



Establishing a Biobank Using Standardisation

15

Mykola Alekseenko, Christine Mitchell, and Svetlana Gramatiuk

Abstract

Interethnic variations in Ukraine may influence the number of chromosomal aberrations detected and the treatment and pharmacokinetics. Studies of different institutions determine the identification of singular oncological diseases typical for Ukraine. The UAB Central Biobank has medical specialists in the institutions, especially in the Central Data Management Department, the Clinical Trial Services Department and the Research Department, which provides highly operational and continuous research support. A Biobank Steering Committee and Medical Advocate have been appointed to support the collection and practical consumption of biospecimens in a multicentre design.

The UAB has applied the ESBB criterion in the SOPs for tissue storage, tanking and processing from the beginning. In general, the SOPs implemented in the network support these standards with minor modifications. Policy coherence and SOP as progress, speed and protocols brought about concerted collaborations of data protection, database management, data sharing, tissue collection and tanking, ethical considerations, sample accessibility and workshops and training.

Keywords

Establishment of a network · Ukraine Association of Biobank · Management Committee · SOP · ESBB · Standards · Commission Ethical and Bio-Ethical (CEB)

An Example from the Ukrainian Biobank Network

M. Alekseenko · S. Gramatiuk (✉)
Institute of Cellular Biorehabilitation, Kharkiv, Ukraine

C. Mitchell
International Biobanking and Education, Medical University of Graz, Graz, Austria

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99

Interethnic variations in the Ukraine may influence the number of chromosomal aberrations detected and may influence medication and pharmacokinetics. Studies of the Institute of General and Emergency Surgery NAMS of Ukraine and Institute of Medical Radiology of S. P. Grigoriev National Academy of Medical Sciences of Ukraine and the Department of pathophysiology of Kharkiv Medical Academy of Post-graduate Education insinuate that undeniable genetic diseases personate a material physical interest for the Ukraine. These embrace genetic oncology, rheumatologic, metabolic, endocrine, neurological, haematological and ophthalmological circumstances, as well as inherited malformations. The hospitals of the Medical Institute also designated the identification of singular oncological diseases, which are typical for the Ukraine.

It is therefore expected that the sectional biobanks will be authoritative for meditation, anticipation and curing oncological diseases. It is also confirmed that they contribute particularized molecular and pharmacological data for expert research.

A network overarching the 23 medical centre managers becomes the project of the Ukraine Association of Biobank. The Central Biobank (ASK-Health, owning the central storage capacities) of the UAB has medical specialists in institutions especially in the central data administration department, the department of clinical trial services (I–IV phases) and the department of research to offer very operative and continuous research maintenance. The Biobank Management Committee and the medical lawyer were appointed to encourage the collection and the hands-on consumption of biospecimens in a multi-centric construction.

The UAB members are increasing the sample collection as well as the biobank service maintenance. Also, a “platform” for the centralization of efforts in the UAB was installed. This generates an arrangement, which encourages a comprehensive, wide-ranged and mutual research with associated medical institutions and hospitals (see Fig. 15.1).

The network of the UAB is important for the region-specific human oncological diseases. The concept suggestion of biobanks for this specific intention must be implemented since biorepositories store collections of human biospecimens. However, in this case the main value is the associated data. Due to economic difficulties in the Ukraine and the lack of state funding of the UAB, a decision was made to create a single central biobank storage facility for all participants and members.

The beneficial progression of any biobank is reciprocal to the general support of the population and the willingness to voluntarily donate. To note that, while the limited data on the Ukraine’s public opinion regarding biobanking is positive, little is known about potential concerns of the general public, and data derived from other areas may not be applicable to the Ukraine. They indicate that aside from the educated part, most of the population is unfamiliar with concepts related to genetic research (e.g., DNA, genes). This factor may limit the willingness without initiatives designed to educate the public and encourage a participation.

