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Chinese biobanks: present and future

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Summary

As the demands of scientific research and application for specimens increase rapidly, biobanks in China have been springing up over the recent years. This paper summarizes Chinese biobanks through investigation and survey on operative, managerial, ethical conditions and challenges of biobanks. At present, hospitals and research institutes in China set up and operate most of the biobanks, collecting human specimens to support clinical and scientific research. With the development of bio-industry and arrival of the big data era, biobanks need not only collect and store human and non-human specimens but also to manage the big data associated with these specimens.

1. Introduction

A biobank is a type of biorepository to collect, process, store and distribute bioresources and record information for scientific research and clinical application (De Souza & Greenspan, 2013). Since the 1990s, biobanks have become a key resource, supporting many types of contemporary research like genomics and personalized medicine. Many countries, including the USA (Henderson *et al.*, 2013), Australia (Vaught *et al.*, 2010), UK (Ollier *et al.*, 2005), Italy (Petrini *et al.*, 2011), Switzerland (Perskvist *et al.*, 2013) and China, struggled to acquire sufficient specimens, and have built or are building various scales of biobanks, such as tumour bank (Li *et al.*, 2004), blood bank (Shan *et al.*, 2002) and bone bank (Li *et al.*, 2010) etc. With increasing application of biobanks, several ethical issues are raised (Cambon-Thomsen *et al.*, 2007), for example, during the specimen collection and utilization, ethical uncertainties about patient rights are invoked, and have provoked discussions in community circles.

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2. Development of Chinese biobanks

In the early 1990s, researchers collected the biological specimens to meet their experimental requirements, and did not have the sense of bioresource sharing and information exchange (Greely, 2007). However, with the development of life science, researchers have realized that bioresource becomes a critical factor to specimen preservation, scientific research and clinic application etc. In China, the Immortalize Cell Bank of Different Chinese Ethnic Groups was set up in 1990s, while since 2000, the number of Chinese biobanks has increased rapidly, such as China Kadoorie Biobank, Guangzhou cohort biobank, Taizhou cohort biobank, Sun Yat-sen University Cancer Center affiliated tumour bank.

Chinese biobanks are scattered around China, and their organizational structure is not the same. In order to find their information, we conducted multiple search strategies by searching China Knowledge Resource Integrated Database (CNKI) and websites, as well as on-site investigating on hospital-affiliated biobanks. In total, 22 Chinese biobanks were surveyed (Table 1). Human-oriented biobanks are classified into disease-oriented biobanks or population-based biobanks, depending on purpose or design; disease-oriented biobanks are usually affiliated with hospitals, such as tumour banks, which collect tumour tissue as well as blood and other specimens from a variety of diseases together with normal controls;

