

Sustainability in Biobanking

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TIGHT ECONOMIC REALITIES in clinical and research operations have spurred the need to re-examine financial models that support the infrastructure of biobanking. Finding ways to streamline operations, trim costs, and become more conscious of the carbon footprint of biobank operations has made “sustainability” a well-used buzzword of our time. This motivated us to organize a special symposium on biobanking sustainability at the International Society for Biological and Environmental Repositories’ (ISBER) 2014 Annual Meeting & Exhibits in Orlando, Florida. The topic crosses all of the sectors that ISBER represents, thus, we invited speakers from clinical, research, environmental, private advocacy, and government biobanks. The speakers were asked to focus on financial sustainability, share their specific experiences, and engage the ISBER meeting participants in an interactive discussion on the topic that could also be shared as a special issue on biobanking sustainability in *Biopreservation and Biobanking*. The goal of the symposium was to identify financial sustainability challenges that biobankers are facing in general and in specific sectors, their current solutions, and unanswered questions that may still need to be addressed.

In preparation for the ISBER symposium, we asked ourselves how we define sustainability in biobanking and the reasons why sustainability in biobanking is necessary. Although we focused on financial sustainability as a topic, it is not the only dimension. Two other dimensions of sustainability exist: social and operational (includes environmental). Social sustainability focuses on the acceptability of the biobank and its activities at large by the major stakeholders (e.g., successful involvement of and collaboration with engagement of the patients and donors). Operational sustainability covers different aspects of efficiency such as whether the biobank is managed professionally, its environmental footprint, and also whether the biobank collects the biospecimens and data that the potential end-user will eventually need (fit for purpose).^{1–4}

Repositories of biospecimens together with a limited amount of associated data have existed for many years in the research and pathology communities. However, only in the last two decades has the number of biobanks increased exponentially. Personalized, targeted medical treatment and prevention is leading the explosive growth of biobanks and biobanking initiatives across the world.^{5,6} The acknowledgment of the key component that biospecimens play in clinical medicine and research has also increased the focus on the quality and the types of biospecimens that are collected.^{5,7} With a few ex-

ceptions, most biobanks have been relatively small,^{8,9} storing a few thousands of biospecimens. As in every developing scientific discipline after the initial establishing of smaller entities, economies of scale will push for a consolidation process, e.g., fewer and bigger biobanks and biobank networks¹⁰ to manage the standardization, sharing, and rising costs. Consolidation and centralization does not necessarily imply a single physical biorepository facility but includes the concept of centralized control of the quality standards for collecting, processing, and storing biospecimens and data.¹¹

Modern biobanking is an emerging scientific and operational area and only recently has become “professionalized.”^{12,13} Signs of professionalization of biobanking are the founding of global societies like ISBER and regional societies like the European, Middle Eastern & African Society for Biopreservation and Biobanking (ESBB) or sector-specific societies like Public Population Project in Genomics and Society (P3G). Biobanking and networking initiatives like Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) were started in Europe, Canadian Tumour Repository Network (CRTNet) in Canada, Biorepositories and Biospecimens Research Branch (BBRB) as part of the National Cancer Institute (NCI) in the United States, and Human Heredity and Health in Africa (H3Africa) as a continent-specific activity.^{14–19} These organizations were founded within the last 10 to 15 years. The overarching goals of most of these organizations is the support harmonization of collection, processing, and storage of biospecimens; to create data standards to annotate biospecimens and research results; to create standards to increase the quality of specimens; and increased sharing of collections to better human and global health. The leaders in biobanking initiatives have created different guidelines^{20,21} and best practices^{18,22} to support the community, and these are regularly updated to capture evidence-based standards. Recently, a technical committee has been established to develop an ISO standards for biotechnology including biobanks.²³ The basic needs of biobanking are increasing the operational costs and threaten to outpace the expense of previous forms of “expensive” research infrastructure, such as animal care facilities and optical imaging units.²⁴ Modeling of important considerations for inclusion in a financial management plan of a biobank is being carried out by several of these organizations around the world.^{7,12,17}

Biobanking as a scientific endeavor, as well as biorepositories as explicit clinical infrastructures, undergo a transforming period from an early phase focusing on the

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number of biospecimens to a phase when the quality of the biospecimens and data are acknowledged as important. We refer to these phases as biobanking 1.0 (primary focus on the number of biospecimens and data) and biobanking 2.0 (primary focus on the quality of biospecimens and data).¹ These areas of primary focus in stages 1.0 and 2.0 are predominantly product-oriented areas and require a mostly internal focus on operational development within the biobank. The last stage—biobanking 3.0—is customer focused and sustainability driven. Biobanking activities must be prioritized based on the needs of existing or potential new customers. Typically, the balance of priorities in most institutions has leaned toward what is feasible and currently affordable and not always the ideal for biospecimen quality and long-term sustainability of collections and infrastructure. The crucial step towards biobanking 3.0 is to use the available resources only for activities and products that are requested by and have an added value for the customers. This may also secure long-term sustainability.