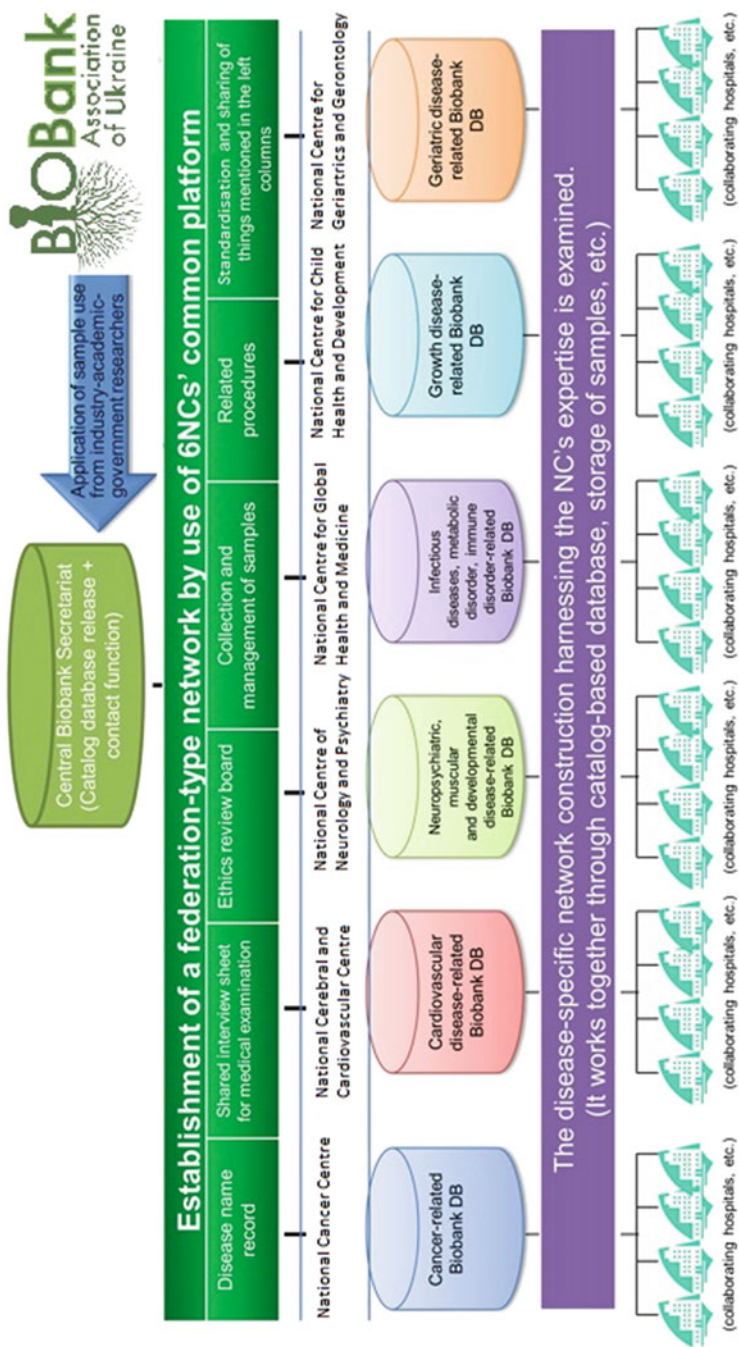


Fig. 15.1 Enterprise of health care improvement for next generation treatment. © Ukraine Association Biobank

Example from UAB

From the beginning, the UAB exercised the ESBB criterion in SOPs to store, tank and handle tissue. The SOPs that were generally exercised across the network are supporting these standards with insignificant modifications. Policy coherence and SOP is a progress, quickness and protocol accomplished harmonious collaborations of workshops and education in data preservation, databank administration, data division, tissue compilation and tankage, ethical considerations, specimen accessibility and quality counteract.

At the outset, it was essential to project an arrangement for the disclosure, revision and approbation of the strategy. It was essential that the policies were conformed with the national and European rules and the directives. It was the first range when the UAB presented the standardization list of the Patients and Volunteers Information Letter (PIL and VIL), the Consent Form Biobank (CFB) and the SAP in the Ukraine. At the beginning, it was difficult to discern the right order of submitting the documents for review in the UAB.

