East African Scholars Journal of Medical Sciences
Abbreviated Key Title: East African Scholars J Med Sci
ISSN: 2617-4421 (Print) & ISSN: 2617-7188 (Online)
Published By East African Scholars Publisher, Kenya

Volume-4 | Issue-1 | January-2021 | DOI: 10.36349/easms.2021.v04i01.001

OPEN ACCESS

Review Article

Banking on Biobank: A Cognizance

Priyanka A[1], Wilma Delphine Silvia CR[2], Venkata Bharat Kumar Pinnelli[3*], Mangala N Sirsikar[4], Debalina Sen[1]

[1]Tutor, Department of Biochemistry, Sri Atal Bihari Vajpayee Medical College & Research Institute, Bangalore-560001, India
[2]Professor & Head, Department of Biochemistry, Sri Atal Bihari Vajpayee Medical College & Research Institute, Bangalore-560001, India
[3]Professor, Department of Biochemistry, Vydehi Institute of Medical Sciences & Research Institute, Bangalore-560066, India
[4]Associate Professor, Department of Biochemistry, Vydehi Institute of Medical Sciences & Research Institute, Bangalore-560066, India

Article History
Received: 16.12.2020
Accepted: 04.01.2021
Published: 09.01.2021

Journal homepage:
https://www.easpublisher.com

Quick Response Code

Abstract: A biobank may be a form of biorepository that stores biological samples (usually human samples) to be used for diagnostic/ research purpose. Biobank became a key resource, supporting many varieties of up to date research like genomics and personalized medicine since 1990. A Biobank acts as a basement with the elaborated detailed information which are associated with the individuals from whom biological materials are collected. Establishment of assorted Biobank, the provision of human tissues/blood samples for translational research has been increased, which successively help in validation and standardization of diagnostic, prognostic and therapeutic predictive biomarkers. Biobank can be used for several research purposes like, in Cell and biological science, Blood Center, Pathology, Genetics, Bioengineering, Cryobiology and Bioinformatics. Biobanking helps in molecular profiling of samples. This review has emphasized on description of biobank, to grasp differing types, collection, storage, retrieval, ethical issues, applications, functionality of Biobanking in India and its limitations.

Keywords: Biobank, biological material, virtual biobank, health care, databank.

INTRODUCTION

A biobank may be a style of biorepository that stores biological samples (usually human samples) to be used for diagnostic/ research purpose. Biobank became a key resource, supporting many sorts of latest research like genomics and personalized medicine since 1990. A Biobank acts as a crypt with intricate detailed information regarding the individuals from whom biological materials are collected. Establishment of assorted Biobank, the provision of human tissues/blood samples for translational research has been increased, which successively help in validation and standardization of diagnostic, prognostic and therapeutic predictive biomarkers. Biobanks can be used for several research purposes like, in Cell and biology, Blood Center, Pathology, Genetics, Bioengineering, Cryobiology and Bioinformatics. Biobanking helps in molecular profiling of samples. This review has emphasized on description of biobank, to grasp differing kinds, collection, storage, retrieval, ethical issues, applications, functionality of biobank in India and limitations. A 'bank' could be a place where individuals or groups deposit their own assets for short- or long-term periods. The individual think that bank will be held responsible and take care of their things safely nut never own them. And a depositor is absolving to withdraw his/her assets anytime. Similarly, a biobank may be a facility for safekeeping and storage of biological specimens for research. Biobank collect, process, store and distribute biological material and related data to research organizations. These "biospecimens" and data are employed by scientists to find out more about human diseases, their causes and effects are applied to develop better prevention measures, better diagnostic tests and better therapies [1]. By definition: a service whereby biological materials are human sample, like tissue, blood, body fluids etc., and also the data is any information, including medical information regarding the donor of that sample are collected, stored, processed and distributed for the aim of research project and/or medical treatment. It encloses the placement still because the full range of procedures involved during this operation [2-7]. Biobanks are established within a Institution, medical colleges, research laboratories, pharmaceutical and biotechnology companies. They will even be stand-alone organizations, including independent companies that may provide biobanking services and access to samples as a service to the research community or patients. There are multiple

***Corresponding Author:** Dr. Venkata Bharat Kumar Pinnelli

designs in line with different possible goals. Briefly, human sample-related biobanks include three major types: Human biobank classification relies on: Tissue type (tumor tissue, cells, blood, DNA or RNA), Purpose/intended use (research, forensics, transplantation, source for therapeutics, e.g., umbilical blood, vegetative cell biobanks for individual or community use, or diagnostics) & ownership (academic and research institutions, hospitals, biotechnology and pharmaceutical companies or government run).

Currently, the widely accepted classification comes from the pan-European Biobanking and Biomolecular Resources Research Infrastructure (BBMRI):

Population oriented biobanks: The main aim is to make biobankers population identity and susceptibility. It will start from the DNA of various different healthy individual donors representing from different countries, region, and ethnic cohort.

Disease-oriented biobanks for epidemiology: These are involved mainly in targeting biomarkers of exposure, uses large sample size, usually they follow a healthy exposed cohort/ case- control study and that may include germ line DNA studying also or serum markers and enormous amounts of specifically designed and picked up data.