Biobanking 3.0 capitalizes on the earlier stages, dictating a shift in focus to enhancing the value and impact for the three major sets of external stakeholders (donors/patients, funders, and research customers) and creating a path to balanced and planned investment in biobank infrastructure and the sustainability of the enterprise of biobanking. The acceleration of new technological advancements in biospecimen science, downstream assays, and biorepository infrastructure will continue to require new investment in processes, methods, tools, and equipment. Larger and more complex data sets and analyses require a focus on new computing methods and mitigation of privacy concerns as datasets are aggregated and made available to many more researchers.²⁵

International ethical, legal, and social awareness of research and clinical medicine and biobanking as a key infrastructure is a volatile and evolving landscape.²⁶ One relatively new societal focus in biobanking is implementation of mechanisms to enhance the enrollment of donors (participants and patients) and providing broader access to their biospecimens. An example that allows direct engagement of all patients attending health facilities is a “permission to contact” platform to enable the consent process for biobanks.²⁷ Another approach is to directly involve the patients in the consenting process for biobanking.²⁸ Within specific advocacy communities, donors can provide their biospecimens to a biobank and determine the inclusion of their samples in particular research studies that partners women and men with researchers to enable research into the causes of specific diseases that are important to these donors. In this way, the donor becomes an active research partner. This not only can increase potential enrollment rates in studies but may also decrease the costs of enrollment and so impact directly and indirectly biobank efficiency and cost control. This approach also strengthens public awareness and acceptability of biobanking and increases use of banked biospecimens.

Awareness and clinical needs of the donors and/or patients are also driving the push to address the return of incidental findings. These social efforts are complex and include planning for additional staffing, infrastructure, and ethical/legal management policies associated with data return. How to interact with donors/patients as well as operational sustainability (how to effectively manage to return these findings to the donors/patients) are widely debated.^{29–32} If the issue of returning incidental findings is not approached appropriately by a biobank/clinical researcher, it could dramatically undermine

the relationship with existing donors and, even more importantly, with potential new donors of biospecimens and data. This could lead to social unsustainability of the biobank and research infrastructure. And by doing so a biobank puts itself at risk of gradually falling below the critical input and use of the collections it stores, leading to the potential of failure to effectively operate the biobank. This lack of trust could lead to operational unsustainability.

If a biobank fails to stay technologically relevant with the purchase and maintenance of equipment and updated processes, as well as the use of the latest evidence-based guidelines, biospecimen quality at the biobank could be questioned and the collections could go unused. This is another issue that may lead to operational unsustainability. Each evolutionary change in biobanking operational practices requires a re-analysis of the biobank’s financial plan and its resulting sustainability or not.

Acquiring the funds to support the creation or maintenance of a biobank in today’s economic environment necessitates the development of a detailed business plan with market research of need, clear intake and usage targets, rational growth, customer identification, and financial strategy.²⁴ Only approximately one third of existing biobanks were started with a business plan in place.⁹ not to mention a biobank strategy that is based on market research and surveys, specified targets for intake, consideration of data on trends in biospecimen use, and plans to obtain customer satisfaction information. A biobank business plan should include understanding the biospecimen needs of the potential customers, marketing strategies to grow the target customer base, and a specific plan for product offering, if those are applicable outside of providing biospecimens and the appropriate data. The plan will include vital information and will be the backbone to allow a biobank to focus its resources and to rationally expand or develop additional services. For example, a biobank may grow to provide consultation services to researchers and clinical trial groups (e.g., on collection design, selection of the appropriate biospecimens, regulatory requirements for biomarker research), to expand its customer base to other sectors; to lease storage capacity to outside research groups or institutions; and to provide emergency backup support for other biobanks. All growth should be rationally based on the needs of identified customers from market research.

An important strategic element related to the development and monitoring of a business plan is determining and measuring common internal and external performance metrics to inform any change decisions by both the biobank leadership and infrastructure funders. Biobank leadership must determine an appropriate internal balance between elements such as the size and number of existing collections of biospecimens, amount of data collected or created about the specimens and returned research results from customers, and patient outcome data (if applicable), appropriate culling of biospecimens, its capability to attract new collections to store (inputs), and the outflow of biospecimens transferred for use. Funders of biobank infrastructure need to be constantly updated and educated about the status of the biobank since its operational needs are complex and dynamic. In addition, the same funders may not only support the biobank infrastructure but also the researchers who are collecting and using the biospecimens, data, and other services from the supported biobank. The available funding may have to be balanced between the research projects that provide for the

collection of new specimens and the development and sustained maintenance of the biobank for the current and future studies using the specimens.