Table 1. *Chinese biobanks summarized in this review*

	Hospital/Institute	Founding time	Scope	Specimen type	No. of specimen	Website
1	CMDP	1992	population-based	Blood	1 650 000	www.cmdp.com.cn
2	The Immortalize Cell Bank of Different Chinese Ethnic Groups	1994	population-based	Immortalized cell line and DNA	Cell line:3982; DNA:7210	——
3	Clinical Oncology Institute in Beijing Cancer Hospital	1996	disease-oriented	Tumour tissue and blood	500 000	www.bjcancer.org
4	Wuxi No. 4 People's Hospital Affiliated to Suzhou University (Li *et al*., 2004)	1999	disease-oriented	Tissue, RNA, serum, plasma, lymphocyte, stem cell and cell line	3138 (until 2003)	www.wuxihospital.com
5	Tongji Hospital (Yang, 2012)	1999	disease-oriented	Tissue, blood, DNA and cell	61 408	www.tjh.com.cn
6	Sun Yat-sen University Cancer Center	2001	disease-oriented	Blood, serum, plasma, blood cells, bone marrow cell, protein, DNA, RNA and paraffin section	1 000 000	www.sysucc.org.cn
7	China Kadoorie Biobank	2003	population-based	Blood	510 000	www.ckbiobank.org
8	The Key Laboratory of Xinjiang Endemic and Ethnic Disease	2004	population-based	Blood	20 000	——
9	Tianjin Medical University Cancer Institute & Hospital	2004	disease-oriented	Tumour tissue and blood	Tissue: 36 000; Blood: 35 000	www.tjmuch.com
10	Taizhou Hospital (Bao *et al*., 2010)	2004	disease-oriented	Fresh frozen tissue, paraffin-embedded tissue, blood, serum, plasma and cerebrospinal fluid	46 576 (until 2009)	www.tzhospital.com
11	The First Teaching Hospital of Xinjiang Medical University	2004	disease-oriented	Tumour tissue and blood	50 000	www.xydyfy.cn
12	The Tumour Hospital of Guangxi Zhuang Autonomous Region (Ge *et al*., 2010)	2006	disease-oriented	Tissues, tumour adjacent tissue, adjacent non-cancerous tissue, serum, plasma and lymphocyte	Tissue: 2618; Serum: 726; Plasma: 655; Lymphocyte: 670	www.gxzlyy.com
13	Zhejiang Cancer Hospital	2007	disease-oriented	Tissue, tumour adjacent tissue, benign tumour, serum, plasma and white blood cell layer	140 000	www.zchospital.com
14	Eighth Hospital of Wuhan City (Chen *et al*., 2012)	2007	disease-oriented	Tissue, blood, plasma, serum, biological fluid, DNA, RNA and proteins	1600	www.wh8yy.cn
15	Sixth subsidiary Sun Yat-sen University Hospital	2007	disease-oriented	Tissues, serum, plasma, blood cells, blood and faeces	Tissue: 20 000; Blood: 30 000; Faeces: 100	www.zs6y.com
16	Taizhou (Fudan University) Institute of Health Sciences	2007	population-based	DNA	100 000	www.fdcmc.com
17	Ren Ji Hospital (Shanghai Jiao Tong University)	2008	disease-oriented	Serum, plasma, tissue and DNA	7000	www.renji.com
18	West China Hospital (Yang *et al*., 2012)	2009	disease-oriented	Tissues, adjacent tissues and blood	70 000	www.cd120.com
19	Eastern Hepatobiliary Surgery Hospital, the Second Military Medical University of Chinese PLA (Yang *et al*., 2010)	2009	disease-oriented	Fresh tissue, paraffin, blood, urine, and DNA, RNA	Tissue: 5000; Blood: 4000 (until 2010)	www.ehbh.cn
20	Jiangsu Province Hospital	2010	disease-oriented	Tumour tissue and blood	30 000	www.jsph.net
21	The Fifth People's Hospital of Shanghai	2010	population-based	Blood and urine	108 691	www.5thhospital.com
22	CNGB	2011		Blood, urine, faeces, saliva, tissue, cell etc.	1 800 000	www.nationalgenebank.org

population-based biobanks are generally situated outside hospitals (Hewitt, 2011). This paper will introduce existing biobanks in China in the perspective of background, sample types and status and the ethical awareness raised in biobanking.

(i) *Disease-oriented biobanks*

In recent years, some disease-oriented biobanks have been established for disease research, which provided various valuable specimens for research needs. The establishment of disease-oriented biobanks is helpful in sharing bioresource and information effectively.

As early as 1996, the clinical tumour bank of the Clinical Oncology Institute in Beijing Cancer Hospital (Ji, 2005) was established to collect, store and utilize human tumour tissues and blood specimens, and about 500 000 specimens were are collected currently. The tumour bank focuses on collecting human common tumour tissue specimens and tumour adjacent tissues, including gastric cancer, oesophageal cancer, colorectal cancer, liver cancer, pancreatic cancer, lung cancer and breast cancer; meanwhile, serum and plasma isolated from blood were also stored in the bank. The biobank resources are mainly used to support research for affiliated research units of Peking University and other research institutions. Furthermore, a database is applied for the biobank to record basic information of specimens.

