collecting and storing high-quality biological samples from Iranian populations so that we can better characterize, understand and apply the research findings to improve the community health. For this purpose, we participated in an elderly health cohort and in a cross-sectional study related to osteoporosis, cardiovascular and diabetes. The EMRI's biobank is a valuable and developing resource for multidisciplinary research in Iran. This facility is both a disease-oriented biobank to store samples and also a population-based infrastructure to use samples of nationwide studies.

Future plans

The biological samples of a population-based prospective cohort including cardiovascular, cognitive, and osteoporosis-related data are currently being collected in our biobank facility. Annual follow-up will be performed for all participants. Also, automated biobanking is increasingly considered in the EMRI's biobank. Furthermore, we are going to establish an "Endocrine Tumor Bank (ETB)". Therefore, a dedicated space is allocated to this facility and required equipment are provided according to IARC and ISBER standards [6–8, 15]. This tumor bank will be committed to provide tumor samples of endocrine neoplasms, mainly thyroid cancers that have been collected and stored under optimum conditions for national and international collaborative research projects. Through the analysis of these samples, this tumor bank is deemed to have an important impact in the prevention, diagnosis, and treatment of endocrine neoplasms.

Abbreviations NCDs, Non-communicable diseases; EMRI, Endocrinology and Metabolism Research Institute; LIMS, Laboratory Information Management System; QC, quality control; IARC, International Agency for Cancer Research; ISBER, International Society for Biological and Environmental Repositories; HIS, Hospital Information System; SOPs, Standard Operating Procedures; WHO, World Health Organization; ETB, Endocrine Tumor Bank; EPSS, Emergency Power Supply Systems

Acknowledgements The authors are grateful to Mrs. Hajipour for her English language comments on the initial draft of the manuscript. Also, the authors are thankful to Mrs. Sahar Jahangiri for her helpful

suggestions and advice. The authors also thank the World Health Organization (WHO), as recognized in the references, for providing permission to reprint the free data.

Data availability Not applicable.

Code availability Not applicable.

Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethics approval Not applicable.

Consent to participate Not applicable.

Consent for publication Not applicable.

References

1. Khabour OF, Abu-Siniyeh A. Challenges that face the establishment of diabetes biobank in Jordan: a qualitative analysis of an online discussion forum. J Multidiscip Healthc. 2019. https://doi.org/10.2147/JMDH.S194161.
2. Vaught J. Biobanking comes of age: the transition to biospecimen science. Annu Rev Pharmacol Toxicol. 2016. https://doi.org/10.1146/annurev-pharmtox-010715-103246.
3. De Souza YG, Greenspan JS. Biobanking past, present and future: responsibilities and benefits. Aids. 2013. https://doi.org/10.1097/QAD.0b013e32835c1244.
4. Hewitt R, Watson P. Defining biobank. Biopreserv Biobank. 2013. https://doi.org/10.1089/bio.2013.0042.
5. Linsen L, Van Landuyt K, Ectors N. Automated sample storage in biobanking to enhance translational research: the bumpy road to implementation. Front Med (Lausanne). 2019. https://doi.org/10.3389/fmed.2019.00309.
6. Mendy M, Caboux E, Lawlor RT, Wright J, Wild CP. Common minimum technical standards and protocols for biobanks dedicated to cancer research. Lyon: International Agency for Research on Cancer; 2017. https://publications.iarc.fr/Book-And-Report-Series/Iarc-Technical-Publications/Common-Minimum-Technical-Standards-And-Protocols-For-Biobanks-Dedicated-To-Cancer-Research-2017
7. ISBER. Best Practices: Recommendations for Repositories 4th ed. International Society for Biological and Environmental Repositories. 2018. https://cdn.ymaws.com/www.isber.org/resource/resmgr/best_practices_4th_edition/isber_best_practices_recomme.pdf. Accessed 20 Dec 2020.
8. Campbell LD, Astrin JJ, DeSouza Y, Giri J, Patel AA, et al. The 2018 revision of the ISBER Best practices: summary of changes and the editorial team's development process. Biopreserv Biobank. 2018. https://doi.org/10.1089/bio.2018.0001
9. Soo CC, Mukomana F, Hazelhurst S, Ramsay M. Establishing an academic biobank in a resource-challenged environment. S Afr Med J. 2017. https://doi.org/10.7196/SAMJ.2017.v107i6.12099.
10. Abayomi A, Christoffels A, Grewal R, Karam LA, Rossouw C, et al. Challenges of biobanking in South Africa to facilitate indigenous research in an environment burdened with human immunodeficiency virus, tuberculosis, and emerging noncommunicable diseases. Biopreserv Biobank. 2013. https://doi.org/10.1089/bio.2013.0049.
11. Akinyemi RO, Akinwande K, Diala S, Adeleye O, Ajose A, et al. Biobanking in a challenging african environment: unique experience from the SIREN project. Biopreserv Biobank. 2018. https://doi.org/10.1089/bio.2017.0113.
12. WHO. Noncommunicable diseases country profiles 2018. Introduction and mortality, p. 10. Geneva: World Health Organization. 2018. https://www.who.int/publications/i/item/ncd-country-profiles-2018. Accessed 20 Dec 2020.
13. Farjam M, Bahrami H, Bahramali E, Jamshidi J, Askari A, et al. A cohort study protocol to analyze the predisposing factors to common chronic non-communicable diseases in rural areas: Fasa Cohort Study. BMC Public Health. 2016. https://doi.org/10.1186/s12889-016-3760-z.
14. WHO. Noncommunicable diseases country profiles 2018. Iran (Islamic Republic of), p. 108. Geneva: World Health Organization. 2018. https://www.who.int/publications/i/item/ncd-country-profiles-2018. Accessed 20 Dec 2020.
15. ISBER. Best Practices: Recommendations for repositories, Addendum 1: Liquid nitrogen-based cryogenic storage of specimens. 4th ed. International Society for Biological and Environmental Repositories. 2019. https://cdn.ymaws.com/www.isber.org/resource/resmgr/best_practices_4th_edition/addendum-1/isberbestpractices-cryad-ful.pdf. Accessed 20 Dec 2020.