Depending on the biobank type, especially if the business model is dependent on outside customer use of collections, the rate of requests/outflow may be dependent on the perceived “value” of the samples to attract requesters/customers of the biospecimens. If this is the case, then the biobank leadership must focus on specifically planning for the type, quality, and need for the specimens being collected for use. If the collections are stored from specific scientific studies, this balancing of need is not as crucial, unless there is a plan to market the collections for ancillary use after the scientific studies are complete. Outflow partly depends on building a “stock” that is of value as well as marketing the available collections. Several initiatives to provide aggregators of biospecimens available for different diseases are gaining momentum.^{33–37} Measures of future-use biobank value are generally related to the requests/outflow, quality, and the research impact in translating science into clinical use, rather than the collection size in storage at the biobank.³⁸ Managing the biospecimens and data being collected and stored will also optimize the workload and cost of every step in the biobanking process. An important approach to creating value metrics for biobanks is to implement certification and accreditation processes³⁹ that provide standards to achieve and external assurance that the biobank has quality harmonized practices in place, including reportable metrics.⁴⁰ Quality specimens and confidence from the user community is relevant information to funders to support their investments. Documentation of processes for biospecimen collection and management also play an important role in establishing a high value of the biobank and its collections as well as gaining public trust of the resource.^{41–43}

The researcher-customer comprises the third group of external major stakeholders. Researchers’ current requirements should define focus and extent of accrual, processing, and annotation, and their future needs and demands should define the scale of storage. Some quantitative and qualitative data in these areas is available. Examples are the trends in the average number of biospecimens of different formats needed for publications or the applications for these biospecimens and their products.^{9,44,45} It should become standard and part of every material transfer agreement for all research users to assume the responsibility of reporting back the results produced to the biobank (at least in general terms, including quality assessments, amalgamated data, and publication outputs), while using biospecimens and data received from a biobank. The sharing between biobanks of experience with repeated contacts with researchers is one possibility to develop an in-depth knowledge about the biobanking market and the requirements of its different research stakeholders. But requirements are partly driven by the specific questions and available levels of funding that dictate scale of cohorts that can be assessed, and also by pragmatic factors such as requirements set by a journal.^{46–49}

The development and gradual adoption of guidelines on data that should accompany research articles describing findings based on patient cohorts (e.g., REMARK)⁵⁰ and their biospecimens (e.g., BRISQ)⁴¹ creates a new driver for what data annotation is important to researchers.^{48,51} Proof of the professionalism of the biobank through accreditation and certification processes may also become a required component in higher impact journals. At the same time, if

biobanks can respond by collating and providing these kinds of data to researchers in an efficient format then it becomes a new product valued by its customers.

To gauge the audience at the ISBER sustainability symposium, we asked each person to answer a few simple questions. The answers were designed to help the speakers understand the viewpoints of the audience and allow for some inferences when the question and answer period was opened. Of the participants, 52% of the audience were representing hospital-integrated biobanks, 26% were focused on disease-based/project-based biobanks, 11% were population-based banks, and 4% were representing commercial operations. It was interesting to note that 7% of the audience noted that they were representing future-use focused banks.

The majority of the biobanks had been in operation for 5 to over 10 years. The primary support for the represented biobanks was nearly evenly divided among grant support, public (government), and private funding at nearly 30% each. Only 10% of the banks were primarily commercially supported. Seventeen percent of the banks reported no funding issues at the current time, whereas the majority had less than 5 years of funding support currently identified. Very few of the banks did not attempt to recover any costs for their operations and when possible the vast majority of the biobanks would charge their commercial customers more than their academic customers (66%) while the remaining 30% would just recover their expenses. The varied financial plans and views provided a lively discussion at the 2014 ISBER meeting and highlighted the opportunity for several different models of sustainability based on the goals of the biobank. It was clear that there was also a strong feeling from many of the participants that financial sustainability was not achievable on a cost recovery basis and that institutional support of their biobank would always be necessary.

Given the differences in perspectives from the session participants and the speakers, you will see in the accompanying articles in this issue and in the December issue of *Biopreservation and Biobanking* different financial models at work in each of the biobanks being highlighted. The topic was also the focus of several posters presented at the ISBER Annual Meeting and, we invited each of these authors to contribute their unique views on financial sustainability for this issue.

