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REVIEW ARTICLE

Specialized biobank for diabetes research: current prospect

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ABSTRACT

The exponential increase in human population depicted by the recent population trend shows that every 15 years the world population would increase by at least 1 billion. Consequently, there is a large increase in the use of human biospecimens for academic and pharmaceutical research. The global demand for human biospecimen is estimated to be worth $700 million and projected to increase 20%–30% annually. Biospecimens and associated data sharing are essential for biomedical research findings, discovery of disease markers, and improving patients' health care. One of the most prevalent chronic diseases worldwide that involves extensive interdisciplinary research-based studies is diabetes. In this review, we emphasized the need and importance of biobanks in diabetes, which will serve as a resource to promote research in understanding disease link, and mechanisms related to molecular pathways, protein and drug targets, and also in improving health outcomes.

Keywords: biospecimens, biobanking, diabetes, healthcare.

Introduction

According to United Nations reports, the current world population has seen an exponential growth of 1.18% per year or approximately an addition of 83 million people annually. Global population is projected to increase by more than 1 billion within the next 15 years, reaching 8.5 billion in 2030, 9.7 billion in 2050, and 11.2 billion in 2100 [1]. This exponential increase in human population coupled with proportionally increasing demand for human biospecimens in academic and pharma industry research gave birth to the idea of biobanking. The global demand for human biospecimens areis estimated to be worth approximately $700 million, with a potential of 20%–30% increase in the worldwide biobanking market annually [2]. The market for tissue samples in the United States (US) biobanks alone is estimated to be more than 300 million, and is increasing at a rate of more than $20 million per annum [3]. The global market demand for biospecimens areis estimated to have been tripled over a decade reaching approximately $2,150.48 million in 2015, and is expected to reach $3,731.03 million by 2020 [4]. The key factors contributing to global biobanking market growth isare the increased incidence and prevalence of chronic diseases and healthcare expenditure. Moreover, literature shows that the global biobanking market in human medicine will generate US $25 billion in 2019 and will further expand by 2025 [5].

Need of Biobank in Diabetes Research?

At present, biobanks are found in every continent and the number of biobanks around the globe has increased considerably. Most of the biobanks are located in high-income countries, while only a few biobanks are located in low- and middle-income nations such as China, Mexico, etc. [6]. Globally coordinated efforts are being made to strengthen research collaborations, and legitimate the organization, and running of biobanks in low- and middle-income nations [6].

A specialized biobank is defined as collection, preservation, and storage of high-quality biospecimen for a specific disease. They are important resources for identifying the causes and underlying mechanisms of many complex diseases, such as cardiovascular diseases, diabetes, and cancer. They facilitate research scientists to investigate the combined influence of genetics, environmental and sedentary lifestyle factors in the development of multifactorial diseases. In addition, specialized biobanks make it possible for research scientists to collect biospecimens prior to the appearance of complex diseases. They provide infrastructure to compare various disease stages at the molecular level. Identification of signaling pathways elaborates disease initiation or progression,

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which may lead to the discovery of new therapeutic targets for specific disease. Identification of these signaling pathways may result in the detection of biomarkers for prediction of disease progression. An example of a specialized diabetes biobank is the New National Biobank of the Danish Center for Strategic Research on Type 2 Diabetes (DD2) [7]. Integration of specialized biobank infrastructure in developing countries will make a great contribution to the research and discovery arena, and more efficient use of bio-specimens for Omics research [7]. This review provides a summary of different types of available biobanks with a focus on specialized biobanks, like diabetes and their ethical and legal sample data sharing barriers.

Types of Biobanks in Diabetes Research

Biobanks usually vary in size, storing information, and sharing biospecimens for research. They also differ in scope such as disease-oriented and population-based biobanks [8]. Disease-oriented biobanks are most often hospital-based and are meant for epidemiological studies. They store collection of tissues, blood, or other biospecimens in context of medical diagnosis and treatment. The ability to examine various stages of diseases or forms of treatment at the molecular level is instrumental for finding biomarkers during the diagnosis of a disease or prediction of disease progression [9]. Population-based biobanks represent nation, region, specific nationalities, communities, and are managed by national governments. The main objective of population biobank is to collect, analyze, and store phenotypic and genetic information on the representative bio-specimens, and allow for further discovery of genetic associations of chronic diseases [10].