One of the largest tumour banks in China was established based on the Sun Yat-sen University Cancer Center and the State Key Laboratory of Oncology in South China in 2001. Specimens were collected from tumour patients and healthy people, including blood, serum, plasma, blood cells, bone marrow cells, proteins, DNA, RNA and paraffin sections. The biobank stored 30 000 blood specimens from tumour patients, 6400 normal blood specimens and 6000 normal control tissues until 2008. Currently, the number of specimens is 1 million.

Tianjin Medical University Cancer Institute & Hospital joint American Cancer Research Foundation funded a tumour tissue bank located in Tianjin in 2004. Currently, the tissue bank had already collected 36 000 tissue specimens and 35 000 blood specimens with clinical data. A database was established, including data from tumour tissue specimens, blood specimens, related clinical information and follow-up information.

The tumour bank of Zhejiang Cancer Hospital was established in 2007 (Ye *et al.*, 2012), which was guided by Yale University Cancer Center. Sharing resources and improving resource utilization are their starting point. The hospital sets up a management team to take charge of daily operations and research work. The current area of the tumour bank is about 500 m^2, which enables it to store nearly 140 000 specimens from 4700 patients. The types of specimens include tumour tissue, tumour adjacent tissue, benign tumour, normal tissue, serum, plasma and white blood cell layer.

As a matter of fact, many disease-oriented biobanks are set up according to research projects in Chinese hospitals. For example, Qidong Liver Cancer Institute had established several biobanks by 2011, according to chemoprophylaxis research, biomarker research, pedigree research of liver cancer etc., these biobanks mainly stored a lot of specimens (serum >100 000, plasma >65 000 and white blood cells >40 000 (Chen *et al.*, 2011)). The Specimen Bank of Xinjiang Key Disease was established in 2004, which is a joint project of The First Teaching Hospital of Xinjiang Medical University and Harvard University. The Specimen Bank focuses on the high incidence diseases in Xinjiang, involving echinococcosis, oesophageal cancer, diabetes etc. Currently, this biobank has collected nearly 50 000 specimens, including tissues and blood.

(ii) *Population-based biobanks*

Population-based biobanks mainly collect specimens from normal volunteers. For example, the China Marrow Donor Program (CMDP) was established in 1992 and then reactivated in 2001. It owns 31 provincial sub-banks with 1·65 million specimens by the end of 2012. In addition, CMDP carries sociological information, personal medical information and population biology information. CMDP respectively signed cooperation agreements with cord blood banks in Beijing, Shanghai, Guangzhou, Tianjin, Sichuan and Guangdong in April 2009.

China Kadoorie Biobank had started to be built since 2003, the biobank is a collaborative project between the Clinical Trial Service Unit of Oxford University and the Chinese National Centre for Disease Control, and is funded by the Kadoorie Charitable Foundation in Hong Kong. The project is aimed at collecting blood specimens and various lifestyle and medical data from more than 510 000 middle-aged adults from ten geographic areas of China, to investigate the genetic and environmental causes of common chronic diseases in the Chinese population.

The Key Laboratory of Xinjiang Endemic and Ethnic Disease has set up a biobank for Xinjiang ethnic diseases research. The biobank was established in 2004 (Zhao *et al.*, 2010), which stored 20 000 blood specimens from nationalities of Uygur, Kazak and Han from 2004 to 2009.

Besides, the cohort study biobank in Guangzhou was established in 2003 (Zhu *et al.*, 2006). In 2007, Taizhou (Fudan University) Institute of Health Sciences established a biobank based on a population health-tracking research project, which had collected

100 000 DNA samples. The Institutional Specimen Bank was set up by the Fifth People's Hospital of Shanghai in 2010, and collects over 100 000 blood and urine specimens for chronic diseases research.

The cell is the basic unit of the structure and function in organisms and plays an important role in scientific research. There are several cell banks which have been established in China. For example, the Immortalize Cell Bank of Different Chinese Ethnic Groups, the largest immortalized cell lines bank in China, has been established in 1994. The immortalized cell bank stored 3982 immortalized cell lines and 7210 DNA from 70 ethnic groups until 2008 (Chu *et al.*, 2008). There is a database used for data analysis. The resources of the cell bank can meet permanent research needs; some of the cell lines and DNA from the bank have been provided to establish national and international collaboration.