Schacter et al., “Funding Sources for Canadian Biorepositories: The Role of User Fees and Strategies to Help Fill the Gap,” focuses on the results of two surveys conducted by the CTRNet on how the role of funding from various sources, including user fees, now contribute to their biobanks’ ability to create financial sustainability. Based on the results, CTRNet have created a tool set to support their business modeling of costs to better understand and attract the necessary funding for long-term support.

Wilson et al., “The Challenge of Sustaining a Hospital-Based Biobank and Core Molecular Laboratory: The Beaumont Experience,” acknowledges that like many biobanks, sustainability and commercialization were not considered during the initial growth and development of the Beaumont biobank business model. Their article describes the period after the initial startup grant funding, when the bank undertook process improvements and defined business modeling, enhancing services and accreditation to expand the value proposition to attract new customers to provide financial sustainability.

In Thomson and Matharoo-Ball, “Nottingham Health Science Biobank: A Sustainable Bioresource,” an overview

of the Nottingham Health Science Biobank (NHSB) that was established in 2011 with a three-year startup grant is presented. Through systematic business modeling, it has gained a stable financial status after the initial grant was expended.

In Bromley, "Financial Stability in Biobanking: Unique Challenges for Disease-Focused Foundations and Patient Advocacy Organizations," the motivation to create registries and biobanks by disease-focused foundations and patient advocacy organization to support biomedical research is reviewed. These biobanks are supported by many different funding models, and the review discusses the unique challenges of sponsoring sustainable biobanks.

Albert et al., "Biobank Bootstrapping: Is Biobank Sustainability Possible Through Cost Recovery?," present an evaluation of the financial sustainability of three mature Canadian cancer biobanks based on their original business plans for cost recovery. The factors that affect the ability to self-sustain are discussed.

In Carpenter, "Sustainability: Australian Breast Cancer Tissue Bank (ABCTB)," the uncertainty of long-term funding of the biobanking infrastructure in Australia with the specific example of the ABCTB is discussed. Seeking alternate customer sectors to enhance their funding streams to the biobank is a key future direction.

In Parry-Jones, "Reviewing Biobank Structure for Sustainability: The Wales Cancer Bank Case Study," highlights the Wales Cancer Bank's (WCB) review, at the biobanks' 10-year anniversary, of its strategic principles and operating procedures using sustainability as evaluation criteria. The WCB recommends that all biobanks put in place this type of review to evaluate thoroughly all three sustainability pillars.

In Riegman, "From AAA+ to BB- and on the Way Back Again," the impact of changing resource funding from a new health-care cost recovery system in The Netherlands on the financial sustainability of the Erasmus MC Tissue Bank is discussed. Several possible models toward sustainability are presented.

Warth et al., "Which Business Model for Biobanks," focuses on the business models for financial support of biobanks in Switzerland through the Foundation Biobank-Suisse (BBS). Based on the overall financial insecurity of the biobanks in Switzerland, they propose financial viability through receiving a per capita supplement to the biobank system from the Swiss health-care system participants.

In Wiles, "Implementation of an Error-Reporting Module within a Biorepository IT application to Enhance Operations," the CHTN Western Division at Vanderbilt University Medical Center (CHTN-WD) process to clearly define and align activities with business strategy and priorities to increase the sustainability of the biobank are discussed. Their team identifies operational inefficiencies that they address by redesigning workflows and innovating the processes using IT solutions.

Biobanking has finally attained recognition as a key infrastructure for scientific research and clinical care. The articles in this issue and in December's issue highlight various states of biobank financial sustainability and whether, within their sectors or within their model, it is desirable or even attainable. The overarching take-away message on the difficulties in attaining financial sustainability in our sector is that the biobanks must think "professionally" from the 1.0 start to be able to attain financial

sustainability and maintain it. Rethinking how biobank planning is orchestrated and bringing seasoned business expertise as well as the scientific and operational expertise to support that planning and implementation of new facilities will support the professionalization of our biobanks. Just as we plan a biospecimen collection with the "end in mind," we need to plan for financially sustainable biobanking from the beginning of the planning process to create a biobank. As our biobanks mature from stage 1.0 to 3.0, continual business "checkups" should be scheduled, so that the models continue to evolve with the financial and scientific times.

We hope you enjoy reading these perspectives, learn from the experiences of these biobankers, and hope that you will consider presenting your own experiences at the next ISBER Annual Meeting & Exhibits in Phoenix, Arizona, from May 5 to 9, 2015.

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