Genome-wide association studies are measure a common hereditary variants in substantial number of affected cases to those in normal controls to determine if any relationship with disease exists. Genome-wide association studies provide an important approach for interpretation of the association between normal hereditary variations and risk of disease. Recent advances in the understanding of human hereditary variations and the innovation to quantify such variations have made genome-wide association studies practicable [11]. Genome-wide association studies have identified a large number of SNPs associated with cardiovascular, diabetes, and auto-immune disease phenotypes in the European population [12]. Biobanks help to extend the genome-wide association studies to diverse populations for the mapping of genetic determinants of chronic diseases for the human population [12].

Importance of Specialized Biobank

The global healthcare and medical management systems are stressed out by the huge growth of aging population with increasing incidence and prevalence of chronic diseases [13]. Specialized biobanks play an important role in the validation of novel discovery of biomarkers. Specialized biobanks are highly relevant for scientists and researchers in case of complex diseases. In order to investigate complex diseases, researchers might have to wait for years to collect high-quality biospecimens. Therefore, a specialized biobank consisting of human biospecimen of patients with specific diseases are valuable and will save months. Finally, disease-based specialized biobanks are needed to validate discoveries made in animal studies using an animal models. Regarding diabetes, animal studies have helped us to a great extent to elucidate the pathophysiology of diabetes and its complications. There is an increasing need for specialized biobanks for a disease like diabetes, which can facilitate basic and clinical research. So, developing and building specialized biobank infrastructure will allow us to better understand chronic diseases like diabetes.

Diabetes is a group of metabolic disorders associated with abnormal levels of blood glucose resulting from defects in insulin secretion, insulin action, or both. According to an International Diabetes Federation report, 415 million people worldwide have diabetes and this alarming number is set to reach 642 million by 2040 [14]. Diabetes is undoubtedly one of the most challenging global health problems of the 21st century. It puts a huge economic burden on individuals, families, and healthcare systems of the affected countries. The chronic hyperglycemia is associated with long-term damage, dysfunction, and failure of different organs especially eyes, kidneys, and heart. The most evident risk factors for diabetes includes genetics, environmental factors, family history and history of gestational diabetes, obesity, and sedentary lifestyle [15].

It is difficult to standardized risk factors and effective therapies for diabetes. Advances in latest technology (Genomics, Epigenomics, Proteomics, and Metabolomics) will enable a more comprehensive overview of these biochemical changes and reduce the risk factors for diabetes [16]. Researchers and scientists actively pursue discoveries for novel diagnostics in the hope of better identifying susceptible individuals in the early stage of their disease, and subgroups with specific organ involvement predisposition [17]. Extensive studies of diabetes have been carried out at multiple biological levels including at DNA level (genomics), mRNA level (transcriptomics), protein level (proteomics), and metabolites level (metabolomics). Extensive profiling using multiple omics platforms have yielded novel insights on a wide spectrum of diseases as summarized in Table 1.

These global technologies are proving to be equally informative in the study of diabetes. With the rapidly increasing research on biospecimens, these biobanks act as goldmine for epidemiological research [30].

Integration of different research (genomics/epigenomics, proteomics, and metabolomics) within the biobanks will strengthen biomedical and translational research [31]. Using these research capabilities for biomarker discovery, specific molecular markers for disease response can be

Table 1. *Examples of multidisciplinary studies in diabetes based on omics* platforms*

Objectives	Omics	Associated actions	Studies	References
Pathogenesis	Transcriptomics	Gene expression profiling	Type 2 diabetes	[18]
	Genomics	Micro RNA profiling	Type 2 diabetes	[19]
	Proteomics	Methylation profiling	Type 2 diabetes	[20]
	Metabolomics	Metabolite profiling	Type 2 diabetes	[21]
Diagnosis and prognosis	Cytomics	Cytopathology	Type 2 diabetes	[22]
	Genomics	Gene expression profiling	Type 1 diabetes	[23]
	Proteomics, metabolomics	Biomarkers identifications	Type 2 diabetes	[16,24]
	Genomics	Micro RNA profiling	Type 2 diabetes	[25]
Therapy	Genomics	Targeted Treatment	Type 2 Diabetes	[26]
	Pharmacogenomics		Type 2 diabetes	[27]
	Chemogenomics		Type 2 diabetes	[28]
	Bioinformatics		Type 2 diabetes	[29]

*Omics (Trascriptomics, Genomics, Proteomics, Metabolomics, Cytomics, Pharmacogenomics, Chemogenomics, and Bioinformatics).

identified, monitored, and validated [31]. Specialized biobanks like New National Biobank of the Danish Center for Strategic Research on DD2 are an important resource to elucidate mechanisms as well as to improve the diagnosis, prognosis, and treatment. High-quality bio-specimen stored in specialized biobanks like Danish National Biobank created research infrastructure and allowed the researchers to study risk factors, biomarkers, and genetic determinants for chronic diseases [7]. However, population-based biobanks arestore biospecimen from donors being normal volunteers, rather than patients.

