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REPORT ON HARMONIZED COST RECOVERY PROCESS

Executive Summary

Despite significant advances in the biobanking field over the last decade, significant issues and limitations remain that are restricting the impact of translational research. The major issues include the need to increase the quality and standardization of biospecimens collected, to enhance accrual capacity in terms of scale and disease representation, and above all, to maintain public trust in these activities. Underlying these issues is the need to ensure sustainability of biobanks. In a first phase we investigated the funding streams of biobanks in Europe, results showed the limited scale, the fragmentation of streams as well as the non-systematic resources dedicated to biobanking.

It has been the expectations that biobanks should be able to conform to business plans of other research technology platforms and that sustainability could be achieved by cost recovery strategies for biological resources retrieval and processing. Thus in a second phase we investigated the real costs of samples and in Europe, which led us to develop a calculation tool for harmonizing the cost access to biological samples. Furthermore, our results show that that financial sustainability of biobanks is unlikely to be achieved solely with a cost-recovery policy.

Since the long-term sustainability of biobanks is a key issue in biomedical and translational research that has not been resolved yet, we examined return-on-investment models for biobanks in more details. Investigations for closely related deliverables 4.2 and 4.3 of the ADOPT BBMRI project. highlighted the fact that it is rare for biobanks to secure long-term funding. We found that most biobanks rely on short-term institutional

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1. Approaches (Methods)

1.1 Harmonised cost recovery process

We examined funding streams for biobanks by carrying out a survey in 23 centers in France and 22 centers in the Netherlands (part of BBMRI preparatory phase). Results from this survey revealed that three funding streams of comparable size contribute to their budget: public funding (32%), funding by research institutions (27%) and funding by research grants (25%). Cost recovery for biological samples contributed just 1% of the budget. Similar trends with mixed funding streams and limited revenues from user fees were reported in biobanks reviewed by a literature review of 109 biobanks and networks of biobanks. More details on ways to implement a harmonized cost recovery strategy in Europe are provided in the next paragraph.

A calculation grid was tested across 16 biobanks (11 in France and one in each of the following countries: Austria, Germany, Italy, Poland, UK) to evaluate costs for collections of various types of biospecimens (tumor tissue, blood, other biological fluids, DNA, fungi and bacteria).

2. Results

Analysis of the data permitted estimates of costs based on expertise, labor time and rates, as well as biospecimen type. 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 interesting 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 processing of biospecimen, annotation of biological samples with detailed medical information, biobank management, and skilled expertise.

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3. Discussion and Conclusions

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, 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 may 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. 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 [see Table 1 below; described elsewhere in greater detail]—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.

Table 1. 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 €

This report on the harmonization of the cost recovery process highlighted the need for examining possible solutions to the issue of long-term sustainability of biobanking.

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