BIOPRESERVATION AND BIOBANKING
Volume 13, Number 6, 2015

DOI: 10.1089/bio.2015.0089

The Biobank Economic Modeling Tool (BEMT): Online Financial Planning to Facilitate Biobank Sustainability

Hana Odeh,[1,2] Lisa Miranda,[3] Abhi Rao,[1] Jim Vaught,[1,4] Howard Greenman,[5] Jeffrey McLean,[6] Daniel Reed,[7] Sarfraz Memon,[1] Benjamin Fombonne,[1,2] Ping Guan,[1] and Helen M. Moore[1]

Background: Biospecimens are essential resources for advancing basic and translational research. However, there are little data available regarding the costs associated with operating a biobank, and few resources to enable their long-term sustainability. To support the research community in this effort, the National Institutes of Health, National Cancer Institute's Biorepositories and Biospecimen Research Branch has developed the Biobank Economic Modeling Tool (BEMT). The tool is accessible at http://biospecimens.cancer.gov/resources/bemt.asp.
Methods: To obtain market-based cost information and to inform the development of the tool, a survey was designed and sent to 423 biobank managers and directors across the world. The survey contained questions regarding infrastructure investments, salary costs, funding options, types of biospecimen resources and services offered, as well as biospecimen pricing and service-related costs.
Results: A total of 106 responses were received. The data were anonymized, aggregated, and used to create a comprehensive database of cost and pricing information that was integrated into the web-based tool, the BEMT. The BEMT was built to allow the user to input cost and pricing data through a seven-step process to build a cost profile for their biobank, define direct and indirect costs, determine cost recovery fees, perform financial forecasting, and query the anonymized survey data from comparable biobanks.
Conclusion: A survey was conducted to obtain a greater understanding of the costs involved in operating a biobank. The anonymized survey data was then used to develop the BEMT, a cost modeling tool for biobanks. Users of the tool will be able to create a cost profile for their biobanks' specimens, products and services, establish pricing, and allocate costs for biospecimens based on percent cost recovered, and perform project-specific cost analyses and financial forecasting.

Introduction

Biospecimens are an essential prerequisite for medical research including precision medicine approaches that can predict patient response to targeted therapies and disease outcomes based on the assessment of biological molecules (DNA, RNA, and proteins) in patient biospecimens.[1] Given the growing demand for high-quality biospecimens and associated annotation, biobanks face an abundance of economic challenges that can affect their ability to provide biospecimens and services in a sustainable manner.

Operational economic challenges are many and include: acquisition of funding for start-up operations, maintenance and growth; ability to finance implementation and auditing of best practices, regulatory and accreditation standards; managing the costs of under-utilized inventory; and balancing effective operations while demonstrating a return on investment.[2–5] In addition, many biobanks have difficulty determining the total cost of their biobanking operations, allocating costs to specimens, and determining equitable cost recovery user fees that align with the market and reflect the true cost of banking and storing individual samples.[6] As a result, implementing cost recovery-based business models

[1]National Cancer Institute, Biorepositories and Biospecimen Research Branch (BBRB), Bethesda, Maryland.
[2]Kelly Government Solutions, Rockville, Maryland.
[3]Biobusiness Consulting Inc., Newburyport, Massachusetts.
[4]Gray Sourcing, San Diego, California.
[5]Provia Laboratories LLC, Littleton, Massachusetts.
[6]Leidos Biomedical Research, Inc., Rockville, Maryland.
[7]Wrycan Inc., Cambridge, Massachusetts.

remains one of the most common operational challenges that thousands of biobanks face worldwide.[7]

Lack of sustainable biobank operations compounds the risk to return on investment and too often increases the cost of clinical and scientific research collaborations.[8] There is very little published information about the costs involved in operating and maintaining a biobank, from the collection, processing, and storage process through to the distribution of specimens and products. The limited published data tend to be highly variable and specific to the type of biobank. For example, start-up costs for an academic core bioresource facility have been reported to vary from $3- to $6 M USD based on level of infrastructure[8] and degree of sampling. Start-up costs for population-based biobanks are reported to range between $2.5 and $212 M.[9]

Details on infrastructure costs for a variety of different settings (e.g., pharmaceutical sample management facilities and commercial biobanks) and financial contexts (e.g., initiation, expansion, or closure) are not well known. A full understanding of the total cost of supporting all phases of biobanking is fundamental to enabling sustainable operations.