Conducting genetic and genomic analysis of diabetes research on biospecimens depends on the availability of a large number of biospecimens and biological data. Biobanking activity is carried out in hospitals, clinical laboratories, research laboratories, universities, and pharma industries [32]. Most existing biobanks are research oriented and differ in their scopes. Large scale biobanks are population based and are active in long-term longitudinal prospective studies. Small-scale biobanks are set up mostly for specific research projects. Despite their small scale, these types of biobanks are an important resource for diagnostic research [33]. Regardless, whether biobanking is conducted on a small scale or on a large scale, practices in biobanking have many common elements that are universal to all biobanking activities. A biobank success is defined by the nature and usage of biospecimens and the value of its research output, rather than the number of biospecimens stored in it [34]. Earlier, Time magazine published a special issue on "Ten Ideas Changing the World Right Now," in which biobanking for research was highlighted as an important activity for medical field [35]. It is anticipated that biobanks will serve as an important tool to authorize the research in understanding genetic diseases, improving health outcomes, and personalized medicine [17]. Recently, hospitals and research laboratories have been collaborating and bringing together biobanks in order to increase the sample size and data sharing.

Types and Optimal Storage of Biospecimens for Collaborative Research

Biobanks provide an ample opportunity to scientists and researchers to maximize research from the new high throughput research technologies. Biospecimens such as blood, serum, plasma, urine, or tissues from specialized biobanks are an attractive source for biomarker studies. Validated biomarkers with clinical information will be used for diagnosis, disease screening, evaluation of risk predisposition, assessment of prognosis, monitoring, and prediction of disease response to treatment [36]. Genetic material (DNA and RNA) from biobank is used for genome-wide association studies and epigenome-wide association studies and have become a popular method for next generation sequencing in order to discover the genetic basis of chronic disease like diabetes [20,36]. The stability and quality of blood with respect to the study investigation may be affected or controlled based on the following factors: i) anticoagulants (EDTA, Citrate, and heparin) used in blood collection, ii) stabilizing agents (e.g., EDTA and ascorbate), iii) the elapsed time between blood specimen collection or removal from an appliance and subsequent processing, iv) the temperature at which blood specimens are handled and stored, v) freezing and thawing of biospecimens, and vi) enzymatic degradation. Biological specimens require standard procedures to maintain their integrity at the time of biospecimen collection and processing, and addition of RNase inhibitors to protect RNA integrity. Inventory tracking should be established to minimize disruption of the stable environment during bio-specimen recovery [36]. Standardized protocols should be maintained consistently in storing biospecimens to ensure quality and to avoid variability in research studies. The biospecimen resource personnel need to record storage conditions along with any variations from SOPs, including information about temperature, thaw/refreeze episodes, and any equipment failures. Storage of biospecimens at −20°C was

commonly used in the past but in recent decades, ultra-low temperatures of −80°C and −150°C have emerged as standard for long-term storage of biospecimens [37]. Many research centers currently use −80°C as standard for storage of biospecimens.

The Platform for Data Sharing through Biobanks

The expansion of specialized biobanks require a network of medical contributors, secure storage facilities, bioinformatics skills, database administrators, and ethical working practices for it to function ideally. Large supply of biospecimens will allow researchers to collaborate, and further develop partnerships for the prevention and management of chronic diseases around the globe [38]. Funding aspects changed over the time as biobanks developed gradually. Sharing of biospecimens with diabetes biobank, for example, the New National Biobank of the Danish Center for Strategic Research on DD2 will not only help in better research outcomes, but also in the development of national and international strategies to prevent and cure diabetes complications. The established, potential upcoming, and specialized biobanks have the ability to support the following: i) research that has the potential to understand disease epidemiology and other associated diseases in relation to risk factors, ii) support tissue biomarkers in pharmaceutical research and development, iii) interdisciplinary clinical research, iv) future analysis of biospecimens using an high throughput omics technologies, and v) allow long-term recession-proof funding to support ongoing research activities and employ the principles of economies of scale including duplication [8,13].

