Advancing Professionalization of Biobank Business Operations: Performance and Utilization

Marianne K. Henderson,¹ Kirstin Goldring,² and Daniel Simeon-Dubach³

Biobanks are now in the spotlight as key enablers supporting preclinical, clinical, and environmental research. Awareness of their value has increased along with the need for these infrastructures to be sustained through business-focused practices. Following our 2017 pilot survey on biobank business planning, we initiated a more comprehensive 38-question multiple-language worldwide survey on biobank sustainability. Two hundred seventy-six biobanks of various sizes and stages of business planning (in place, in progress or none) responded. About two-thirds were established in the last 10 years. Survey results confirm our hypothesis that biobanks with business plans or preparing such plans are trending toward more professional structures. Specific survey data focusing on performance metrics and utilization, as related to sustainability, are presented. Biobanks most frequently measured basic performance metrics (sample utilization, samples collected, samples distributed, internal projects supported). Metrics less often reported included sample and data quality, cost recovery, citations, and publications, typically correlating with higher levels of biobank complexity and professionalism. Biobanks reported supporting projects for both internal and external use, with support of projects within their own organizations as the main driver of biobanks, independent of business plan status. Having a business plan seemed to be a key factor for biobanks that had developed sustained support for external commercial projects. While under half of the biobanks reported both target and actual utilization rates, the responses provided valuable data on utilization. Target utilization rates were much higher (2.5 to 5 times higher) than the rate of actual use. Many of the biobanks report less than 10% utilization. Biobanks with low utilization rates make sustainability a very distant and likely unreachable goal. Our survey has provided some basic data about biobank business planning globally. Continued research should be done, with the data and information shared within the community for the good of all biobank stakeholders.

Keywords: business planning, performance metrics, utilization, sustainability, biobanking

Introduction

BIOBANKS ARE KEY INFRASTRUCTURES that support a wide range of research endeavors. As a result, over recent years biobanks have been increasingly considering strategies to ensure their long-term sustainability and success, and more examples of this are emerging and being shared.^{1–7} We have previously highlighted that the business planning required for an underlying strategy toward the goal of sustainability is not a “one size fits all model,” because of the huge variability in biobank type, purpose, and operational models. Each biobank can consider examples shared by others, to look at the key pillars of sustainability—

operational, financial, and social, to support their own business planning.^{7,8} While examples of business planning are becoming available, there have been relatively few studies or data collected on the level of business planning^{9–12} in biobanks globally. In particular, there is little information on the success of business planning in terms of performance indicators and increased utilization.

A business plan helps a biobank analyze and assess current activity and future development opportunities for their operations. The business plan outlines the objectives of a biobank and describes in detail the measures taken to achieve them. Thus, business planning provides a basis for a biobank to do an in-depth analysis of its goals, the needs of

¹National Cancer Institute, National Institutes of Health (NIH), Bethesda, Maryland.

²Sample Management, Discovery Science, IMED Biotech Unit, AstraZeneca, Cambridge, United Kingdom.

³Medservice, Biobanking Consulting & Services, Walchwil, Switzerland.

its stakeholders, and its organizational support. Ideally, this should be done as an initial step before creating an operational structure. A quality business plan begins with a thorough SWOT (Strengths, Weaknesses, Opportunities, Threats), risk and market analysis as the backbone of the planning process. Without planning, a biobank may end up creating an expensive infrastructure that may not meet the needs of stakeholders and/or fail to gain stakeholders and operationally collapse. Being unsustainable financially, operationally, and socially is a potential mistake of failing to plan.

Early in 2017, we published the results of a pilot survey focused on the awareness and level of business planning in biobanks, which included the participants of the sustainability symposium at the 2016 Annual Meeting of the International Society of Biological and Environmental Repositories (ISBER) held in Berlin, Germany.⁹ While the survey, delivered through a smart phone application, gave us some clues to the level of business planning and that biobanks are starting to implement such practices, the participation was small and may not represent the whole community. Hence, we acknowledged that the results and any interpretation had its limitations. To achieve a greater sample size and to ensure better representation of the global community, we decided to extend the scope of the survey and do more extensive sampling of biobanks worldwide. Recently, we reported these initial findings,¹³ looking at sustainability and business planning in research biobanks in terms of how that related to advanced professionalization of biobank business operations. We reported that organizations that support biobanks have increasingly recognized the need to professionalize their management, staffing, and operations, particularly those with large collections and a drive to work with industry. However, biobanks are still in the early “wave” of becoming professionalized, as a notable proportion are in the process of developing their business plans and there seems to be a need for greater consideration of appropriate marketing of biobank resources.

