MATHEWS Open Access Journals

Mini Review | Mathews Journal of Urology and Nephrology

Challenges of Ethical Reviews in China's Biobanks

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Received Date: 24 Aug 2017

Accepted Date: 25 Sep 2017

Published Date: 27 Sep 2017

Citation: Xiao Y, Qian K, Zheng L, Cao X, et al. (2017). Challenges of Ethical Reviews in China's Biobanks. M J Urol. 1(1): 004.

ABSTRACT

Biobanks are repositories consist of biological samples and the related information for the purpose of research. Being considered as key infrastructures for biomedical research and translational medicine, biobanks have undergone dramatically development in China. A medical ethics committee aims to ensure that medical experimentation and human research are carried out in an ethical manner. The first Chinese medical ethics committee was established in 1991, far lagged behind the developed countries. Due to the feature of future-orientated research and the complex of genetic research, the ethical reviews on biobanks become more complicated and controversial than the ordinary clinical research. Investigations showed that ethics committees in China lacked independence, personnel engaged in medical ethics, ethical education and training as well as relevant laws and regulations. According to the ethical particularity of biobanks and China's current national condition, we focus on the challenges that the hospital ethics committees in China faced and how to overcome them.

WHAT IS A BIOBANK?

A biobank is a repository that collects, stores and manages biological samples (cells, tissue, urine, blood, DNA or RNA fragments, etc.) and information related to the biological samples (clinical records regarding donators and their families, genealogical data, lifestyle information, etc.) for the purpose of research, especially for the future research [1,2]. In post-Human Genome Project era, the role of biobanking has been gradually accepted as a vital resource, because knowledge from biobanks contributed to the understanding of the etiology of non-communicable diseases caused by both various gene mutations and the influence of environmental factors [3,4]. Being considered as key infrastructures for biomedical research and translational medicine, which brings scientific research results to clinical practice, biobanks have undergone dramatically increase in number and size over the recent decades all over the world [5]. Generally, human biobanks can be classified into two categories: population-oriented biobanks and disease-oriented biobanks (also known as clinical biobanks) [6]. In this mini review, we focus on the clinical biobanks, which are often established by major hospitals.

BRIEF HISTORY OF BIOBANKS

As early as 1949, the United States Navy established the first tissue biobank in the world. In 1994, the Johns Hopkins Brady Urological Institute Biorepository was founded and played pivotal roles in urological research [7]. China, with a population of approximately 1.4 billion inhabitants, requires its own biobanks to support indigenous translational medicine due to the huge and increasing burden of non-communicable diseases, such as cancer, cardiovascular diseases and etc. In 1994, China's first biobank was established for the storage of immortalized cell lines from Chinese ethnic groups. Four years later, in 1998, the Office of Chinese Human Genetic Resources Management was set up. In 2003, The National Infrastructure of Chinese Genetic Resources was initiated [8]. In the recent decade, China's biobanks, especially large-scale genomic biobanks, have developed rapidly in number and size. Beijing and Shanghai are the leading sites for the construction of biobanks, for many biomedical research institutes and clinical facilities are located in the cities [8,9].