Disease-oriented general biobanks (e.g. tumor banks): The main aim of them is to keep in touch with the biomarkers of the particular disease through sample collection and derivatives (DNA/RNA/Proteins) mostly they will be in association with clinical trials or clinical data. The amount of clinical data linked to the sample determinate the provision and biological value of the sample [8].

Genesis of Biobanking

In 1996, Loft and Poulsen were the primary to use the word "biobank", a paper investigating the role of oxidative DNA damage as an independent risk consider cancer, to work out the use of human biological material [9]. Since that point the biobanking has grown and improved within the medical research. Much of this progress occurred following the arrival of genomics, transcriptomics, proteomics, metabolomics then the power to develop large electronic databases that store huge amounts of information (big data) associated with patient clinics [10].

Biobanks can be defined according to Organization for Economic Cooperation and Development as the structured resources which can be used for all type of genetic research which includes human biological materials and/or the individual information generated from genetic analysis and associated information.

The European Commission had published a comprehensive document which highlighting the most role of a biobank: (i) to gather and store biosamples which are annotated with medical data and sometimes epidemiological data; (ii) not consider collection projects static but continuous or long term; (iii) to follow with current and/or future research projects at the time of specimen collection; (iv) to use coding or to assure the donors privacy, together with that a re-identifiable process for particular conditions where clinically regarded information becomes known and can also be provided to the patients and (v) to include established governance structures and procedures (e.g., consent) that protect donors rights and stakeholder interests [11].

Aim and Goals of a Biobank

A human biobank aims to build a central resource that can support research intended to better understand human diseases. Goals of the biobanks are: Creating a collection of samples from different sources, conducting research on the collected samples, facilitating the transfer of knowledge and ensuring sample quality, quantity, and representativeness.

Role of Biobanking Towards Healthcare

Directly involving patients and therefore the public in shaping both the organization and delivery of healthcare services is central to current health reform agendas round the world either a "rights-based" or a "regulatory" approach to healthcare [12].

In 2010, Biological and Biomolecular Resource Infrastructure (BBMRI) individuals who were representatives of the stakeholders' forum produced a "consultation document which on patient perspectives" which was subsequently endorsed by variety of major pan- European patient organizations. This document explains the related principles laid down in European and international instruments that has the patients participation who are involved within the networking of biobanking activities.

There are mainly three key principles which are highlighted for governing the active involvement of patients and also the organizations in biobanking activities, which incorporates Inclusion, Commitment, and Communication. Translating these key principles into practice involves**:**

- Inclusion of patients and patient organizations as partners within the attempt, especially within the areas of communication, advocacy and recruitment (e.g. information to potential donors, preparation of consent forms).
- When establishing sample, tissue and databanks, the experience, knowledge and expertise of patients, families and care takers should be considered.

- Taking note of patients' voices/expectations on research needs from their experience from participating in biobanking as donors.
- Regular, general and reasonable feedback to patients regarding use, sharing and transfer of samples [13]. The chronological development of biobanks over these years as follows:
- Academic/university-based repositories, developed exclusively for specific projects and research requirement Institutional/government-based biobanks that hold greater numbers of samples for wider research purposes Commercial biorepositories
- Population-based biobanks, that holds samples from a broad population who might or won't have a particular disease
- Virtual biobanks that hold no physical specimens but offer location and retrieval services for samples held globally or nationally [14].

Biobanking concept in India

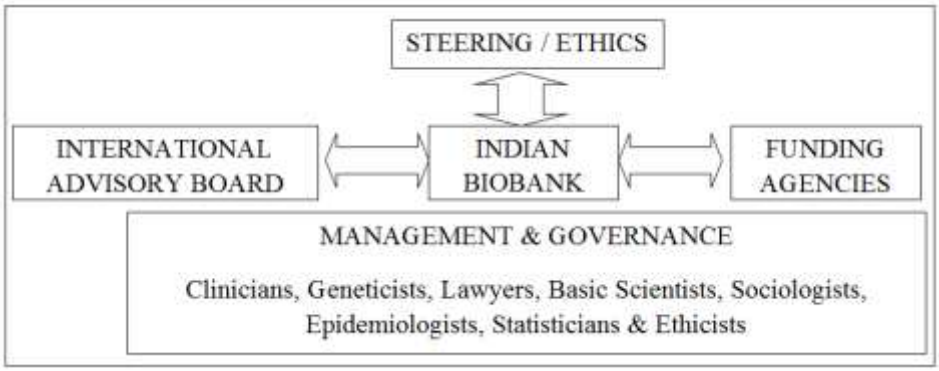

Fig-1: Biobanking concept in India

In the context of India (Fig-1) the ICMR guidelines of 2006 define biobank as "a collection of resources which can be accessed to retrieve human biological material and data" [15]. Because there could be a increasing scope for the research mainly on the stored biosamples, but the ICMR guideline should also include "non – genetic users" of biobanks. This may end in additional clarity for researchers on the moral guidelines to follow [16].

Components of Biobanking

- Biological material handling: Includes biospecimen collection, storage, and distribution.
- Direction system: which consists of the individuals who are involved as donors, so it maintains all the donor related information like patient consent, history, patient life style and demographic information?