The Irish footpath was recognized as the most qualified one, and it could also be recommended that a similar arrangement of instructions can be adopted for the development and compliance in the Ukraine. First, an agreement with every hospital in the network was needed. Secondly, obtaining a formal legal opinion from an independent medical lawyer after the documents have been reviewed by the Risk and Legal Department at UAB. Thirdly, the Ukraine Association of Biobanks assesses all documentation. Fourthly, the applications to the research and ethics committees of the individual clinics within the biobank network were approved. The fifth step comprised the review of the entire documentation by the data protection commissioner, whereby the commissioner explicitly focused on the proposed method of data sharing (see Fig. 15.2).

During the 5-year period, the National Scientific Centre for Medical and Biotechnical Research has been the central institution for Commission on bioethics at the Cabinet of Ministers of Ukraine (Decision of the Cabinet of Ministers of Ukraine from 13.12.01 № 1677). The latter has encouraged a formation of lawful conditions for linking the Ukraine to the global abridge in bioethics ramification and interconnecting quickness of ethical committees of all kinds in the Ukraine.

In the Ukraine, most Commission Ethical and Bio-ethical (CEB) are under the executive inspection of the Administrative Council of each physical centre. In fact, the course realities of any mind that are persistent and solid direction setters or study exponents and researchers are outlined by elementary groups of study institutions and by the healthcare system.

If one considers, regarding performance, that there are no precise regulations in the Ukraine, which could restrict the establishment and direction of biobanks, one assumes an elementary study plan. The ethical regression of adults is on the scale and is more often left to the concerns of CEBs and their associated institutions. Consent configuration and patient enlightenment pamphlets, which have been projected to beseech some authorizations for biobanking, are particularly modern in the Ukraine.

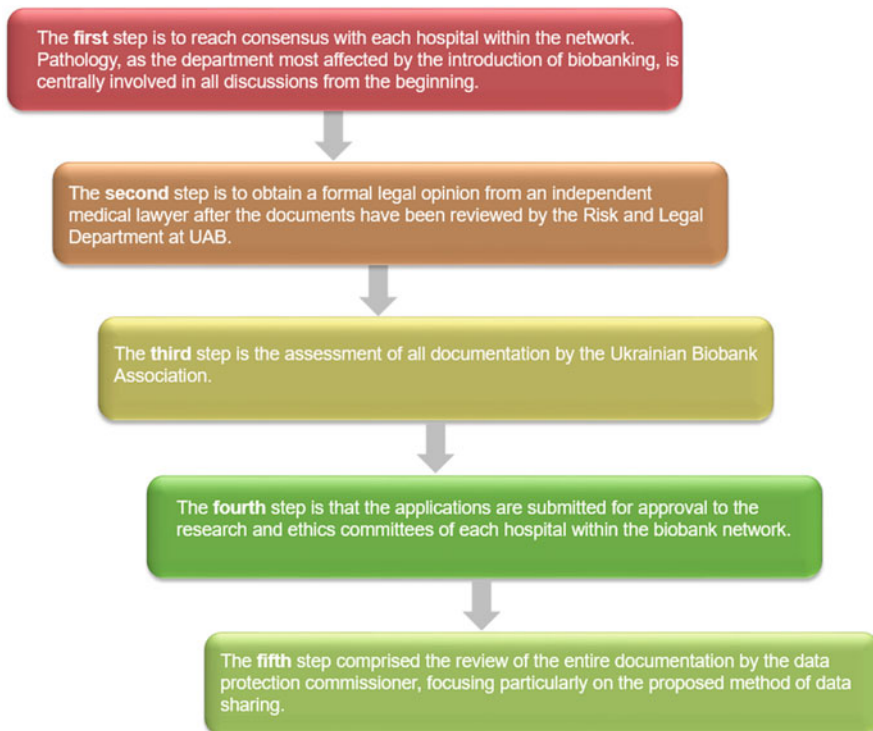


Fig. 15.2 Step-by-step rules on which documents are submitted for consideration in UAB.
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For a long time, the patients implored to present blood and/or tissue for a specific study combination, and advertisement appertain to a discriminating plan was prepared.