Sample and Data Sharing Barriers in Biobanking

In recent years, there has been a steady increase in clinical research involving large number of collaborators, often involving multiple departments and research centers and sometimes among several developed and developing countries. Ethical and legal administration framework in developed and developing countries is in place to manage the biobank activities [39]. It is now possible, and even necessary, for researchers to collect biospecimens from biobank resources, from around the globe, either by sharing clinical or genetic data or by exchanging biospecimen samples among themselves [40].

However, sharing is based on the presumption that the donor has given consent to use their biospecimens. Henceforth, the biobanking stakeholders should choose one of the three options: i) obtain general consent enabling multiple future uses before taking a biospecimen sample from the donor, ii) try to obtain consent again before sharing a previously obtained biospecimen sample, or iii) look for a legally endorsed way to share a biospecimen sample without the donor's consent [41].

Biobank resource accessibility is largely influenced by the legislation of the countries. Lack of harmonization between nation's legislations can slow down data sharing in different nations. To overcome the above issues, global consensus on the legislation is required for efficient sharing of biospecimen. Recently, Minimum Information About Biobank data Sharing was developed in 2012 by the Biobanking and Bimolecular Resource Research Infrastructure of Sweden (BBMRI.Se) through a multicountry governance process to facilitate data discovery through harmonization of data [42]. For example, the Genomic Alliance for Genomics and Health (http://ga4gh.org.) allows the sharing of genomic and health-related clinical data to improve human health [43].

Ethical and Legal Issues for the Use of human Biobanks

In recent years, scientists and researchers have struggled with ethical and legal conflicts identified with the accumulation and utilization of biospecimens in research. This issue extended fights in court over, who own the stored biospecimens as substantial property to charges of improper informed consent and resulting improper exploration utilization of contributed biospecimens. Establishing consortium-based biobank platform facilitate access to stored biospecimen and associated data in an ethically and legally compliant manner. Furthermore, it facilitates therapeutic development for patients with diseases. Biobank consortium EuroBio Bank (EBB) network (www.eurobiobank.org). EBB is the first operating network of biobanks in Europe, that provide biospecimens and associated data for research on rare diseases [44].

Research based on biobanks is effective only if the access to data is allowed and the use of data is maximized through data sharing. This becomes more important during the research on rare diseases. Biobanks adhere to rigorous ethical principles for recruiting patients, participants, volunteers, and for handling and using biospecimens. Numerous studies of genetic epidemiology and post-genomic research rely on human biobanks [45,46]. Key ethical issues include informed consent, confidentiality, secondary use of biospecimens, and data holding over the given time, return of results and data sharing [39,47]. These key ethical issues have produced two powerful but conflicting social reactions. On the one hand, there is a very strong public support for breakthroughs promising better clinical diagnosis and treatment and, on the other hand, there is a concern about the increased loss of privacy and potential for genetic discrimination along with the capacity to regulate genetic science in the public interest. A different approach such as patient advocacy may be used to deal with such issues. Current legal and ethical trends favor the facilitation of secondary use of biospecimens, and an increase in the number of biobanks appears to be an important element in considering the application of the new expertise generated through biobanks in the discipline of public health [39].

Table 2. *Existing, promising, and emerging nationwide biobanks.*

Name of biobank	Size (age group)	Year Established	Funding	Aims	References
U.K. biobank	>5,00,000 (40–69 years), general population	2006	Welcome Trust medical charity (United Kingdom)	The aim of this biobank is to improve the prevention, diagnosis, and treatment of a wide range of diseases such as cancer, heart diseases, stroke, diabetes, arthritis, osteoporosis, eye disorders, depression, and forms of dementia	[49]
Estonia genome project	52,000 donors (≥18 years of age), general population	2000	Ministry of Social Affairs and the Ministry of Education and Rresearch (Estonia)	To investigate genetic and non-genetic causes of chronic diseases in Estonia	[50]
Kadoorie study of chronic disease in China	510,000 (35–74 years), general population	2004	Kadoorie Charitable foundation, the welcome trust (China)	To investigate genetic and non-genetic causes of chronic diseases in China	[51]
The Mexico City prospective study	160,000 (>35 years), general population	1999	Mexican Ministry of Health, the welcome trust (Mexico)	To assess the association between risk factors and common causes of death	[52]
Diabetes Pearl	7,000 Type 2 diabetes subjects	2007	The Dutch Government and the eight Dutch academic medical centers. (Nederland)	The Diabetes Pearl is large-scale cohort of type 2 diabetes aiming to study risk factors, including biomarkers and genetic markers, for disease deterioration and the development of severe diabetes complications.	[53]
Network for nPOD	>351 Diabetes donors (age of 1 day to 90 years)	2007	Funded by Juvenile Diabetes Research Foundation at the University of Florida (USA)	Tissue biobank of pancreatic and related organs from cadaveric organ donors with various risk levels for T1D	[54]
Danish national biobank	3–4 million samples, general population	2012	Denmark	This biobank enables sophisticated analysis of genetic variation and response to treatment, as well as marker studies that better classify disease status, progression, and complications.	[55]
GBCS	30,000 (50–96 years), general population	2003	The university of Birmingham and Hong Kong, and the Guangzhou occupational disease prevention and treatment center in China (China)	Aim of the study is to examine the effects of genetic and environmental influences on health and chronic disease development	[56]
Qatar biobank	>140,000 samples, above 18 year of age, general population	2010	Qatar Foundation for Education, Science and Community development (Qatar)	Discovery and development of health care interventions	[57]
Germany diabetes study	240 Type 1 and 458 Type 2 diabetes subjects	2016	German Federal Ministry of Health (Berlin, Germany)	To identify prognostic markers and mechanisms underlying the development of related comorbidities	[58]
The Danish center for strategic research in DD2	50,000 Type 2 diabetes subjects	2012	Danish Agency for Science and Danish Health and Medicine Authority	Aims to study the progression of type 2 diabetes	[59]