Uncertainty in funding is a prevalent issue for biobanking, since many biobanks do not have reliable established revenue and instead depend on short-term funding to offset their expenses. Implementation of cost recovery models has long been recommended as a best practice to augment and diversify funding support.[10,11] However, as awareness has increased around the total lifecycle cost of biobanking [5] and concern about, and competition for, funding increases,[12] the adoption of cost recovery practices has now become a bottom-line necessity to sustain viability. In one study,[12] 90.9% of biobankers surveyed reported the adequacy of funding to be a concern and 40.5% of those considered it to be a major concern.

Following substantial start-up investments, many biobanks are expected to implement cost recovery to become self-reliant, often within as short a period as 3 years.[13] It is unknown to what degree costs are recovered or how many biobanks successfully recover all their costs. To date, few documented cost recovery models exist to advise biobankers in calculating and allocating costs or addressing subtleties in costing to enable long-term sustainability.[6] It can be especially challenging to calculate direct costs provided by employees who work peripheral to the biobank but provide indispensable expertise and support (e.g., pathologists, quality managers, clinical research coordinators, research nurses) and indirect costs associated with those entering and querying data and maintaining biospecimen databases (e.g., data managers, information technologists).[14]

To support the research community in this effort, the National Cancer Institute (NCI) Biorepositories and Biospecimen Research Branch (BBRB) has developed the Biobank Economic Modeling Tool (BEMT), a web-based application, to enable accurate cost recovery fee determination and to provide a greater understanding of the economic considerations involved in long-range financial planning and sustainability.

Methods

Development and implementation of the BEMT Survey

Survey development and content. In an effort to learn more about the economic considerations of biobanking and to acquire peer-based cost and pricing data to inform the design of BEMT, a comprehensive biobank market survey was conducted. The survey contained 35 questions (Supplementary Table 1; supplementary material is available online at www.liebertpub.com/bio) divided into four sections: biobank demographics, cost recovery and funding, cost and pricing, and specimens, products and services. The survey was approved by the White House Office of Management and Budget (OMB) and executed using SurveyMonkey® (www.surveymonkey.com).

Selection and sampling of survey participants. A target list of 423 biobank managers and directors was created that represented biobanks from across six geographic regions and five key sectors of the biobank community to favor a wide geographic representation and survey data relevancy. The total number of survey participants was determined by the OMB's burden guidelines, factoring the requisite number of responses to achieve statistical significance. The expected response rate was 20%–25%.

Survey participants within each geographic region included biobanks from each of the following key sectors: academic medical centers, community based hospitals, independent research laboratories, commercial entities (which included pharmaceutical and biotech companies) and government programs. Invited participants had experience working in a human specimen biobank for at least 3 or more years. Participant contact information was confirmed through public sources (e.g., biobank websites, LinkedIn) with a minority obtained from internal contact lists.

Survey execution. An invitation to participate in the BEMT survey was distributed to the survey participants via e-mail. The e-mail included an invitation letter along with a link to the SurveyMonkey® survey. Participants clicked on the link provided in the email, reviewed OMB burden statements, and proceeded with the survey. Respondents were able to save and exit the survey as often as needed and were allowed 6–8 weeks to complete their submission. Follow-up efforts included email reminders every two weeks.

Survey data management and quality review. Upon receipt of their survey, all respondents were assigned a numeric ID. Survey responses from individual biobanks were received throughout the 6–8-week survey period. Data underwent a standard quality review. Participants were contacted briefly by phone or e-mail as needed, to obtain feedback from respondents regarding the partially completed surveys and to verify they were submitted as the respondent had intended. Survey responses were taken as self-reported. The resulting data from the respondents was anonymized and used to develop a comprehensive database.

Development and deployment of the BEMT web-based software application

NCI/BBRB worked with a team of contractors and consultants to develop the BEMT web-based application. The team included experts in biobank economics, cost recovery, biobank management, and agile software methodologies.

Approach to software development. The BEMT user interface was developed using an agile software development methodology, where software releases were iterative and incremental in nature. At each stage of development, the software was reviewed by internal subject matter experts. Prior to launch, the web-based application was shared internally with

seven individuals within the NCI and two externally to obtain feedback on the use of the application and essential functionalities. Feedback received from this review informed the development of additional functionalities to improve the utility of the tool.