Types of Samples Collected in Biobanks

Blood, serum, plasma, RBC, white blood cells, DNA, RNA, proteins, cell lines, urine, hormone secretions, bodily fluids, buffy coat are types of samples generally collected in Biobanks.

Evolution of Biobanking

Cell Line Biobanking

In 1951 the cell line history started at Johns Hopkins Hospital, this biobanking started with the generation of the HeLa cell line, where the medical staff obtained the primary neoplastic cell line from a patient named Henrietta Lacks (HeLa). The Cancer cells was taken without her consent after the surgery and the cells were cultured within the lab using an experimental approach that made the cells immortal, thereby achieving an in vitro cancer model system for the first time for the research purpose [17].

The first was the American Type Culture Collection (ATCC) that was established with the aim of providing certified model systems to the scientific community and major cell line repositories include: (i) the ATCC (USA), (ii) the Leibniz-Institute DSMZ (Deutsche Sammlung von Mikroorganismen und Zellkulturen); (iii) the European Collection of Cell Cultures (ECACC); (iv) the Japanese Cancer Research Resources Bank (JCRB); RIKEN BioResource Center (Japan); and (v) the Korean Cell Line Bank (KCLB).

Specimen Biobanking

The university based repositories are first specimen biobanks which are started for the precise research projects. These are established by the researchers which also had the access for the patient populations who has taken the benefits of the provision of "left over" aliquots are done and stored for the immediate and future uses. Samples were stored in one or some freezers, and associated data were recorded in an exceedingly laboratory notebook or basic database [18].

One among the famous case is that the development of the trastuzumab antibody (Herceptin). Which Started from the evaluation of tumor specimens which are stored at National Cancer Institute's

Cooperative carcinoma Tissue Resource, which became jointly of the drugs effectively wont to treat specific subtypes of carcinoma [19]. Recently, biobanks played a critical role within the development of Cancer Genome Atlas (TCGA), a publicly funded project that aims to make a comprehensive "atlas" of cancer genomic profiles by cataloguing major cancer-causing genomic alterations [20].

Qualification of Biosamples

Qualification is that the process won't to verify the standard of biospecimens collected into a biobank. There are mainly two approaches for qualification of biosamples: the primary approach is that the collection of biosamples by avoiding the pre analytical errors [21]. The second approach refers to the reconsideration of the sample collections with appropriate internal control and qualification of the sample or quality stratification. The term "sample qualification" refers to the examination and validation of one biospecimen or a group on the premise of objective analytical parameters. "Quality stratification" defined as the process of classifying and examining biospecimens in different categories like specific in vivo parameters (e.g., protein content) or ex vivo pre-analytical conditions (e.g., pre-centrifugation conditions) [22].

Tissue/Cells Biobanking

Fresh or frozen tissue tends to possess much better-quality DNA and RNA than formalin-fixed tissue, therefore fresh or frozen tissue is that the most appropriate sample for whole-genome amplification, whole-genome sequencing, and cDNA microarray analysis . Keeping the tissue at a chilly temperature immediately after surgery may be the correct thanks to ensure good specimen and, consequently, an extra step for standardization. Today, the quality temperature for storage of tissues and cells are between -80°C and 150°C. Ultra-low temperatures preserve the integrity of proteins, DNA, RNA, and cellular components, whether or not the range of storage temperature doesn't guarantee the soundness of each specimen type. A temperature of -80 °C is now the quality for preserving human tissues/cells, whether or not some authors recommend nitrogen, particularly the vapor phase stage (-150 °C) over the liquid phase (-196 °C) thanks to the danger of contamination by floating tissue fragments [23].

Blood Biobanking

If plasma is straight away separated from blood protein integrity is nice, while an optimal quality of extracted DNA from white vegetative cell blood samples is processed after 24 h at 4 °C. The optimal temperature for blood component storage varies counting on the particular analyte, marker, or molecule of interest. Generally, low (-20°C) and ultra-low temperature (-80°C) for short- and long-term storage, respectively, are the optimal conditions for maintaining the integrity and stability of each blood component [24].

DNA/RNA Biobanking

DNA/RNA Biobanking: Molecular analysis is basically depends on the sample collection/extraction/storage quality of DNA and RNA molecules. A fresh frozen sample will be good for the RNA extraction as these genetic materials are reduced in FFPE tissue to cross link between nucleic acid and induced by formalin and the time interval between tissue resection and fixation. For good RNA quality, samples should be stored at -80 °C without repeated freeze–thaw cycles. DNA is more stable than RNA and can be kept at 4 °C for several weeks. A long gap between sample collection and DNA extraction can cause reduced DNA yield and integrity also, so for that reason the sample should be kept or stored in the -800C if the extraction can not be done immediately soon after the sample collection.