This article focuses on the status and effectiveness of biobank business planning related to key performance metrics, with a particular focus on sample utilization targets and real use. It has become clear that there is not a singular interpretation of how utilization is defined and measured across all biobanks. The introduction to the survey included our definitions for “research biobank” and the distinction of “biospecimen, sample, aliquot,” in an attempt to standardize the understanding of these terms in the responses on levels of utilization (Supplementary Appendix A1). We report metrics being established within the reported biobank business plans and further expand on data on global utilization rates.

Methods

In the second quarter of 2017, we released an extended survey that focused on questions about biobanks and business practices in biobanks globally. To receive responses from the biobankers around the world, the survey was created and coded into the Survey Monkey online tool (www.surveymonkey.com). Our plan to reach biobankers in many areas of the world included translating the survey into Spanish, German, French, and Chinese. The survey was originally coded in English in April 2017 and included 38 questions (Supplementary Appendix A1). The questions

were sent in an Excel file to biobank experts in France, Spain, and Germany to translate the questions into their native languages. Once it was translated, the translations were coded into Survey Monkey and the link to the survey was sent back for a final confirmation to the experts and alternates to make sure the translations, as coded, were completely understandable. For the Chinese survey, we sent the 38 questions to a biobank expert in China to translate the survey and to put it within a tool that could be used to easily reach biobankers in China.

The survey was initiated in English, German, Spanish, and French in late June 2017 and stayed open until January 2018, allowing time for the Chinese survey to be initiated and closed at the same time as the other version. The English, German, Spanish, and French versions were advertised with three major campaigns by the authors and several organizations in the biobanking sector (ISBER, European, Middle East & Africa Society for Biopreservation & Biobanking [ESBB], the Club 3C-R [France], Biobanking and Biomolecular Resource Research Infrastructure [BBMRI] country nodes, and various connections throughout the community). The majority of the responses from the English, Spanish, and German surveys were received in July 2017. The bulk of the responses to the French survey were received in September 2017. The Chinese survey was coded in local software and opened across China. Subsequently, the raw data were translated and delivered back to the authors. The raw data from the other translations were downloaded from Survey Monkey in three data sets and then all data were combined to complete the analyses. A descriptive analysis of the data was performed using Microsoft Access 2013. The survey results focused on the status of business planning were analyzed and submitted for publication as the main analysis.¹³ The current analysis extends the business operations planning by reviewing and interpreting the results of the questions on performance metrics and utilization, as they relate to sustainability. As is customary with these types of surveys, the data reported by the participants were assumed to be given. A monitoring and data cleaning usually does not occur. This, in turn, severely restricts the possibilities of statistical analysis, as the individual groups have an unbalanced number of records.

Results

A total of 276 biobanks participated (China 65, France 40, USA 34, Spain 27, Germany 24, rest of the world 86). More than half of the biobanks (51.4%) were academic biobanks, 21.7% hospital-based biobanks, and 8.7% governmental biobanks. Over one-quarter (28.3%) had a business plan (BP+), 27.2% had a business plan in progress (BP-IP), and 42.8% had no business plan (BP-); 1.8% gave no answer to this question. There was no apparent correlation with the size of the biobanks and their business plan status.

About one-quarter of biobanks did not reply to the question of whether their biobank is assessed against annual performance measures (BP +14.1%, BP-IP 21.3%, and BP- 27.1%). Of those that replied, 59.4% said yes, 27.4% no, and 13.2% did not know. More BP+, BP-IP biobanks measured their performance (71.6%, 67.8%) than BP- (44.2%). In general, in BP-IP, the full array of annual performance metrics is more frequently used than in the two other groups (Table 1). Participating biobanks were then

TABLE 1. PERFORMANCE METRICS USED BY BIOBANKS, ACCORDING TO BUSINESS PLANNING STAGE (RESPONDERS ONLY)

	BP+		BP-IP		BP-	
	N	%	N	%	N	%
% answering yes	48	71.6	40	67.8	38	44.2
Cost recovery	17	35.4	14	35.0	6	15.8
Sample utilization	39	81.3	33	82.5	29	76.3
Samples collected	38	79.2	33	82.5	31	81.6
Samples sent out	35	72.9	32	80.0	34	89.5
Sample quality	25	52.1	28	70.0	22	57.9
Data quality	19	39.6	22	55.0	16	42.1
Internal project supported	29	60.4	35	87.5	26	68.4
External project supported	30	62.5	26	65.0	20	52.6
Reference of resource	24	50.0	24	60.0	24	63.2
Publications	26	54.2	24	60.0	21	55.3