The ethical particularity of biobanks

With the rapid development of the construction and operation of biobanks, the new ethical issues related to biobanks have attracted more attention due to the particularity of biobanks. For instance, informed consent has been considered as the gold standard since its introduction in the Nuremberg Code but it's ill-suited to the nature of biobank. Traditionally, all participants must be well-informed and understand the purpose and duration of the experiment, the methods to be conducted, the inconveniences and hazards to be expected and the effects upon his health which may possibly come from his participation in the experiment. Only after the above process, a really voluntary consent can be obtained from each participant. In fact, the Nuremberg Code and the Declaration of Helsinki both assume a consent must be obtained at the beginning of a specific experiment and the aims, benefits and risks are fully known. However, biobanks are future-orientated projects, so the consent cannot be really 'informed' at the time when it is obtained because the future research is not yet known. Without authentic notification and understanding, "informed consent" explicitly makes no sense. Broad or blanket consent maybe a solution to the problem, but it provides so little protection to a participant that it can be regarded as permission to do anything that biobanks or researchers consider it appropriate [10]. Besides, great attention should be paid to the privacy and confidentiality of the participants, which may lead to discrimination against some participants and relevant groups on buying insurance, obtaining employment, and son on [11]. Even if a growing number of sample access policies (SAPs) have been made [12], current governance mechanisms to protect the privacy of participants still face the increasing challenges due to the development of next-generation sequencing and global data sharing [13,14]. In addition, what responsibilities should biobanks take to deal with incidental findings and individual research results? Only a few biobanks, such as the Singapore Tissue Network and UK Biobank have definitely declared against returning research results to participants [15]. For most biobanks all over the world, it still remain highly controversial [16-18]. Moreover, the ownership of property of biobank participants has been extensively discussed [11,14]. However, a definite conclusion has not been drawn yet.

Ethics committees

The ethics committee originated after the victory of the Second World War, following trials of Nazi doctors at the Nuremberg trials for murdering and torturing victims. A medical ethics committee is a group responsible for ensuring that medical experimentation and human research are carried out in an ethical manner [19]. As we all know, the advancement of medical science inevitably requires human experiments to finally confirm and that is benefit for mankind. But for the participants involved in human experimentation, that means unpredictable risk. Generally, a medical ethics committee should balance the benefit and risk, which are often the two faces of the same coin [20]. To do this, a medical ethics committee should implement reviews independently, objectively, justly, and transparently, in accordance with the principles of beneficence, autonomy, non-maleficence justice [21] and confidentiality as well as honesty [20]. In the 1970s and 1980s, the United States, Canada, Netherlands, France, United Kingdom and other countries have established their own hospital ethics committees [22]. In Germany, the establishment of a HEC is mandatory in all hospitals registered in the Christian Association of Hospitals [23]. The first Chinese medical ethics committee was established in 1991, lagged behind the developed countries for about 20 years [24].

Hospital ethics committees in China

In China, according to different functions, there are three types of ethics committees: medical ethics committees (MECs), institutional review boards (IRBs) and hospital ethics committees (HECs) [25]. The MECs usually undertake the government decision-making consultation and the ethical surveillance, and the latter two are established in hospitals to perform the specific ethical reviews. Since most biobanks in China are established by major general hospitals, we mainly focus on the Hospital Ethics Committees (HECs) in this mini review. Chinese scholars investigated current situation of HECs in China and found some challenges that ethics committees faced:

(1) A sound HEC should be equipped with exclusive office, full-time independent director and secretary. However, HECs in China were basically the subordinate units of the hospital, mostly attached to the scientific research office, the medical affair department, the Chinese Communist Party committee and the Chairmen of most HECs were the hospital leaders. According to an investigation of Chairmen of 13 HECs in Shanghai, 46.15% of the HECs' chairmen were the secretaries of the Chinese Communist Party committee and 30.77% of them were the presidents of the hospitals [26]. This situation led the HECs into the lack of independence and made the ethical reviews vulnerable to interference by the interests of the hospitals.

(2) Lack of the personnel engaged in medical ethics was the prevalent problem in the composition of the HECs in China. According to a survey in 2012, only 4 of the 68 members in the 10 HECs were engaged in medical ethics research and some

medical ethics experts had to serve as members of 4 HECs [27]. The lack of staffing, especially the lack of medical ethics experts, affected the ethical counseling, the ethical training and the ethical review.