Sperms, egg cells, zygotes and embryos can be cryopreserved. The first Chinese human sperm bank was created in Hunan province (Zhang *et al.*, 2001), which is the largest human sperm bank in China. In total, 17 human sperm banks had been set up in 17 provinces respectively by January 2013.

China National Genebank (CNGB) was established in 2011 and located in Shenzhen. It is approved and funded by the National Development and Reform Commission, Ministry of Finance, Ministry of Industry and Information Technology and National Health and Family Planning Commission of People's Republic of China. CNGB is committed to constructing an integrated national institute which is composed of a standardized Biological Bank, Bioinformation Bank and the resource sharing Consortium. The biobank in CNGB collects, preserves and comprehensively utilizes various kinds of human-related specimens including blood, urine, tissues, cells etc. The number of specimens has already reached 1·8 million. Standard specifications are strictly implemented in its practical operation, and first-class facilities and professional staff are employed to support massive storage, processing and application of specimens.

(iii) *Ethical issues*

There are a number of important issues for biobanking and scientific use of biobanks. Many of them are of an ethical nature or somehow related to ethical considerations. As early as 2003, an ethics debate related to biobanks has primarily taken place in connection to the Health Sector Database (HSD) project of Iceland (Zika *et al.*, 2010). HSD ignored the interests of general public on ethical issue, which caused great dispute in Iceland and abroad. Ethical discussion also appears in Chinese biobanking, but the history of bio-ethics in China is a rather short one (Hennig, 2006). A few years ago, there were no specialized agencies or policies to govern the collection, management and application of specimens (including human genetic resources) in China (Su, 2011). In recent years, bioethics has become a hot topic in all kinds of exhibitions and conferences in China and aboard. Concern has been raised among Chinese biobanks, regarding consent procedures, privacy and confidentiality, scientific openness and the appropriateness of monopolizing the database. Many Chinese biobanks have established an Ethics Committee of their own for ethical review and governance.

However, with the development of biobanks, new kinds of ethical challenges related to biobank studies have arisen (Hansson, 2009). For example, the selection of an appropriate consent procedure for future use of biobank specimens, questions about coding of specimens and medical data to protect privacy and the question whether research results should be returned or not (Auray-Blais & Patenaude, 2006). Ethics committees have to deal with these ethical challenges and will play a key role in biobanking.

(iv) *Challenges*

It is possible to handle and store the tremendous amounts of clinical specimens properly for China. However, there are still some problems and challenges in the initial developing phase of China's biobanks.

(a) *Regulatory system*

The construction and governance of the biobank involve the protection of personal information, the application and management of the specimens, intellectual property, the process of informed consent and ethical review etc., and they need to be protected properly and carefully. The Chinese government has introduced some regulations and rules related to human specimen and data, such as *Interim Measures for the Administration of Human Genetic Resources.* There exist some problems in the legislation such as the low level, weak enforcement, narrow content and incomplete system (Li *et al.*, 2012*b*). The regulatory systems have not kept up with the development of biobanking, it is essential and urgent to create comprehensive legal and ethical governance framework by law in China.

(b) *Standard operating procedures*

Every step including collection, transportation, processing and storage etc. influences the quality of the specimens which are required for scientific discoveries and important for the translational medicine research. The national-level criteria of technical specifications and quality control systems related to biobanking have not yet been enacted in China. And all the existing operating guidelines are flexible or not unified, so the biobanks use different collection, processing and storage methods and quality control systems, which lead to variable and uneven quality of the specimens in China (Ge *et al.*, 2010; Zhang *et al.*, 2011; Tian *et al.*, 2013). It is essential to develop and implement standardized national specimen processing and storage methods, clearly define and control over all aspects of the specimens preservation, which allow all of the biobanks to share the same quality criterion and could be the prerequisites for controlling the specimen quality. Staff training should also be taken into consideration, and courses should include sample collection, transport and processing, daily management and related basic knowledge and skill training for personnel.