BP, business plan; BP-IP, business plan in progress.

asked to provide information about 10 specific performance metrics (cost recovery, sample utilization, samples collected, samples distributed, sample quality, data quality, number of internal projects supported, number of external projects supported, citations of the biobank, and publications) (Table 1). Those that answered in the affirmative noted that their assessments of annual performance metrics most often included four items (sample utilization 81.0%, samples collected 81.7%, samples distributed 81.0%, and internal projects supported 71.4%). The metrics least frequently mentioned were data quality (45.2%) and cost recovery (29.4%). Cost recovery was more frequently mentioned in BP+ and BP-IP (35.4%, 35.0%) than BP- (15.8%).

Two hundred nineteen (79.3%) biobanks responded that they supported a total number of 10,882 projects, with 18.9% for own use, 42.9% within own organization, 31.1% for external, noncommercial use, and 7.1% for external commercial use (Table 2). There was a wide range in the number of active projects supported by the responding biobanks, with 17.1% of biobanks that reported between 80 and 1000 projects. The median was 20 active projects and mean was 50.5. External projects were supported by about one-third of BP+ (21.9% external, noncommercial; 12.8% external, commercial), one-quarter BP-IP (17.2% external, noncommercial; 8.5% external, commercial), and nearly half (43.1%) of BP- (40.9% external, noncommercial; 2.2% external, commercial).

Nearly half of the respondents (41%; 114/276) reported both their actual, and their target utilization rate for their collections. The biobanks that responded tended to have

target utilization rates that were much higher than the rate of actual use (Table 3). There is a higher actual utilization rate of samples in those biobanks that have business plans. Overall, the rates of utilization of the responding biobanks are very low, with the majority of the biobanks reporting less than 10% utilization (Table 4). Biobanks with business plans (BP+) has a higher utilization rate of $\leq 20\%$ (30.4%), than BP-IP (25.0%) or BP- (13.1%). Smaller biobanks (≤ 5000 samples) had a higher utilization rate (mean 25.7%, median 11%) than larger ones: 5001–50,000 (19.0%/10%), 50,001–200,000 (11.2%, 5%), and $>200,000$ (13.2%, 5%). Approximately 60% (59.8%) of academic biobanks had a utilization rate $\leq 10\%$, whereas 82.4% of the hospital-based biobanks had a utilization rate $\leq 10\%$. Fifty-nine percent (58.8%) of government biobanks reported a utilization rate $\leq 10\%$, although the absolute number of government biobanks was very small and limited further interpretation ($n=17$).

Discussion

In our survey, we asked the participants whether they had business plans in place or whether they were in progress in putting business plans in place.¹⁰ In our earlier article, we focused on the results of business planning processes by age, size, and type of biobank. We also analyzed stakeholder engagement and marketing processes of the biobanks. Just over half of the biobanks are operating with business plans or are in the process of putting a plan in place. The awareness and trend toward professionalizing biobanking through business processes has clearly taken a strong hold, but it is still in its infancy.

Although we focused on business plan status, we do not have any detailed indication on the completeness and complexity of the content nor on the comparability of the business plans that are in place or in progress. We do know that the existence of a business plan does not mean that all performance metrics included in the plans are similar or in equal number. The SWOT, risk and market analyses help indicate which performance metrics should be incorporated and measured in a plan. As a first-of-its-kind survey, we focused our efforts to gather basic business planning information from the respondents. Future examination of specific business plan details should result in recommendations of planning best practices for biobanks. Gaining business acumen is a key toward professionalizing and the evidence shows that more organizations are providing more attention toward gaining that knowledge within their organization and biobank staff.

The survey asked whether these biobanks had set performance metrics in place to measure their progress toward their

TABLE 2. NUMBER AND PERCENTAGE (%) OF PROJECTS SUPPORTED BY THE BIOBANKS ACCORDING TO STAKEHOLDER CATEGORY AND BUSINESS PLAN STATUS (MEDIAN 20, MEAN 50.5, RANGE 1–1000 PER BIOBANK)

	BP+		BP-IP		BP-	
	n=69/88.5%		n=58/77.3%		n=92/78.0%	
Total no. of projects supported by category of BP	4127		1471		5458	
Own use	694	16.8%	316	20.2%	1081	19.6%
Within own organization	2001	48.5%	844	54.1%	2055	37.3%
External, noncommercial	903	21.9%	269	17.2%	2256	40.9%
External commercial	529	12.8%	132	8.5%	123	2.2%