Software architecture and platform details. The BEMT software architecture was built using the open source Grails web application (Grails Project, Venice, CA) and runs in the open source Apache Tomcat™ application server (Apache Software Foundation, Forest Hills, MD). The technology stack comprises the Grails framework including Groovy (Grails Project, Venice, CA) for scripting and Hibernate (Red Hat, Raleigh, NC) for object relational mapping. The stack runs on top of a Java Virtual Machine platform. Oracle (Oracle Corporation, Redwood City, CA) is used as the backend database server.

Software deployment and URL. The BEMT is hosted at the Frederick National Laboratory for Cancer Research (FNLCR) using existing NCI computing resources including its Oracle and VMware® infrastructure. The web-based application is available to the public at http://biospecimens.cancer.gov/resourcesbemt.asp.

Results

BEMT Survey results

Demographics of survey respondents. A total of 106 responses were received for the BEMT survey, which represents a 25% survey response rate. Of the 106 survey responses received, 57 were complete and 49 were partially completed. Although the partially completed surveys varied slightly in the portions that were completed, most of the partially completed surveys were missing approximately 40% of the answers. These respondents typically completed the first two sections (i.e., biobank demographics, cost recovery, and funding) of the four section survey and partially completed the last two sections (i.e., cost and pricing, and specimens, products and services) of the survey as these sections required significant input of data on behalf of the respondent. Feedback from the respondents who did not complete the survey indicated that they did not have the time to complete the survey within the allotted time due to competing responsibilities at their biobank or did not have access to the information required to address the survey.

The majority of the survey responses were from North America (49%) and Europe (34%) with the remaining surveys from Australia and New Zealand, Asia, Middle East, South America and Africa (Table 1). Approximately 25% of these respondents operated biobanks that were 4 years old or less, while a majority of the biobanks (75%) were older than 4 years old (data not shown). The biobanks ranged in years of operation from newly initiated to 61 years old.

The respondent's organizational demographics (data not shown) indicate that the largest percentage of respondents were from biobanks in academic medical centers (69%), community based hospitals (12%), and independent research laboratories (7%). The smallest numbers of respondents were from commercial entities (6%) and government programs (6%). When respondents were asked about their biobank's organizational model (data not shown), a majority of the biobanks indicated that their biobank had centralized operations (65%), 14% were part of a network of biobanks (i.e., several physical repositories), 13% operated independently, and 8% were identified as federated biobanks (i.e., a network of decentralized biobanks).

Source of funds. Biobank respondents were asked to define their estimated distribution of funding sources annually (Fig. 1A). The top three sources of funding were fees recovered from biobank operations, government/non-profit grants, and internal start-up funds. Funding from donations and private grants were reported as smaller sources of funding. One biobank self-reported investing their personal monies.

Biobank spending (start-up and operating expenditures). Biobank spending was evaluated based on start-up and operating expenditures (data not shown). To aid ease of reporting, start-up expenditure categories were divided into four categories: initial equipment purchases, space planning/construction, inventory management and computers, and other. Survey respondents reported that the greatest start-up expenditures (52%) were for purchasing or leasing equipment in the first year of operation, followed by space planning and/or construction costs (35%). Inventory management costs were reported to be 11% of the start-up budget with 2% reported as other.

Operating expenditures for year two and beyond were divided into the following six categories: employee payroll, consumables, vendors and consultants, additional equipment purchases, equipment maintenance and replacement, and other. Employee payroll was the largest operating expenditure at 59%. Expenditures for laboratory supplies (i.e., consumables) were 15% and the remaining ''other'' costs were 13% of the total operating costs for the biobanks surveyed. Smaller expenditures included, costs for vendors and consultants at 5%, while additional equipment and equipment maintenance each represented 4% of the total operating expenditure.