(c) *Participation*

The biobank resources involve the donors' and their families' specimens and information. The public knows little or even misunderstands about the biobanks. How to get more understanding and support, especially promote the long-term participation is one of the big challenges for Chinese biobanks (Lu, 2012). In order to ensure the long-term participation, trust and support, biobanks have to strengthen the regulatory systems and make it transparent to the public.

(d) *Data management*

A large number of data need to be recorded in biobank, including the donors' information, clinical data, histological data, specimen information and follow-up information. A scientific and reasonable biobank management system with comprehensive and reliable information is one of the important components of the biobank, which could effectively organize and govern all kinds of the data related to the specimens. At present, there is no unified network which could be applied to all the biobanks across the country, the specimen information cannot be shared efficiently, and different biobanks lack communication in some degree and this blocks the progress of bio-medicine research in China (Wang, 2010; Li *et al.*, 2012*a*). On the other hand, it is a big challenge and equally crucial to develop a mechanism for protecting the privacy and safeguarding personal information of the participants while sharing data among different hospitals, academic institutions and biopharmaceutical companies.

(e) *Funding*

Funding is one of the most thorny and critical issues to confront for all of the biobanks. The duties of biobanking cover the collection, processing and storage of specimens, comprehensive facilities, information systems, all of this needs to be supported by manual labour, material resources and financial resources. Most of the biobanks in China are non-profit and funded by government appropriations or scientific funding. The maximum length of a scientific research project fund is 5 years in China, in other words, the financial support is not constant. The contradictions between a short research cycle and a long construction cycle make the biobank hard to maintain (Ji, 2013). How to achieve sustainable development is another problem for Chinese biobanks.

3. Prospects for Chinese biobanks

(i) *Policies*

As China has a large population and abundant disease specimens, the number of biobanks in China increases very fast. Relative policies and funding supply play a key role in biobanking because it is costly to build and maintain biobanks. Most biobanks in China are non-profit and need to get support from the government's research funding. Long-term funding is essential to guarantee sustainable biobank running. There are several official approved documents, such as *National Guideline on Medium- and Long-Term Program for Science and Technology Development (2006–2020)*, *China's Twelfth Five Year Plan (2011–2015) for the Development of Biological Technology*, and *Policies to Promote the Rapid Development of Biotechnology Industry* from the General Office of the State Council, which clearly state to accelerate Chinese genomics research and promote the development of genetically modified industry. Moreover, the National Development and Reform Commission issued the *Guiding Catalogue of Industrial Structure Adjustment (Version 2011)*, encouraging the development of genetic engineering and genebank construction. Above all, these documents indicate that the Chinese government should pay more attention to the management and application of bioresources, and also boost investment in biobanking.

(ii) *Communication*

The advancement of translational medical research and scientific discovery rely on the effective operation of biobanks with high-quality specimens. In order to establish high-standard and professional biobanks and stimulate communication among those biobanks, a lot of institutions endeavoured to organize various biobanking academic conferences and seminars. For example, the second Biobank China was held in 2012, focusing on the ethics and information management of biobanks as well as best practices in biobank development; the fifth China Biobank Standardization and Application Seminar, in June 2013, focused on major diseases (mainly tumour) and construction of unique feature biobanks, and also discussed biobank standardization and application in translational medicine. In the last few years in China, scientists have actively participated in international biobank conference and research collaboration, joined international biobank organizations and introduce Chinese biobanks to the world. For example, more and more Chinese scientists take part in the annual meeting of the International Society of Biology and Environment Repositories (ISBER), which shows their participation and sharing enthusiasm, and the number of Chinese attendees increased from 2 in 2011 to more than 50 in 2013 with little change of the total ISBER attendee. After discussion with Chinese delegates, ISBER are considering to hold an annual meeting in China in the future. These academic exchanges, to some degree, strengthen the regulation of industry specifications and accelerate collaboration among different biobanks in China and abroad.