Sample Collection, Processing and Storage

There are many different types of Biobanks based on population or disease oriented and epidemiology, translational, pharmaceutical research. They will contain data and samples from family studies, patients with a particular disease, clinical trials of recent interventions, or they'll be a component of large-scale epidemiologic collections. Inevitably, data and samples are collected under various conditions and standards and for various purposes. Given the challenges of knowledge collection and sample storage within studies, there has been little standardization across biobanks. variety of international initiatives to provide guidance and protocols were recently developed to pander to the present issue [25]. One of the main aim is to make standardized procedure and harmonization to make the facilities for sharing the data among different resources, therefore it increases the effective sample size, statistical power, especially in case rare diseases [26]. Quality programs should be implemented to attenuate the impact of variability on the integrity of the samples and, where possible, consideration should incline to future proofing the gathering. during this context, in 2014, the ISO/Technical Committee (TC) 2761/ unit (WG) 2 Biobanks and Bioresources was formed to ''elaborate a package of International Standards within the Biobanking field, which includes all the type of samples like human, animal, plant, and microorganism for the research and development, but excluding some therapeutic products.'' The ISO/DIS 20387 was intended to be applicable to "all the organizations performing biobanking activities, which incorporates biobanking of human, animal, plant and microorganism resources for the research and development. Which provides the gathering of sample to establish the biobanks to demonstrate the biobanking entities to control competently and are able to provide biological resources (biological material and data associated with that) of appropriate quality." These

requirements include the individual competence, method validation, and QC to verify that biological material and data collections are of appropriate quality. The main goal of biobanking is to establish and run good qualitycontrolled storage facilities and the infrastructures which are required to establish or enable the future biomedical research. A proposed workflow model for the gathering, storage, and distribution of biological specimens in biobanking is displayed in Fig-2. Briefly, biological specimens are accepted and coded, and recorded on appropriate management software together with corresponding clinical information from patients. Successively, most of the times for sample aliquoting (preferably micro-aliquoting) robotic process automation (Fig-2A) used before storing the sample at low (- 80 °C) or ultralow (liquid nitrogen vapor phase, -150 °C) temperature (Fig-2B). The biobank software program should be ready to manage biological samples and related information (Fig-2C).

To satisfy this purpose, it should have three basics features: (i) biological specimen management (consent management; nonconformity management; and biological resource history associated with patients, samples, aliquots, derivatives, storage, and request management); (ii) sample traceability (follow-up for sample requests, annotation of sample collections which are linked to patient files that includes clinical history, genetic information, imaging data; and (iii) interoperability: interfacing with temperature monitoring systems, interface with the hospital/laboratory to urge further clinical data). Finally, the appliance of a cloth transfer agreement regulates biomaterials transfer between biobanks and recipients (research groups internal or external to the biobank infrastructure) to need care of specific quality and traceability standards for the samples [27].

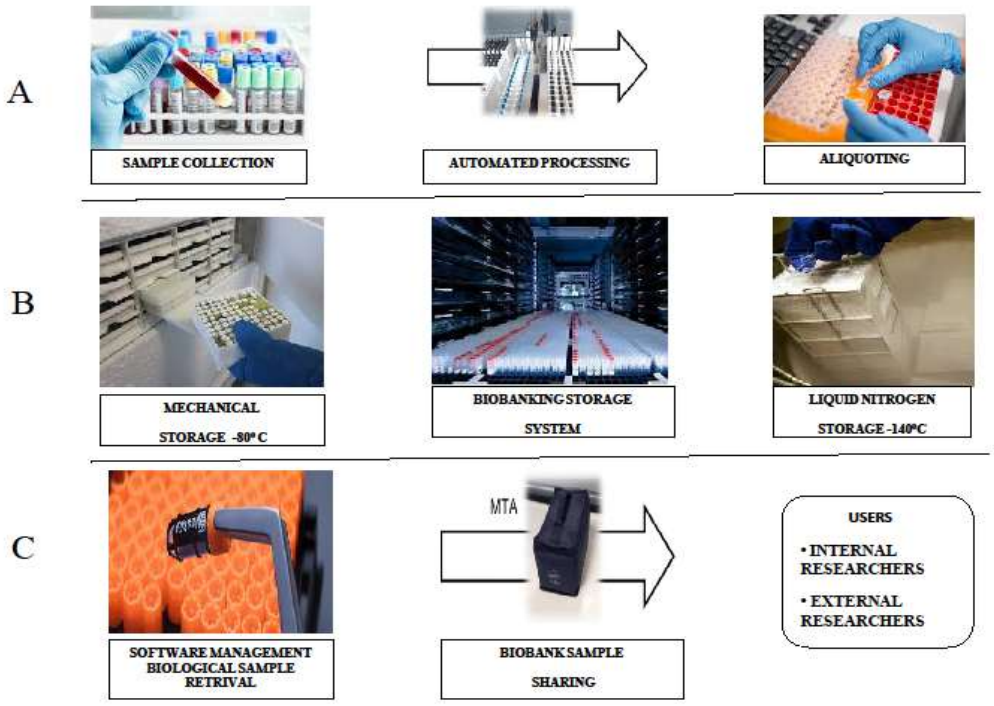

Fig-2: Hypothetical workflow model for collection, storage and distribution of samples in biobanking

A) Displays an example of automation of biological sample aliquoting.
B) Shows a storage unit where biosamples can be stored in mechanical freezers or liquid nitrogen storage device.
C) Displays the phases needed for samples sharing. A software management is needed for samples retrieval and an approved material transfer agreement (MTA) in case of both internal and external users before samples transferring.