Activity. In order to understand how labor efforts are divided at the managerial level, biobank managers and directors were surveyed as to how much of their time is spent on the following biobank-related activities (Fig. 1B):

Table 1. Demographics of BEMT Survey Respondents

Regions	*Percent (%) distribution*	*Sampling size (*N*)*	*Number of respondents*
North America	49.7	189	61
Europe	34	144	27
South America	1.7	7	3
Australia and New Zealand	5	21	5
Asia	5	21	5
Middle East	3.5	15	4
Africa	1.2	5	1
TOTALS	100%	423	106

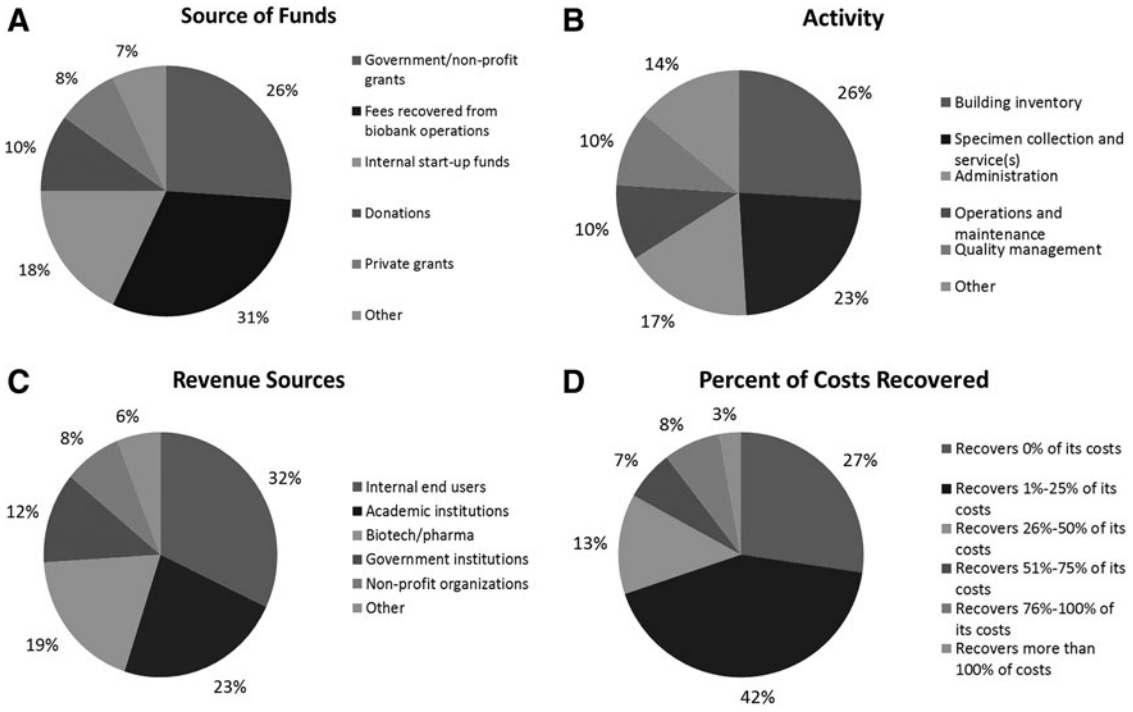

FIG. 1. Results reported by the respondents of the BEMT survey. The survey was designed to gain a greater understanding of the economic considerations involved in initiating, operating, and maintaining a human biobank. **(A)** Percent distribution of funding sources brought in annually. **(B)** Percent of time respondents spend performing biobank related activities. **(C)** Percent of revenue sources obtained annually for the respondent's biobank operation. **(D)** Percent of respondents practicing cost recovery and reported costs recovered.

building their biobank inventory (specimens and data); specimen collection and service provision; administrative time; facility operations and maintenance; quality management and proficiency testing; and other. The respondents indicated that nearly half of their management time was spent on building their biobank inventory and providing specimens and services. Respondents also indicated that 17% of their time was spent performing administrative tasks, with less than a quarter of their time spent on facility operations, maintenance, and quality management.

Revenue. Respondents were also surveyed as to the source of their revenue annually for their biobank operations (Fig. 1C). More than 70% of the revenue was from internal end users, other academic institutions, and biotech/pharmaceutical companies. However, significantly less revenue was obtained from government institutions and non-profit organizations.