(iii) *Application*

As for the application of the specimens, different biobanks vary with the purposes of clinical use, fundamental research and so on. Take CNGB for example, Biological Bank of CNGB collects kinds of specimens not only human-related but also non-human sources (human blood, urine, tissues, cells etc., living cells of animals and plants, microbial strains, marine organisms, endangered species, etc.). CNGB sets up a large-scale, high-quality and standardized biorepository, utilizes bioresources effectively, and protects the diversity of bioresources in China. It is important for personalized medicine and biological breeding ranging from scientific research to potential industrialization. Relying on bioresources and high throughput platform, CNGB aims to build a bridge through bioresource to scientific research and industry.

(iv) *Preservation tendency*

(a) *Specimen types*

With large population and great variety of clinical illnesses, Chinese biobanks have special advantages to collect all kinds of disease-related specimens. On the other hand, researchers realize the importance of the human specimens, and different organizations collect and preserve more and more types of specimens from blood, urine and tumour tissues to hairs, faeces, saliva, umbilical cord, ascites, stem cells and somatic cell (Min, 2012). Integrating all kinds of specimens and comprehensively studying the diseases like cardiovascular disease, diabetes and cancer, can make it possible to predict, prevent, intervene and control the diseases, eventually reduce risks and offer effective solutions for the diseases.

(b) *Micro-specimens*

Long fragment read (LFR) technology for accurate and cost-effective sequencing of the genome was published in *Nature* for the first time in 2012, which uses only 10–20 (about 100 pg DNA) human cells, and is able to phase 91–97% of the available single nucleotide polymorphisms (SNPs) (Peters *et al.*, 2012). LFR allows genome sequencing and haplotyping at a clinically relevant cost, quality and scale and provides new insights into small amount of specimens preservation. Trace amount of DNA extracted from small amount of specimens could meet the requirement of whole-genome sequencing; the method offers facilities for the specimen collection and storage with the goal of sequencing. It is possible to detect and analyse the proteins and metabolites using trace amount of specimens with technological advancements. The amount of specimen collection moves towards micro-quantity, which could save an enormous amount of human labour, material resources and financial resources. How to control the quantity and quality to fulfil the application demands and decrease the consumption of the original specimens will be a big challenge for micro-specimens collection and preservation.

(c) *Novel storage technologies*

For now, most specimens use cold chains or are deep-frozen in the transportation and preservation process, but the emergence of novel storage reagents and technologies allows preservation of specimens at room temperature. For example, as an aqueous, non-toxic tissue storage reagent, RNAlater can rapidly permeate tissue to stabilize and protect cellular RNA *in situ* in unfrozen specimens, eliminate the need to immediately process tissue specimens or to freeze specimens in liquid nitrogen for later processing, this is convenient for simplified specimen handling and shipping (Dekairelle *et al.*, 2007); there are well-documented high-quality nucleic acids preservation solutions such as GenTegra (IntegenX), RNAstable (Biomatrica) and RNAshell (Imagene), all of these commercial matrices could preserve DNA/RNA at room temperature for long-term and reduce energy costs (Mathay *et al.*, 2012). All of these new types of preservation reagents and technologies, which are technologically feasible and economically reasonable both in quality and cost, provide new directions for specimen preservation at ambient temperature.

(d) *Trans-OMICS*

Next-generation sequencing technologies and mass spectrometry etc. has brought revolutionary impacts on life science research. Massive omics data would be generated relying on high-throughput sequencing platforms and mass spectrometers. Systematic study can be carried out including genomics, transcriptomics, proteomics and metabolomics and discover their internal relation by analysing these big data, at the same time, it is possible to make the most of the all kinds of specimens. To reveal the occurrence and development of diseases, clarify the inherited susceptibility of certain diseases and complexity of genome, could help to improve the diagnosis and treatment. The big challenge is to achieve high-quality and multilevel preservation of the specimens including DNA/RNA, proteins, small-molecule metabolite etc. Preserving and utilizing specimens and related information and data effectively can be a firm foundation for translational medicine research.

The three elements, involving high-quality and sufficient amount of specimens and related comprehensive information (especially clinical information), as well as research-generated big data supported by high-performance storage and computing platform, will be the vital foundation for and stimulate the development of future translational medical research and personalized medicine. Integration and application of resources and big data by extensive collaborations will accelerate transition from science to technology, and to industry.

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Declaration of Interest

None.

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