ECONOMICS

Public Biobanks: Calculation and Recovery of Costs

Bruno Clément,[1,2]* Martin Yuille,[3] Kurt Zaltoukal,[4] Heinz-Erich Wichmann,[5] Gabriele Anton,[5] Barbara Parodi,[6] Lukasz Kozera,[7] Christian Bréchot,[8] Paul Hofman,[1,9] Georges Dagher,[1] and the EU-US Expert Group on cost recovery in biobanks[10]

A calculation grid developed by an international expert group was tested across biobanks in six countries to evaluate costs for collections of various types of biospecimens. The assessment yielded a tool for setting specimen-access prices that were transparently related to biobank costs, and the tool was applied across three models of collaborative partnership.

Although infrastructures that collect, process, store, and distribute human biospecimens are working to improve access, no single accepted business model exists that enables long-term operation of biobanks. To address this sustainability problem, an international expert group (table S1) developed a transparent tool that sets actual cost-related prices for access to specimens and data. Here we describe this process and apply the tool to set access prices for a variety of biomedical translation partnerships.

BIOBANK BOTTLENECK

As repositories of biological materials (tissues, cells, and microorganisms) and databases that contain molecular, physiological, and structural information relevant to these collections, biobanks are part of the essential infrastructure for life science research. Indeed, the goal of hospital-based biobanks is to make high-quality biological resources available to academic and industrial (*1*) research settings in accord with international standards that comply with societal values and ethical and regulatory policies. However, academic biomedical research and biotechnology and pharmaceutical research and development all suffer from blocks in access to human biospecimens and their associated data.

National and international initiatives have laid the groundwork for facilitating access to large-scale collections of biological resources. Scientific associations and international organizations have released guidelines for best practices in biobanking and have created bodies to support improved harmonization and to contribute to the building of an international biobank community [see www.oecd.org/health/biotech/38777417.pdf and (*2*)]. Furthermore, the European Union (EU) funded the Biobanking and BioMolecular resources Research Infrastructure (BBMRI) project to acquire the information necessary for the development of a pan-European biobank network (*3*, *4*). The BBMRI project engaged with more than 320 biobanks in EU member and associated states to assemble the European Research Infrastructure Consortium (BBMRI-ERIC; http://bbmri.eu), which is now constructing an EU biobank network. Such initiatives contribute to the provision of infrastructure that can serve current and future biobanking needs.

However, biomedical research, innovation, and translation require this infrastructure to be maintained and improved over many decades. For biobanks to achieve longevity, they must be financially sustainable—a key issue in biomedical translation that has not yet been resolved. It is rare for biobanks to have access to secure long-term funding. Most rely on short-term institutional sources or project-related research income (*5*). Strategies are emerging that seek to recover the costs of data and biospecimen processing and retrieval (*6*). However, anecdotal evidence suggests that these strategies are difficult to deploy so as to ensure long-term sustainability. This situation threatens to waste large public investments in biobank construction and to hinder scientific advances through loss or fragmentation of the biological resources that they manage. Achieving financial sustainability is further complicated by the fact that the operation of a biobank has substantial overhead costs. Moreover, biobanks often rely on voluntary contributions from medical personnel and health care systems, which makes specification of the cost structure of the biobank difficult. This unclear funding system is at odds with the clear need—especially for chronic diseases—to annotate biological resources with outcome information over many years.

BY THE NUMBERS

The selling of human biological specimens for profit does not comply with EU ethical values and legal requirements (*7*). Hence to ensure compliance, it is essential to show that prices for access to resources are transparently related to reasonable costs. Such cost assessment then becomes a tool that provides essential information to donors, patient groups, and the general public about the nonprofit activity of a biobank.

Recognizing that sustained biobanking requires financial sustainability, we assembled a group of biobank experts from the EU and the United States to (i) enumerate the different steps and variables that could be included in cost assessment of biospecimens and annotations; (ii) seek a consensus on a minimal variable set that should be included in such an assessment in the future; and (iii) propose a policy to assess the cost of these various steps and variables.

The expert group identified 46 different biobanking activity tasks and then assigned to each task an indicator of the expertise required (A: high; B: medium; C: low) and an indicator of the duration or complexity of the task (1: <1 hour/low complexity; 2: 1 to 2 hours/medium complexity; 3: >2 hours/high complexity) (cost-estimate pricing tool is described in supplementary methods). Related tasks were grouped together to form five blocks (prebanking data; collection of biological specimens; collection of data related to biological specimens; expertise; and administration and management) (Table 1). This calculation grid (table S2) was then completed by 16 biobanks (11 in France and one in each of the following countries: Austria, Germany, Italy, Poland, and the United Kingdom) for various types of bio-

[1]INSERM, National Biobank Infrastructure, Paris, France. [2]INSERM, CRB-Santé and U-991, Pontchaillou Hospital, Rennes, France. [3]Centre for Integrated Genomic Medical Research, University of Manchester, Manchester, UK. [4]Institute of Pathology, Medical University of Graz, Graz, Austria. [5]Institute of Epidemiology, Helmholtz Center, Munich, Germany. [6]Biobank, IRCCS Azienda Ospedaliera Universitaria San Martino-IST, Genoa, Italy. [7]Biobank, Wroclaw Research Centre, EIT+, Wrocław, Poland. [8]Institut Pasteur, Paris, France. [9]Hospital-Integrated Tumor Biobank, Pasteur Hospital, Nice, France. [10]Members of the EU-US Expert Group on cost recovery in biobanks convened by the BBMRI project (table S1).
*Corresponding author. E-mail: bruno.clement@inserm.fr