Percent of costs recovered. To assess the use of cost recovery, the survey asked respondents to self-identify as actively recovering or not recovering costs for their biobank. A majority of the respondents (72%) reported that they practice some form of cost recovery while 28% practice no cost recovery at all (data not shown). In addition, the survey asked respondents to estimate their degree of costs recovered. Notably, 27% of respondents reported that they recover none of their costs (Fig. 1D). Approximately 42% of respondents recover 1%–25% of costs, while the remaining respondents recover more than 25% of costs.

BEMT overview

Integration of the anonymized survey data and iterative software development resulted in the creation of the BEMT to support cost recovery and financial planning for biobanks. The tool is composed of four distinct modules: My Biobank; My Specimens, Products and Services; My Projects; and My Forecast. Each of these modules represents specific steps towards developing an accurate cost model, including defining labor, equipment and supplies, products and services, and project-related costs. The BEMT workflow (Fig. 2) was designed to progress in a stepwise fashion to facilitate cost recovery modeling relevant to the user's biobank requirements. Outputs of the BEMT include the following: labor, equipment and laboratory supply lists; specimen, product and service cost lists; project quotes; 3-year financial forecasts; and survey data.

The BEMT tool can be accessed online using a user-generated login ID and password. To compare and contrast multiple plans for a user's biobank, the home page can be accessed at any time while using the BEMT. The homepage also hosts a help guide, system previews (e.g., screenshots), and a glossary of terms used throughout the BEMT. User data that is entered into the BEMT is specific to that user, is login and password protected, and will not be utilized by NCI in data analysis.

Key BEMT features

Key features of the BEMT include a biobank template, biobank dashboard, market data summary and query tool, cost recovery calculator, user fee schedules, and financial forecast snapshot.

Biobank template. A key feature of the BEMT is the ''template biobank,'' a sample data set of costs and pricing information that can be used to create a biobank profile.

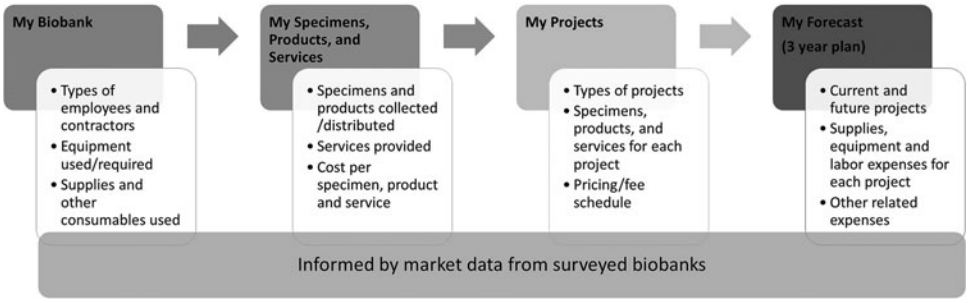

FIG. 2. BEMT workflow schematic: Four modules that comprise the BEMT and the stepwise considerations associated with each module.

The template was created as a result of user feedback to facilitate quick use of the tool. The template biobank is a data set that contains cost or pricing information for a variety of supplies, equipment, and labor categories that were informed by the cost and pricing data from the market-based anonymized survey data.

The template data set is not a comprehensive data set of costs or pricing data, but instead contains a representative selection of cost data that can be used, expanded, or edited when using the tool. The user can elect to use the template data to test out the tool and determine its utility quickly and efficiently by using the pre-loaded data and going through the stepwise process to determine unit costs and percent cost recovery without first having to input cost data. The template data can be edited and/or modified to more appropriately reflect the cost and pricing associated with the user's biobank. If the user prefers to enter data at any time that is unique to their biobank, the user can add, subtract, or modify labor, supplies and equipment cost, and additional direct/indirect costs.

Biobank dashboard. Multiple biobank profiles can be created using the BEMT in which each ''biobank'' created will have a complete economic model that can be used to compare and contrast with other biobank profiles created (Fig. 3). The homepage on the BEMT contains a table or dashboard that lists the biobank models that have been created. Only one biobank can be accessed, reviewed, and/or edited at one time.

