

Methodology

This study was conducted in accordance with the principles of health policy surveillance.¹ On the basis of a literature review related to biobanks, we have carried out a theoretical analysis which was the general foundation for our research. Based on the practice needs and the analysis of the changes in foreign legislation, we developed an analysis grid to cover all types of existing biobanks without being limited to biobanks for research purposes. On the basis of this first analysis grid and the list of questions raised by the Federal Office of Public Health (FOPH), a three-part questionnaire was developed covering (1) the legislative framework and the competent authorities, (2) the protection of participants (*e.g.*, consent, data protection), and (3) issues relating to the establishment, governance, and dissolution of a biobank. This questionnaire was submitted for validation to Swiss experts (representatives of the FOPH and Swiss Biobanking Platform) and European experts (from BBMRI-ERIC) to ensure its compatibility with the practice needs and the current reality of the biobanks in Switzerland and Europe. Moreover, it has been evaluated by experts at the Temple University (Philadelphia, USA) as well as Legal Science, LLC (Philadelphia, USA) to assess its compatibility with the methodological requirements of health policy surveillance.

Seven countries have been selected for analysis of their laws and regulation: Switzerland, the United Kingdom, France, Germany, Belgium, Denmark, and Norway.

A comparative law study *stricto sensu* was carried out by applying a method as defined on the site <http://www.lawatlas.org>. This approach allows public access to all collected data online and facilitates the comparison of the different regulation variants. The collection of answers has been done using a software called MonQcle (<https://monqcle.com/>).

The language of the questionnaire and for the study as a whole is English, with the aim being to enable effective collaboration with experts from the aforementioned European countries. During the review phase of the relevant legislation, the national languages were preferred when it was French, German, or English. When French or German was the national language, the coding in the MonQcle software was done directly in that language. However, given the time and resources available, only the data for Switzerland are presented in French and English.

¹ Burris S, Hitchcock L, Ibrahim JK, M Pennanathan, T. Policy Surveillance: a Vital Public Health Practice Comes of Age. *Journal of Health Politics, Policy & Law*. 2016; 41 (6): 1151-1167. For more details, see also <http://www.phlr.org/theory-methods> (last consultation 29 May 2018).

In January 2018, the questionnaire developed for the study was coded into the MonQcle software. Three datasets have been created; each dataset corresponds to one of the parts of the questionnaire mentioned above.

The collection of the legislation of the selected European countries and answers to the questionnaire was carried out with the support of experts in the field of biobanks in the selected countries. National experts were contacted to ensure the relevance and validity of the data collected and, therefore, to guarantee the high quality of the study. For Switzerland, the tasks of collecting regulations and coding answers in the software were carried out by Vladislava Talanova and Agnès Hertig Pea of the FOPH. These two recordings were compared to obtain a single and complete record. The analysis of the French legislation was carried out in collaboration with Emmanuelle Rial-Sebbag and Gauthier Chassang of the National Institute of Health and Medical Research (INSERM). For Norway, the answers to the questionnaire were collected in collaboration with Øyvind Grønlie Olsen of the National Research Ethics Board (De Nasjonale forskningsetiske komiteer). For Denmark, data collection was performed with the support of Susanne Pihl Jakobsen of the Danish National Committee on Health Research Ethics. We encountered difficulties related to the Danish language and the availability of Danish legislation in English. As a result, the coding was carried out with available English translations, including the general comments of the national expert, to allow an overview of the Danish system. For Belgium, Prof. Myriam Remmelink from CUB ULB Erasme Hospital participated in the study. The data relating to the German system could not be collected and coded in their integrity according to the questionnaire. However, the essential information on the applicable legislation is available thanks to the contribution of Prof. Dr Sebastien Graf von Kielmansegg, Professor of Medical Law at Christian-Albrechts-Universität in Kiel (CAU). Finally, and unfortunately, despite numerous attempts to contact, no expert from the United Kingdom has been able to validate the data relating to the English system.

The data presented covers the laws and regulations that have been applicable along the study, *i.e.* between 1 October 2017 and 28 February 2018. In the future, it will be possible to code (introduce into the monitoring program of these regulations) the previous laws as well as their future revisions, thus allowing a longitudinal analysis. However, for now, the study remains a snapshot of the period studied.