GBCS, Guangzhou biobank cohort study; nPOD, pancreatic organ donors with diabetes; T1D, Type 1 diabetes.

Many international biobanking organizations have already been established like the International Society for Biological and Environmental Repositories, Public Population Project in Genomics and Society, European Middle Eastern and African Society for Biopreservation and Biobanking, Biorepositories and Biospecimen Research Branch, and the Biobanking and Biomolecular Resources infrastructure. These organizations have developed practice guidelines to addresses the technical, legal, and ethical issues relevant to biospecimen repositories. Thus, the establishment of these organizations clearly indicates that the domain of biobanking is a scientific and professional entity. We acknowledge that biobanks are not regulated or governed at an international level. Nations with a national biobank, for example, the United Kingdom, Denmark, and the Netherlands don't have biobank legislation. Additionally, personal data protection (privacy legislation) and research ethics laws represent biobank data in the absence of biobank legislation [48].

Here, we conclude that broader consent and consent to future research studies are ethically recommended for biobank research, if the biospecimen and data are handled safely, and donors/volunteers/participants of biospecimen are allowed the privilege to withdraw the consent from research, and the potential disclosure of results and the future research studies being subjected to the approval of an ethical review board [47].

Existing Specialized Biobanks in Diabetes Research

The newly emerging research organizations are building their own biobanks for international collaborations, harmonizing regulatory legislations, and facilitating the use of biospecimens in basic research. Data in Table 2 show the promising and emerging nationwide biobanks. The term emerging is defined as prominent biobanks for research in different nations. In recent times, most important biobank in diabetes research is the New National Biobank of the Danish Center for Strategic Research on DD2. Diabetes research-based biobank and a registry are effective if access to the biological data is granted and the use of clinical data/biospecimen is maximized through data sharing. To address the research needs, several academic research centers are forming biorepositories that collect and store biospecimens and are often linked to registries. A registry collects personal health information from individuals who have a chronic disease, support retrieval and querying of huge amounts of biological data. Biobank research-based registries and the linking of data in large databases across national borders are viewed rather differently [59]. Thus, the linking of registry to biobanks haves the potential to immensely facilitate the tedious and cumbersome work of data analysis for biomedical research [5]. The linkage of diabetes registry and biobank biological data allows long-term follow-up studies and accelerates diabetes-specific research among different ethnic populations. For example, the Danish Center for Strategic Research in DD2 biobank jointly with the DD2 database that is linked to the various Danish population-based registries provides a unique infrastructure for studying the progression of T2D [5]. Prediagnostic samples are beneficial in identifying biomarkers for the early detection of diabetes and in investigating possible associations between life course exposures and the risk of diabetes.

Conclusion

Specialized biobank is an invaluable resource for biomedical research. They are reformulating numerous forms of research. For example, permitting access to stored biospecimens for research, examining the method of consent and governance, and generating new models for research. High-quality biospecimens stored in specialized biobanks will create research infrastructure and allow us to study risk factors, biomarkers, and genetic determinants. Specialized biobanks can contribute enormously to chronic diseases like diabetes. Specialized biobanks can support translational medicine both nationally and internationally.

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