Ethical Guidelines

In 2006, to deal with the end result of ethical issues which are associated with the usage of human biospecimens for research, the Council of Europe adopted the advice of the Committee of Ministers to Member States on Research on Biological Material of Human Origin in 2006 so updated them in 2016 [28]. Among the provisions of the advice are exact protocols for storing, accessing, using, and transferring specimens and independent oversight of every collection, further as requirements for consent. Governance, guided by transparency and accountability, is a very important theme of the revised recommendation. The planet

Medical Association (WMA) also weighed in with guidelines for biobanks in 2016 by issuing the WMA Declaration of Taipei on Ethical Considerations regarding health databases and biobanks [29].

This guideline only applies to identifiable specimens. Among the provisions of the declaration may be a very narrow provision for waiver of consent to be used of identifiable specimens, that is, only where there's a ‘‘clearly identified, serious, and immediate threat where anonymous data won't suffice.’’ just like the Council of Europe Recommendation, governance is a very important theme, with a specific paragraph associated with governance mechanisms supported transparency, engagement, and accountability.

Ethical Considerations

Consent of the donor must be freely given, to be specific, per purpose, to be told, has to be an unambiguous indication, Consent is an act: it must incline by an announcement or by a transparent act, to be distinguishable from other matters; The request for consent must be in clear and in plain language.

Data Protection

Ability to trace back the identity the donor is a difficulty where the samples don't seem to be anonymized. Various methods by which the information may be coded: Direct identification – Coded - identifiable data is physically separated from the private data but the procurer of the sample has access to the code – encrypted - third party persons transform the code into variety of characters, thus identifiable by third party – Anonymized - connection between the code and therefore the identifiable data is totally lost – Anonymous - samples were donated during a completely anonymous form - no personal identifier data.

Regulations

On the regulatory front, concerns about privacy in health records, furthermore as other privacy concerns, led to new privacy rules during the past 15 years, both within the us and in Europe. In 2000, the U.S. Department of Health and Human Services (HHS) published the insurance Portability and Accountability Act (HIPAA) Privacy Rule, followed by modifications to the HIPAA Privacy rule out 2002 [30]. The Rule generally requires authorization from a personal for the utilization and disclosure of their individually identifiable health information, although there are some exceptions if certain conditions are met. variety of important changes were made to the Privacy rule out 2013 to scale back the burdens on research [31]. These changes include clarification that an authorization for the future use of individual identifiable health information which needn't to be studied specifically. Other changes include a general restricted on the sale of ‘‘protected health information’’ without particular patient authorization, although an inexpensive compensation for the value of processing the data is permissible. Various biobanks and types of biobanks have been depicted in Table 1 and 2.

Table-1: Biobanks in India

Biobank	**Place**
National Bureau of Animal Genetic Resources	Haryana
National Bureau of Plant Genetic Resources	Pusa
National Bureau of Fish Genetic Resources	Lucknow
National Bureau of Agriculturally Important Microorganisms	Uttar Pradesh
National Bureau of Agricultural Insect Resources,	Bengaluru
National Centre For Cell Science	Pune
Tata Translational Cancer Research Centre Biobank	Kolkata
National Cancer Tissue Biobank	IIT Madras
Advanced Centre for Treatment, Research and Education in Cancer	Mumbai
CSIR- Institute of Microbial Technology	Mysore
National Institute of Mental Health and Neurosciences	Bengaluru
National JALMA Institute for Leprosy and Other Mycobacterial Diseases	Agra

Table-2: Biobank types and websites [32]

Name of Bank	Biobank Type	Website
Adolescent & Young Adult Biorepository	Disease-specific Biobank	http://www.ohsu.edu/xd/health/services/cancer/outreach-programs/programmatic-outreach/how-is-young-adult-cancer-uniq.cfm
Australia- Breast Cancer Bank	Disease-specific biobank	http://www.abctb.org.au/abctbNew2/AboutUs.aspx
Cancer Human Biobank - caHUB	NCI sponsored national biobank	http://cahub.cancer.gov/
Cincinnati Biobank	Pediatric biobank	http://www.cincinnatichildrens.org/research/cores/biobank/default/
Coriell Cell Repositories	Cell culture biobank	http://ccr.coriell.org
Danish National Biobank	Population based biobank	http://www.biobankdenmark.dk/
Duke Institute for Genome Sciences & Policy Biospecimen Repository	Centralized biobank for Duke University Investigators	http://www.genome.duke.edu/cores/biorepository
Estonian Biobank	Population based biobank	http://www.itfom.eu/partners/associate-partners/18-associate-partners/198-estonian-genome-center-university-of-tartu-estonia
Kaiser Permanente Research Program on Genes, Environment, and Health (RPGEH)	Kaiser member based biobank	http://www.dor.kaiser.org/external/DORExternal/rpgeh/index.aspx
Northwest Biobank at Kaiser Permanente	Partnership between Oregon Health & Science University and the Kaiser Permanente Center	http://www.ohsu.edu/xd/research/centers-institutes/octri/funding/nw-biobank.cfm
Sera Care Life Sciences	Commercial biobank	http://www.seracarecatalog.com/default.aspx
Specimen Central	Virtual biobank	http://specimencentral.com/about-us.aspx
Tissue Solutions	Virtual bobank	http://www.tissue-solutions.com/
Tumor Tissue Repository	Cancer biobank	http://www.bccrc.ca/dept/ttr
UCSF AIDS & Cancer Resource	Disease- specific biobank	http://acsr.ucsf.edu/
UCSF AIDS Specimen Bank	Disease-specific biobank	http://ari.ucsf.edu/programs/asb.aspx
UK Biobank	Population based biobank	http://www.ukbiobank.ac.uk/
Univ. of Minnesota Tissue Procurement Facility	Centralized biobank for Univ. of Minn. Investigators	http://www.bionet.umn.edu/tpf/hone.html

Biobank Taxonomy

There are different types of biobanks. Watson and Barnes had stressed the importance of classification biobanks. Mainly, population based biobanks, disease-oriented biobanks genetic or DNA/RNA based biobanks, tissue versus multiple specimen type, project-oriented commercial type and virtual biobanks.