Market data. At any point while using the BEMT, the anonymized survey data from individual biobanks can be reviewed using the search tool option. The anonymized survey data provides users with information about what other biobanks with similar characteristics (e.g., size, location, type) have reported. The data are searchable by institution type, country of origin, years of operation, and whether cost recovery is practiced. Users can browse the search results for information regarding costs, labor categories, types of equipment and prices, and products and services offered by other biobanks (Fig. 4), and can import data into their own cost model using the copy tool. Browsing the anonymized survey data provides an opportunity for BEMT users to query the BEMT survey data regarding equipment costs, number of pieces of equipment, types of labor, typical prices for specific biospecimens, types of products and services, and typical volumes associated for a specific type of biobank in a specific geographical location and year of operation from the biobanks surveyed.

Cost recovery calculator. The cost recovery calculator feature is designed to automatically calculate the percent of costs recovered for specific biospecimens and their associated services. This feature is intended to provide guidance as needed in determining percent cost recovery by allocating costs involved in collecting, processing, storing, and distributing the specimen.

User fee schedule. The My Project module can be used to create cost recovery fee schedules for their biobank and any biospecimen-based projects that they support. This feature is useful after the user has loaded the Template Data or has

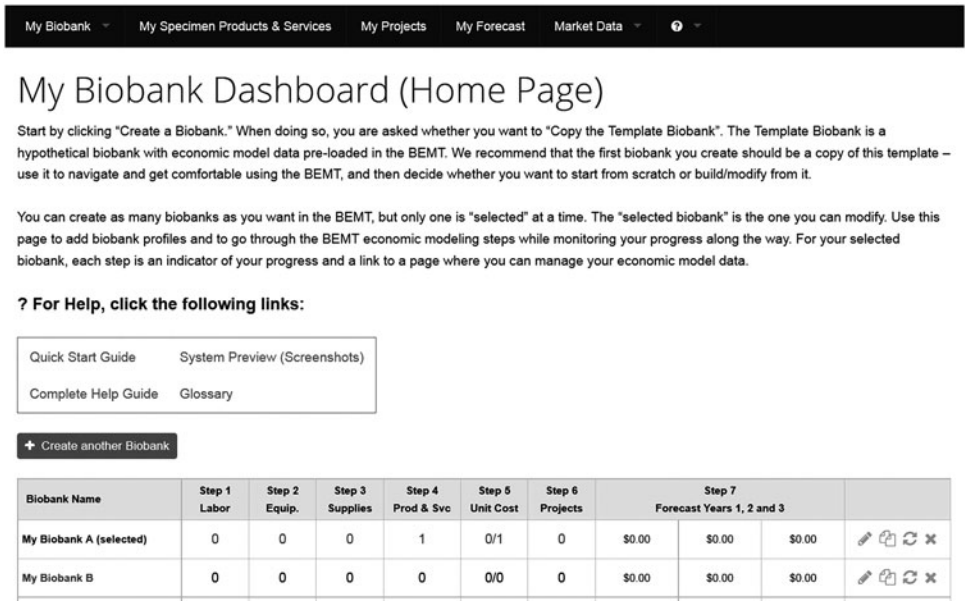

FIG. 3. The Biobank Dashboard provides an at-a-glance view of the biobank profiles created in the BEMT system. The screenshot depicts two different biobanks that the user has created and operates. The user can then proceed to enter specific data for each category shown.

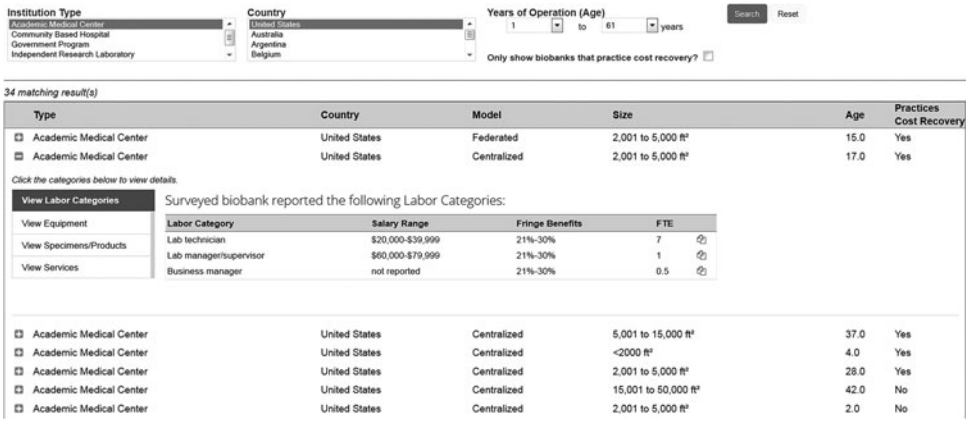

FIG. 4. Market data query tool. BEMT users can query and browse the anonymized survey data by institution type, country, and years of operation.

performed their own custom unit costing for specimens, products and services. The user fee schedule is intended to offer documentation to support service provision, customer quotes and marketing and promotional activities.