Table 1. Tasks in biobanking.
Block 1: Prebanking data
Clinical data from general practice
Questionnaire and survey
Imaging
Histopathology and cytology
Serological tests
Communication, information to donors, and informed consent
Recording, processing, and data management (for example, LIMS)
Storage and updating clinical data
Data release
Monitoring, audit
Others
Block 2: Collection of biological specimens
Collection
Accrual
Processing of samples
Storage
Distribution and transport
Dispatch management
Quality control
Monitoring/audit
Others
Block 3: Collection of data related to biological specimens
Recording, storage, and data management
Data analysis and linking with samples
Quality control and computer-system engineering
Dispatch management
Monitoring, audit
Others
Block 4: Expertise
Project management, advisory, and study design
Recruitment
Data generation
Data analysis and statistics
SOPs and support
Processing
Storage
Quality management, certification and accreditation, audit
Education and training
Communication and public engagement
Others
Block 5: Administration and management
Financial and administrative management
Scientific management and strategy
Loads and running charges
Maintenance of equipment and consumables
Internal R&D
Investments
Ethics and regulatory issues
Partnership development, business development, contracts, networking
Others

Abbreviations: LIMS, Laboratory Information Management System; SOPs, Standard Operating Procedures.

logical resources (tumor tissue, blood, other biological fluids, DNA, fungi, and bacteria).

Analysis of the questionnaires permitted estimates of costs based on expertise, labor time and rates, and biospecimen type (table S3; cost-estimate pricing tool is described in supplementary methods). As expected, cost differences were related to the type of biospecimens collections (for example, tumor blocks, 1500 €, versus DNA from blood, 460 €, in France), the labor cost (for example, blood DNA samples in United Kingdom, 490 €, versus Poland, 239 €), and the complexity of the task (cryopreserved tissue sample, 1639 €, versus formalin-fixed paraffin-embedded tissue sample, 628 €, in Austria). One remarkable finding of this assessment was that the highest fraction of the cost (from 60 to 80%) was attributed to the management and biobanking expertise required to ensure compliance with quality standards, ethical standards, and legal requirements, regardless of the nature of the biological resource. The most important differences arose as a result of the varying range of activities of biobanks; depending on the bank, functions ranged from those that required minimal handling and expertise (for example, storage and distribution) to those that required an extensive set of skilled activities (such as data management, biostatistical analysis, and transformation of derivative products). It is noteworthy that publicly available prices for access to biospecimens in many biobanks are usually calculated based on a partial assessment of the cost to acquire and maintain that resource. However, this pricing approach often omits the most expensive steps of the process: preanalytical biospecimen processing, annotation of biological samples with detailed medical information, biobank management, and skilled expertise.

Our data suggest that biobank financial sustainability is unlikely to be achieved with the use of a cost-recovery policy based on setting prices for users that reflect biobanking costs in full. Biomedical research funders would find the prices unpalatable. Institutions would be under pressure to disclose their detailed financial arrangements so as to justify their prices. Moreover, biobanks would need to raise prices still further to fully include transaction costs (accountancy, debt-chasing, regular analysis of the changing costs of processes) and the costs of ensuring contract compliance. In addition, from our experience, biobank maintenance via cost recovery is hampered by the reality that maintenance costs are continuous,

Table 2. Models for collaboration around biobanking costs.

Model components	Model 1: Full-cost model	Model 2: Partial-cost + fee model	Model 3: Marginal-cost model
Items to which access is provided	Biological samples	Biological samples	Biological samples
	Minimum data set defined by BBMRI	Data set defined by MTA	All data
			Medical and scientific expertise
Material transfer agreement	No restriction on legal use	Restricted to specific project	MTA is part of a collaboration agreement
Intellectual property	Not claimed	User has right of first refusal to IP	IP shared as per collaboration agreement
Publications	Biobank acknowledged	Biobank acknowledged and described in Materials and Methods	Co-authorship + biobank acknowledged and described in Materials and Methods
Costs	Full cost of each sample	Percent of full cost plus a contribution to the biobank	Consumables and handling costs
Example of prices / sample	1000 to 2000 €	200 to 500 €	10 to 100 €

while income is irregular and unpredictable. Although biobanking is fragmented, this problem can only be addressed by raising prices still further.

However, even if full cost recovery is impractical, the pricing tool we describe here may, for now, be useful for evaluating biobank policies aimed at some recovery of costs and in structuring public-public and public-private collaborative partnerships that share project costs (*8*, *9*). The extension and deepening of such partnerships is widely recognized for its importance in improving human health and is one way of strengthening the financial position of biobanks. These partnerships may adopt one of three general cost models [Table 2; described elsewhere in greater detail (*9*)]—full cost (model 1), partial cost plus fee (model 2), and marginal cost (model 3). The models differ in the degree of collaboration between the partners, and this is reflected in differing prices; the table shows the prices we calculated based on our analysis of responses to our calculation grid. Thus, the participation of the biobank must be discussed before contracts between parties are written. This approach may benefit from template licensing agreements in order to avoid any delay in collaborative projects.

Further work is required to define a full solution for the problem of long-term financial sustainability of biobanking. This work should entail investigations into attempted solutions for the problem of long-term financial sustainability of research infrastructure in other areas of the natural sciences. Also needed are studies of the role of biobanking simultaneously for research and for health service delivery in an era of personalized (or stratified) medicine.

SUPPLEMENTARY MATERIALS

www.sciencetranslationalmedicine.org/cgi/content/full/6/261/261fs45/DC1

Supplementary Methods

Table S1. Expert group.

Table S2. Calculation grid for biobanks.

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