(3) The education and training of HECs in China were weak. The ethical training activities were always spontaneous and involved in very limited staff, so the effects were very poor. A survey of 7 HECs in Wenzhou City found that 69.7% of the HEC members did not receive the systemic ethics training [28]. Another survey performed in Shanghai to investigate the projects leaders showed that 70% of the leaders received ethical trainings and 42% of them evaluated the trainings as "good", 29% of them evaluated the trainings as "better", 28% of them evaluated the trainings as "general" [29]. Another investigation of 13 HECs about ethical trainings in Fujian province revealed that only 6 had trained the medical staff, only 1 had trained the patients [30]. In summary, the trainings that the members of HECs, scientific researchers and medical staff had received were very limited in China.

(4) The relevant laws and regulations were still inadequate in China. In the United States, researchers and HECs must comply with federal law "45CFR46" (policy for protection of human research subjects) [31], "21CFR56" (the general standards for the composition, operation, and responsibility of an IRB) [32] and "National Research Act" (signed into law on July 12, 1974) [33], which are protection of human research subjects. However, at present, China has no relevant laws and regulations formulated by the State Council, nor a powerful law enacted by the National People's Congress to regulate human experimentation. There are only some departmental rules and regulations [34]. This is one of the reasons why there are so many problems in the construction and operation of HECs in China.

(5) Historically, HECs in China were primarily responsible for reviewing ethical issues in drug clinical trials and clinical studies. In fact, most of Chinese medical ethics committees were rarely engaged in ethical review of biobanks. However, it's the medical ethics committees that reviewed or will review biobanks ethic issues in China. Given the particularity of the ethical issues of biobanks and the inadequate ethical review capacity of the Chinese medical ethics committees mentioned above, the ethical reviews of China's biobanks will face more challenges in this complex context.

How to face the challenges?

First, self-education and training must be improved urgently for HECs in China urgently. In Shanghai, a leading city of biobanks construction in China, a questionnaire survey showed that the medical staff had the basic awareness of bioethics, but lacked the cognition of specific ethical issues related to biobanks, especially lacked the cognition of the informed consents [35]. Biomedical researchers, especially those who are familiar with biobanks should be recruited into ethics committees to contribute more professional comments. Second, ethical trainings must be strengthened. Mandatory ethical trainings must be provided to HECs members, medical staff and biomedical researchers. The systemic training should comprise scientific methods, ethical principles, regulatory framework and the particularity of biobanks. Besides, the internet can provide a convenient learning channel for ethics committees. For example, one can browse the latest annual report from the Ethics and Governance Council of UK biobanks via its website at any time [36]. For the lack of the personnel engaged in biobank ethics in China, it might be a better way to learn ethical issues related to biobanks. Furthermore, HECs members should be encouraged and supported to attend international symposiums about ethical issues of biobanks that can widen viewpoints and new practical methods. In addition, the new laws and regulations related to biobanks should be learned promptly. For instance, the "Regulations on Ethical Review of Biomedical Research Involving Human Subjects" has been promulgated and implemented since December 1, 2016 by the National Health and Family Planning Commission (NHFPC), which provides basic principles for ethical review on human samples stored in biobanks [37]. Moreover, biobanks and ethics committees need more publicity. Even in European Union, most Europeans haven't heard of their nation's repositories of human blood and tissue samples [38]. However, currently there is little study on public awareness of biobanks in China. The managers of biobanks and medical ethics committees should make the general public aware of what's a biobank, what a biobank can provide and what they can do for a biobank. Public awareness and understanding of biobanks is very helpful not only for biobanks to develop sustainably, but also for ethics committees to resolve the ethical issues.

CONCLUSION

Taken together, to better protect the benefits of participants and promote the sustainable development of biobanks, as well as to improve the biomedical research, the self-education and training of ethics committees must be strengthened in China in current circumstances.

ACKNOWLEDGMENTS

We appreciate the grants from Hubei Province Health and Family Planning Scientific Research Project (No. WJ2017H0002), Wuhan Clinical Cancer Research Center of Urology and Male Reproduction (No. 303-230100055) and Hubei Province Urological Clinical Research Center of Laparoscopy.

DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST

The authors declare no potential conflicts of interest.

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