In fact, from past few years the cord blood biobanking becoming popular and also it make sure that the cord blood collection will be registered with Central drug standard control organization (CDSCO), but no data are available on them. Based on the diversity of medical and health research institutions in India, it is important to build up many more organizations for collecting all types of biomaterials. Recently, the Department of Science and Technology has sponsored a cancer tissue biobank at IIT Madras in the Department of Biotechnology. Still it is not functioning, but it can be considered as the presence of the cancer institute and other hospitals offering oncology treatment in South India, particularly in Madras, this is the one of the well-known biobank established as the specialized biobanks with different types of samples which are related to cancer.

Ownership of Biological Material

Ownership of biological material most of the research biobanks will collect the samples and data of which can be of human origin for his or her research. In many literature about the ownership of the biological samples has been discussed, is one among the foremost issue which is unsolved. This argument includes legal and ethical issues in biobanking and also those are involved in the biobanking like patients/subject, institutional infrastructures and researcher/clinicians should be considered. ranging from the worldwide-recognized concept that nobody can own another person, as this is able to constitute slavery and violate article 4 of the Universal Declaration of Human Rights [33], many of the biobanks have agreed to be custodians rather than being the owners of biological samples [34]. This statement is in line thereupon of International Agency for Research on Cancer (IARC) declaring, as a general rule, "There is no ownership of biosamples exists, and also the biobank should assign ownership or

custodianship supported national and institutional guidelines." However, it's important to contemplate that local scientists who are going to be contributing to the biobank by collecting the bio-samples can view the samples as "theirs." Indeed, principal investigators may well be the one having priority access for specific collections or impose co-authorship in publication or veto rights to take care of a degree of control over biosamples thanks to scientific competition. This argument remains an issue of intense debate within the scientific literature.

Sample Access

The biobanks stores human biological materials and related data which are valuable resources for biomedical research. But some of the recent debates highlight challenges in their practical application like Transparent, effective, and efficient governance structures and procedures for access, compensation, and priority settings are needed. From past few years there is debate related to Access of biological samples and data which are related to it; indeed, access policies are neither standardized nor harmonized. Langhof *et al*., [35] recently highlighted the need for governance structures accepted by all stakeholders (patients/donors, researchers, research funders, public, and others) to ensure appropriate sample access for research. The authors proposed some particular topics which are based on interviews of the biobank experts on the BBMRI-ERIC infrastructure. Regarding biological sample sharing, several debates has raised in different aspects but still not resolved, among the main ones [36]:

- **Access committee:** Implementation for the access of the sample is in an exceedingly one amongst one in every of the foremost important aspects in a scientific board to scrutinize the project proposals and access inquiries. Different access committees are organized, looking on their decisions only experts will evaluate the standard of research project projects and so it'll be considered because the best use of the stored bioresources.
- **Veto rights:** As we already discussed in "Ownership of biological material", local clinicians or principal investigators contributing to a selected collection (samples from patients suffering from rare diseases or innovative clinical trials) may impose veto rights to take care of a degree of control over biosamples. Although this an honest solution, the argument about sample ownership still continues, especially just in case of pharmaceutical companies, because the hope is that results obtained from human samples could yield profitable benefits.
- **Prioritization of bioresources:** we should always consider the human biological materials as finite resources are extremely much important. Whereas the DNA is accessible in relatively large amounts for large DNA analysis methods (e.g., NGS), postgenomic research (metabolomics, transcriptomics, and proteomics) mostly used other biological materials are serum, plasma, tissue, and urine. These samples more valuable for multitude research projects and are very rare normally.
- Recognizing the biological sample sharing is one of the major barriers for bioresource access. The impact of each biobank in can be measured by a system called Bioresource
- Research Impact Factor (BRIF) in biomedical research and other forms of recognition such as including biobankers/researchers as coauthors of scientific papers.

The idea behind the BRIF is to allow external researchers (e.g., who are interested in the research but have not affiliated with biobank and/or not contributed for the specific sample collection) to access parts of the biosample collection; therefore, the biobank build up and maintain its collection to receive long term recognition. Moreover, the BRIF is focused solely on the biobank or its institutional host (e.g., a university hospital) and thus fails to acknowledge others who are significantly contributing the biosample acquisition (e.g., clinicians and their contributing departments/institutes or individual researchers)

LIMITATIONS

There are bottle necks in each stage of biobanking like sample collection, processing, storage and sharing, sample quality, capacity, sustainability and to confirm an efficient, personal data protection, ethical access to biological samples and associated clinical data related that influence sample availability for biobanking activities. Two approaches are implemented to deal with these limitations: the standard top-down approach, employed as creating networks of regional and national biobanks that enhance standardization and research access to biospecimens, and therefore the bottom-up approach, employed, which focuses on connecting donors and biobanks effectively through implementing a versatile paradigm of donor's consent.