TABLE 3. ACTUAL UTILIZATION RATE (%) VERSUS TARGET UTILIZATION RATE (%) OF BIOBANK COLLECTIONS ACCORDING TO BUSINESS PLAN STATUS (RESPONDERS ONLY)

	<i>Average actual annual sample utilization rate (%)</i>	<i>Target annual sample utilization rate (%)</i>
BP+/N = 46		
Mean	21.2	54.5
Median	10.0	50.0
BP-IP/N = 24		
Mean	16.0	40.8
Median	10.0	30.5
BP-/N = 44		
Mean	18.4	39.7
Median	10.0	30.0

goals and whether they were meeting those goals, especially for utilization. Goal setting and creating S.M.A.R.T. (Specific, Measurable, Achievable, Relevant, and Time bound) processes to measure and evaluate the stated goals is a key component within business plans. Based on the overall stage of business planning in biobanks, it was somewhat expected that there would be a portion of the survey responses that did not answer the questions on metrics enforcement. It could be interpreted that these null responses were from a proportion of biobanks that do not have business acumen at the time of the survey or that the respondents do not know what biobank performance metrics can mean in action. This interpretation of business acumen status in the biobanks was further supported by the proportion of responses that “didn’t know” whether their biobanks had metrics in place, though this may reflect that respondents completing the survey are not involved in these activities for the biobank. It is apparent that implementing business training for the biobank management and potentially other staff, or pairing the organization’s business office with the biobank, is an important step toward professionalized biobanking.

The performance metrics that were most often reported by the respondents are those that focus on movement of samples into and out of the biobank and tracking of sample use for projects internal to the organizations. These are the most basic of resource utilization performance measurements. Those metrics that were less often reported (sample and data quality, cost recovery citations, and publications)

are ones that correlate with higher levels of biobank complexity and of biobank professionalism. A focus on quality is highly cost relevant, in terms of investing in processes that can track and maintain quality parameters of the biospecimens in storage. We recognize that some biobanks do not have full overall control of all activities associated with biospecimens and data stored in their facilities, thus, leading to the absence of certain metrics in their business plans. For example, if the collection processes are occurring outside of the biobank’s hands, metrics for collection will not be in a biobank’s business plan.

Creating and employing a cost recovery mechanism illustrates a focus on financial sustainability. Cost recovery is often employed to recoup operational costs that are not being funded centrally and/or possibly for diversification of revenue. The emphasis on collating citations resulting from biospecimen use or publishing by the biobank staff, are most often seen in academic organizations to advertise the value they provide to their communities. We strongly believe that all biobanks can increase the value proposition of their collections and/or services by collecting the citations and more importantly the data that have resulted from the use of their resources. Biobanks may take the additional step of validating the data being returned, but there will be operational and financial considerations within the business model to conduct this task. Highly valued collections and biobank services can attract future investments and additional stakeholders/users.

The responding biobanks that either have a business plan in place or one in development (BP+ and BP-IP) tend to be more recently established facilities and resources (BP+: 1970–2017; median 2005/BP-IP: 1972–2017; median 2011/BP–: 1957–2017; median 2008). The BP+ and BP-IP biobanks have a higher percentage of implementation of all of the performance metrics we queried. It is likely that their completed or ongoing business planning is resulting in more active engagement to establish metrics that are useful in gauging biobank performance. Measuring and adjusting operations to optimize performance in these areas should enable a greater probability of long-term sustainability of the biobank.

When we focused on those responses, where the metric questions were answered, it was heartening to see that even without a business plan (BP–), most of these biobanks are recording basic performance metrics for their operations. It would be interesting to know what percent of these biobanks use these measures to proactively support *ad hoc* business planning at their facilities. These metrics were more often than not measured annually and analyzed. The recording of

TABLE 4. REPORTED PERCENTAGE (%) UTILIZATION OF SAMPLES BASED ON THEIR BUSINESS PLAN STATUS GROUPS (RESPONDERS ONLY)

% Annual utilization rate	BP+			BP-IP			BP–		
	N	%	% Cum	N	%	% Cum	N	%	% Cum
0–5	21	30.4	30.4	21	37.5	37.5	39	46.4	46.4
6–10	17	24.6	55.1	12	21.4	58.9	20	23.8	70.2
11–20	10	14.5	69.6	9	16.1	75.0	14	16.7	86.9
21–30	6	8.7	78.3	5	8.9	83.9	1	1.2	88.1
>30	15	21.7	100	9	16.1	100	10	11.9	100

Results are presented as the number of biobanks reporting the specific range of % annual utilization rate, the % of biobanks in the group reporting the specific range of % annual utilization rate, and the cumulative percentage (% cum) of biobanks for each group, additive from lowest to highest % annual utilization rate range.

inputs and project withdraws may be active business tracking or could be the byproducts of their inventory system activity.

