



Establishing an External Evaluation System of Biobanks in Taiwan.

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Introduction

To understand the risk factors and processes of diseases, many countries have established biobanks. Biobanks collect and store biological samples, demographic data, and experimental data. These data help researchers study epidemiology. In 1999, the Organisation for Economic Co-operation and Development (OECD) suggested that national governments should develop an accreditation system for biobanks to ensure their quality, expertise, and financial stability. The United Kingdom, the United States, and Canada developed their accreditation system, then biobanks joined the system voluntarily.

In Taiwan, the government passed the Human Biobank Management Act in 2010 and the Administrative Regulations on the Establishment of Human Biobanks in 2011. There were 30 biobanks in Taiwan. To promote quality and stability, the Joint Commission of Taiwan (JCT) and the Ministry of Health and Welfare established the first biobank accreditation system in Asia. In the other hand, this accreditation system was comprehensive for all biobanks in Taiwan. Standards were established for standard operational procedures (SOPs), Ethical Governing Committee (EGC) management, biological sample management, information security, participant protection, and published data. This study aim to investigate biobanks in Taiwan to provide a reference on the accreditation system.

Table 1. Characteristics associated with biobank regulation.

	N	%
No.	30	100.00
Established worker training standards		
Yes	28	93.33
No	2	6.67
Time of worker training		
≤3 hours	14	46.67
3-6 hours	7	23.33
>6 hours	9	30.00
Independent spaces with controlled access and data backup mechanisms		
Yes	30	100.00
No	0	0.00
The user password update period did not exceed 6 months		
Yes	28	93.33
No	2	6.67
Video recording storage duration in the security zone		
1 month	8	26.67
2 months	10	33.33
3 months	7	23.33
others	5	16.67

Methods

This was a cross-sectional study conducted in 2017. We surveyed 30 biobanks operating in Taiwan. The content of the questionnaire was based on accreditation standards, including worker training and equipment regulation. The worker training standards were established to ensure biobank workers possessed the necessary knowledge on participant protection and ethical standards. Biobank equipment was regulated to ensure data protection for the biological samples. We collected the number of biological samples and number of applications from 2014 to 2017. These data were used as a reference for biobank establishment.

Results

JCT audited of 30 biobanks in Taiwan (Table 1):

1. Worker training standards: Most biobanks had established worker training standards (N=28, 93.3%). Half of these biobanks regulated 3 hours per year (N=14, 46.7%).
2. Biobank equipment regulation: All 30 biobanks were independent spaces with controlled access and data backup mechanisms (N=30, 100%). The user password update period did not exceed 6 months (N =28, 93.3%). Video storage duration in the security zone was 2 months as much (N=10, 33.3%).

The JCT documented biological samples volume from biobanks from 2014 to 2017, biobanks with more than 5000 biological samples increased from 7 to 10 (23.3% to 33.3%). (Table 2) Additionally, the number of applications increased each year. Biobanks with more than 5 applications increased from 4 to 7 (13.4% to 23.3%). (Table 3)

Table 2. Biological samples volume from biobanks from 2014 to 2017.

Biological samples	2014 N(%)	2015 N(%)	2016 N(%)	2017 N(%)
0	8(26.7%)	5(16.7%)	4(13.3%)	4(13.3%)
1~1000	6(20.0%)	7(23.3%)	6(20.0%)	8(26.7%)
1001~3000	7(23.3%)	7(23.3%)	7(23.3%)	6(20.0%)
3001~5000	2(6.7%)	4(13.3%)	3(10.0%)	2(6.7%)
>5000	7(23.3%)	7(23.3%)	10(33.3%)	10(33.3%)
Total	30(100%)	30(100%)	30(100%)	30(100%)

Table 3. Number of applications from biobanks from 2014 to 2017.

Number of applications	2014 N(%)	2015 N(%)	2016 N(%)	2017 N(%)
0	17(56.7%)	13(43.3%)	13(43.3%)	12(40.0%)
1~5	9(30.0%)	10(33.3%)	10(33.3%)	11(36.7%)
6~10	2(6.7%)	2(6.7%)	1(3.3%)	3(10.0%)
≥11	2(6.7%)	5(16.7%)	6(20.0%)	4(13.3%)
Total	30(100%)	30(100%)	30(100%)	30(100%)

Conclusion

Overall, most biobanks conformed to the accreditation standards for worker training and equipment regulation. However, the implementation of the SOPs should be confirmed. In the future, the JCT will elucidate these standards at a meeting for biobanks. Subsequently, the JCT will conduct annual accreditation and invite surveyors to observe the experience. We expect the operation and quality of application reviews in biobanks to improve. This study found that the number of biological samples increased each year. However, 12 biobanks remained without applications in 2017. Without sufficient samples, the researcher couldn't analyze these data. Therefore, JCT-accredited biobanks should publish data to share their results with researchers. When more research projects apply biobank data, medical research in Taiwan will improve. In the future, we can cooperate with other countries to contribute to the global field of epidemiology.

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