CONCLUSION

Biobanks are complex systems of systematically programmed storage of human material and associated data, within the past 20 years the science of biobanks has become an integral a part of personalized medicine. A good number of biobanks are established everywhere the planet to support the dramatic development in diseases prevention, prediction, diagnosis and treatment.

ACKNOWLEDGEMENTS

The authors appreciate all the scientists whose works contribute to this review article. We also

apologize to scientists whose works were not included in this review due to space constraint.

Funding: Not applicable.

Contributions

Wilma Delphine Silvia CR conceived the Project and edited the manuscript. Venkata Bharat Kumar Pinnelli did final editing. The author(s) read and approved the final manuscript.

Ethics Approval and Consent to Participate: Not applicable.

Consent for Publication: Not applicable.

Competing Interests: All authors declare there is no conflict of interest.

REFERENCE

1. Riegman, P. H., Morente, M. M., Betsou, F., De Blasio, P., Geary, P., & Marble Arch International Working Group on Biobanking for Biomedical Research. (2008). Biobanking for better healthcare. *Molecular oncology*, *2*(3), 213-222.
2. Grizzle, W. E., Bell, W. C., & Sexton, K. C. (2012). Issues in collecting, processing and storing human tissues and associated information to support biomedical research. In: Srivastava, S., & Grizzle, W. E. (eds). Translational Pathology of Early Cancer. Amsterdam, The Netherlands: IOS Press. 531–549.
3. Grizzle, W. E., Sexton, K. C., & Bell, W. C. (2016). Issues in operating a human tissue biorepository supporting biomedical research. In: Areman, E., & Loper, K. (eds). Cellular Therapy: Principles, Methods, and Regulation. Bethesda, MD: AABB; 497–509.
4. Hewitt, S. M. (2018). Why All the Names. 2018. Available at: https:// www.linkedin.com/pulse/biobank-biorepository-biolibrarybiovault-biohoard-biotrust-hewitt/ (accessed May 13, 2019).
5. Bledsoe, M. J., Watson, P. H., Hewitt, R. E., Catchpoole D. R., & Grizzle, W. E. (2019). Biobank: What's in a name? *Biopreserv Biobank*. 17:204–208.
6. Campbell, L. D., Betsou, F., & Garcia, D. L. (2012). Best practices for repositories: Collection, storage, retrieval, and distribution of biological materials for research, 3rd edition, International Society for Biological and Environmental Repositories. *Biopreserv Biobank*. 10:79–161.
7. Campbell, L. D., Astrin, J. J., DeSouza, Y., Giri, J., Patel, A. A., Rawley-Payne, M., ... & Sieffert, N. (2018). The 2018 revision of the ISBER best practices: summary of changes and the editorial team's development process. *Biopreservation and biobanking*, *16*(1), 3-6.
8. De Souza, Y. G., & Greenspan, J. S. (2013). Biobanking past, present and future: responsibilities and benefits. *AIDS (London, England)*, *27*(3), 303.
9. Loft, S., & Poulsen, H. E. (1996). Cancer risk and oxidative DNA damage in man. *Journal of molecular medicine*, *74*(6), 297-312.
10. Carey, D. J., Fetterolf, S. N., Davis, F. D., Faucett, W. A., Kirchner, H. L., Mirshahi, U., ... & Ledbetter, D. H. (2016). The Geisinger MyCode community health initiative: an electronic health record–linked biobank for precision medicine research. *Genetics in medicine*, *18*(9), 906-913.
11. Zika, E., Paci, D., Braun, A., Rijkers-Defrasne, S., Deschênes, M., Fortier, I., ... & Ibarreta, D. (2011). A European survey on biobanks: trends and issues. *Public health genomics*, *14*(2), 96-103.
12. Meyer, U. A. (2012). Personalized medicine: a personal view. *Clinical Pharmacology & Therapeutics*, *91*(3), 373-375.
13. BBMRI stakeholder's forum patient participation in BBMRI (Internet). updated 2010. Available at: http://bbmri.eu/events-and-consultations. Accessed 02 February, 2014
14. Indian Council of Medical Research, Ethical Guidelines for Biomedical Research on Human Participants (New Delhi: ICMR; 2006): at 71.
15. Vaz, M., & Srinivasan, K. (2014). Ethical challenges in biobanking: moving the agenda forward in India. *Indian Journal of Medical Ethics*, *11*(2), 79-88.
16. Mauffrey, C., Giannoudis, P., Civil, I., Gray, A. C., Roberts, C., Pape, H. C., ... & Stengel, D. (2017). Pearls and pitfalls of open access: The immortal life of Henrietta Lacks. *Injury*, *48*(1), 1-2.
17. Coppola, L., Cianflone, A., Grimaldi, A. M., Incoronato, M., Bevilacqua, P., Messina, F., ... & Salvatore, M. (2019). Biobanking in health care: evolution and future directions. *Journal of translational medicine*, *17*(1), 1-18.
18. De Souza, Y. G., & Greenspan, J. S. (2013). Biobanking past, present and future: responsibilities and benefits. *AIDS (London, England)*, *27*(3), 303-312.
19. Slamon, D. J., Clark, G. M., Wong, S. G., Levin, W. J., Ullrich, A., & McGuire, W. L. (1987). Human breast cancer: correlation of relapse and survival with amplification of the HER-2/neu oncogene. *science*, *235*(4785), 177-182.
20. Weinstein, J. N., Collisson, E. A., Mills, G. B., Shaw, K. R. M., Ozenberger, B. A., Ellrott, K., ... & Cancer Genome Atlas Research Network. (2013). The cancer genome atlas pan-cancer analysis project. *Nature genetics*, *45*(10), 1113-1120.
21. Lehmann, S., Guadagni, F., Moore, H., Ashton, G., Barnes, M., Benson, E., ... & DeSouza, Y. (2012). Standard preanalytical coding for biospecimens: review and implementation of the