It is not surprising to note that the support of projects within their own organizations seems to be the main driver of all biobanks, independent of the status of having a business plan. However, we were surprised to see the high percentage of external, noncommercial projects supported by biobanks without a business plan. Perhaps this reflects the fact that the biobanks without business plans were established earlier and may have a greater focus on long-standing academic collaborations. Based on the data we collected, it seems that having a business plan is a key factor for biobanks wishing to develop sustained external commercial projects. Industry use of collections for commercial projects often requires additional ethical and legal transfer considerations that must be incorporated within a sound business plan and the resultant biobank operations.

We did find that the definition of utilization likely differs across different biobanks. We believe that utilization should be measured based on the highest number of samples (aliquots and/or portions of a parent specimen) in the biobank and not based on the number of parent samples as the denominator of the calculation of rate. This would standardize the utilization definition based on the “unit” that is most often distributed.

About three-quarters of the participating biobanks reported on their average annual utilization/distribution rate. In general, the reported actual utilization rate was very low. In more than half of the biobanks, utilization rate was reported to be 10% or lower. Those biobanks with business plans or plans in progress were more likely to have set a measurable target for utilization, than those biobanks without a business plan. Unfortunately, the target rates for most of the biobanks were wildly overestimated, when compared to their reported actual annual utilization rates of samples (2.5 to 5 times higher target than actual utilization rate). Low utilization rates are the key issue that the biobanking community must move to solve soon.

Underutilization is an issue that involves all three dimensions of sustainability. Based on a sound biobank business plan, a clear strategy can be defined to identify the likely end users for the samples and data (operational dimension of sustainability). With the understanding of the potential market, more samples may be distributed and potentially more revenue may be generated (financial dimension of sustainability). But the most important dimension impacted by (under-)utilization is social sustainability. Even if a biobank has the best operational infrastructure in place and secure long-term funding, underutilization breaks the trust between the scientists/biobanks and the donors. It is our opinion that patients and participants may stop consenting and sharing their precious samples and data for scientific discovery if they understand that their samples and data continue to sit unused in “biovaults.”

It is imperative that the research community examines the type of biospecimen collection models that are currently employed for different types of studies, so that we as a biobank community can address the over-collection and underutilization of biospecimens around the world. A clear understanding of market and stakeholder needs, as part of business planning, should precede any new collection. Increased local and global sharing of previously collected quality specimens should be encouraged. Governance and

access policies for current biobanks should be examined to ease restrictions on sharing, as much as possible. The collection of “convenience” or “discard” biospecimens should be drastically limited, unless users or sponsors are identified in advance. Perhaps a shift to focus on “just in time” requests for research specimens of common disease types and limiting over-collection (i.e., volume) should be encouraged. Continuing to collect biospecimens without stakeholder and market need is financially unsustainable and socially reckless. Biobanks with low utilization rates make sustainability a very distant and likely an unreachable goal.

The aim of our survey was to reveal quantitative answers on biobank business planning for the first time. We now have some of the basic data for this field. We plan to continue this research into biobank business plans by seeking to gain access to several of the business plans from the respondents. The goals are to view the details of their plans and analyze the general comparability of elements within them. Our analysis of plans would allow for more insight into biobank business planning across the globe with potential recommendations of a basic framework for biobank business plans for those biobanks that may not have one in place. Of course, there may be some biobanks that do not have a compelling need for a business plan, based on their organizational requirements and support. Further examination of specific business operations and plans will be important to gain more insight into the progress of biobank professionalization.

Guidance like the recently published 4th edition ISBER Best Practice¹⁴ and the emerging ISO biobanking standards¹⁵ will help reinforce the progress toward professionalization of global biobanking. The information based on our existing quantitative, and hopefully, future qualitative survey on global biobank business planning will be integrated into the next update of these guidance documents to further support the worldwide biobanking community at large in moving toward sustainability and increased utilization, for the good of all stakeholders involved.

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Supplementary Material

Supplementary Appendix A1

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Address correspondence to:
Marianne K. Henderson, MS, CPC
National Cancer Institute
National Institutes of Health (NIH)
9609 Medical Center Drive, SG 7E590
Rockville, MD 20850-9777

E-mail: hendersm@mail.nih.gov