Biobanking – The Croatian Experience

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Author : Kate Enright



In a short but informative essay published recently in the Croatian Medical Journal, Borove?ki et al. (2014) offer an overview of the proposed Croatian National Centre for Biobanking.¹ Their paper shows how Croatia, one of the smaller countries within the European Union (EU), could draw together its biobanking institutions under a single organizational entity for managing and dealing with ethical issues, in addition to fostering international collaboration.

In Europe, biobanking is defined as the collection and storage of biosamples alongside their related databases of research data, donor details and other information. Biobanks vary in terms of size and also the method used to collect the biosamples, namely collection for a specific study or sample remaining after diagnostic procedures. They also differ according to their intent—whether the repository focuses on research into a specific disease, for example, or holds population specimens for wider study. Biobanks also include facilities holding samples destined for transplantation, and for clinical blood and allied transfusion needs, as well as those involved in forensic investigations.

European biobanks also use diverse methods to attain donor consent and privacy; there is no standardized consensus. Although some specimen collection requires active opt-outs from the donor, most biobanks use informed consent, often with a multilayered approach to cope with ongoing and novel studies using the samples. Efforts are in progress to implement dynamic consent as biobanking responds to the changes in experimental design and technological innovation in research that enable use of samples beyond the initial study proposal.

Oversight for European biobanks comes from ethics committees based in the respective institutions that deal with issues such as experimental design and sampling, consent and data exchange. Governance occurs at the national level based on country-specific legal frameworks and requirements, with overarching legislation through EU-wide directives and recommendations. These are in addition to standards, quality controls and organizational

incentives administered by various European biobanking networks.

Croatia itself possesses various private and public biobanks, ranging from the Croatian Bone Marrow Donor Registry and cord blood bank/transfusion medicine repositories, to the population-based <u>10,001 Dalmatians Biobank</u>, which collects samples from remote Croatian populations for investigation of complex disease genetics. The country also has forensic DNA laboratories that collate specimens from the 1991–95 war for victim identification.

As of yet, there is no centralized coordination for all biobanking within Croatia. For this reason, Borove?ki and co-authors, all active participants within biobanking organization and research, suggest following a model based on the recommendations proposed for the Polish National DNA bank.² The central organization proposed, the Croatian National Centre for Biobanking, would assume a role overseeing a virtual network of the nation's repositories. The authors propose the organization should draw its management from among representatives of the institutions it represents, thus minimizing costs through use of existing resources.

Borove?ki et al. propose management oversight of the virtual network by two committees, a Scientific Advisory Committee and an Ethics Governance Committee, with overarching administration by a number of government ministries already involved in biobanking regulation.

- The Scientific Advisory Committee would comprise qualified individuals drawn from each member biobank, and from within the national and international biobanking community. This group would oversee quality standards, biosample storage and technology, and research projects.
- The Ethics Governance Committee, composed of experts in law, biobanking and ethics in addition to representatives from the general public, would deal with issues of consent, privacy, donor rights and transparency, among other areas of concern.

The authors advise that a centralized national approach similar to that which they propose could benefit Croatia, promoting trust in biobanking from potential donors in addition to expanding research output and collaboration nationally and across Europe. They assert that the system described would draw on existing resources, thus imposing no additional financial burden.

Borove?ki and co-authors are eager to hear feedback from their peers. They hope that the proposal stimulates discussion within the community and also provides useful information for other small countries embarking on bringing national biobanking repositories under centralized organization.

References

1. Borove?ki, A. et al. (2014) "<u>Croatian National Centre for Biobanking – A new perspective in biobanks governance?</u>" Croatian Medical Journal, 55 (pp.416–22), doi: 10.3325/cmj.2014.55.416.

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2. Sak, J. et al. (2012) "<u>Population biobanking in selected European countries and proposed</u> <u>model for a Polish national DNA bank</u>," Journal of Applied Genetics, 53 (pp.159-65), doi:10.1007/s13353-012-0082-4.