Sample PREanalytical Code (SPREC). *Biopreservation and biobanking*, *10*(4), 366-374.
22. Betsou, F., Bulla, A., Cho, S. Y., Clements, J., Chuaqui, R., Coppola, D., ... & Gunter, E. (2016). Assays for qualification and quality stratification of clinical biospecimens used in research: a technical report from the ISBER Biospecimen Science Working Group. *Biopreservation and biobanking*, *14*(5), 398-409.
23. Shabihkhani, M., Lucey, G. M., Wei, B., Mareninov, S., Lou, J. J., Vinters, H. V., ... & Yong, W. H. (2014). The procurement, storage, and quality assurance of frozen blood and tissue biospecimens in pathology, biorepository, and biobank settings. *Clinical biochemistry*, *47*(4-5), 258-266.
24. Nederhand, R. J., Droog, S., Kluft, C., Simoons, M. L., De Maat, M. P. M., & investigators of the EUROPA trial. (2003). Logistics and quality control for DNA sampling in large multicenter studies. *Journal of Thrombosis and Haemostasis*, *1*(5), 987-991.
25. Coppola, L., Cianflone, A., Grimaldi, A. M., Incoronato, M., Bevilacqua, P., Messina, F., ... & Salvatore, M. (2019). Biobanking in health care: evolution and future directions. *Journal of translational medicine*, *17*(1), 1-18.
26. Dedeurwaerdere T, Broggiato A, Manou D. Global scientific research commons under the Nagoya protocol: Governing pools of microbial genetic resources. In: Kamau E, Winter G, eds. Common Pools of Genetic Resources: Equity and Innovation in International Biodiversity Law. EarthscanRoutledge; 2013.
27. Master, Z., Campo-Engelstein, L., & Caulfield, T. (2015). Scientists' perspectives on consent in the context of biobanking research. *European Journal of Human Genetics*, *23*(5), 569-574.
28. Heredia, N. I., Krasny, S., Strong, L. L., Von Hatten, L., Nguyen, L., Reininger, B. M., ... & Fernández, M. E. (2017). Community perceptions of biobanking participation: a qualitative study among Mexican-Americans in three Texas cities. *Public health genomics*, *20*(1), 46-57.
29. Goddard, K. A., Smith, K. S., Chen, C., McMullen, C., & Johnson, C. (2009). Biobank recruitment: motivations for nonparticipation. *Biopreservation and biobanking*, *7*(2), 119-121.
30. Watson, P. H., & Barnes, R. O. (2011). A proposed schema for classifying human research biobanks. *Biopreservation and Biobanking*, *9*(4), 327-333.
31. Ahram, M., Othman, A., Shahrouri, M., & Mustafa, E. (2014). Factors influencing public participation in biobanking. *European Journal of Human Genetics*, *22*(4), 445-451.
32. Petrini, C. (2012). Ethical and legal considerations regarding the ownership and commercial use of human biological materials and their derivatives. *Journal of Blood Medicine*, *3*, 87-96.
33. Yassin, R., Lockhart, N., Del Riego, M. G., Pitt, K., Thomas, J. W., Weiss, L., & Compton, C. (2010). Custodianship as an ethical framework for biospecimen-based research. *Cancer Epidemiology and Prevention Biomarkers*, *19*(4), 1012-1015.
34. Langhof, H., Kahrass, H., Sievers, S., & Strech, D. (2017). Access policies in biobank research: what criteria do they include and how publicly available are they? A cross-sectional study. *European Journal of Human Genetics*, *25*(3), 293-300.
35. Langhof, H., Kahrass, H., Illig, T., Jahns, R., & Strech, D. (2018). Current practices for access, compensation, and prioritization in biobanks. Results from an interview study. *European Journal of Human Genetics*, *26*(11), 1572-1581.
36. Howard, H. C., Mascalzoni, D., Mabile, L., Houeland, G., Rial-Sebbag, E., & Cambon-Thomsen, A. (2018). How to responsibly acknowledge research work in the era of big data and biobanks: ethical aspects of the Bioresource Research Impact Factor (BRIF). *Journal of community genetics*, *9*(2), 169-176.

Cite this article:
Priyanka A *et al* (2021). Banking on Biobank: A Cognizance. *East African Scholars J Med Sci*, *4*(1), 1-10.