Financial forecast ''snap shots''. An ability to create and save ''snap shots'' of financial forecasts for each project that the biobank supports can be performed using My Financial Forecast. This feature is intended to help biobankers with revenue predictions to support budgetary and long-term financial planning for their biobank and projects they support. The forecast can be used as a reference document for annual reports and funding applications.

Custom data entry for individual biobanks

The first module, My Biobank (steps 1–3), requires the user to enter information into a master list for each of the three categories using drop-down lists and ''save and add another'' options regarding allocation of labor (e.g., pathologists, histotechnologists), equipment purchased or leased (e.g., cryostat, freezers), and supplies utilized (e.g., gloves, slides). Inputs regarding specific labor categories, base salaries, and a fringe benefits rate are added to the labor master list in the labor category (Fig. 5). The labor master list will be used to assess total labor costs, project specific labor costs and labor costs associated with specific products and services.

Input data regarding the purchase or lease price of equipment, service contract price, lease duration, annual billable hours and usable life can be added in the equipment master list in the equipment category. Creating an equipment master list will assist the user in determining total equipment costs, planning for project equipment costs, and allocating the cost of equipment used in products and services offered by the biobank. The supplies category is designed to enter biobank supplies that are utilized when collecting, handling and processing biospecimens. The supplies master list will aid the user in allocating the cost of these supplies to products and services that are collected and distributed.

My Specimens/Products/Services. The My Specimens, Products, and Services module (step 4) is designed to allow the user to define the type of specimens, products and services offered by their biobank (Fig. 6). This module facilitates the calculation of the unit costs associated with collecting the specimen and/or providing an associated service (step 5) by using the unit cost calculator. After the biobank's specimens, products, and services and associated unit costs are defined, the user can then add projects and project-related labor, as well as equipment and supplies required for completion of the planned project(s) to calculate the total cost for each project in the My Projects category (step 6).

My Projects. My Projects is designed to define projects that include specimens, products, or services offered by the

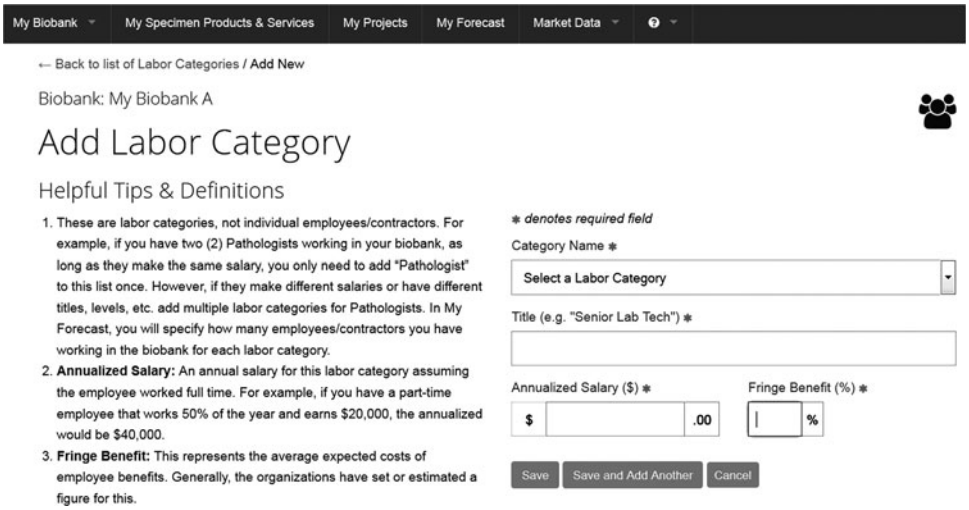

FIG. 5. My Biobank Labor (module 1). BEMT users can enter specific data for labor categories, their associated salaries, and fringe benefits in the MyBiobank Labor module.

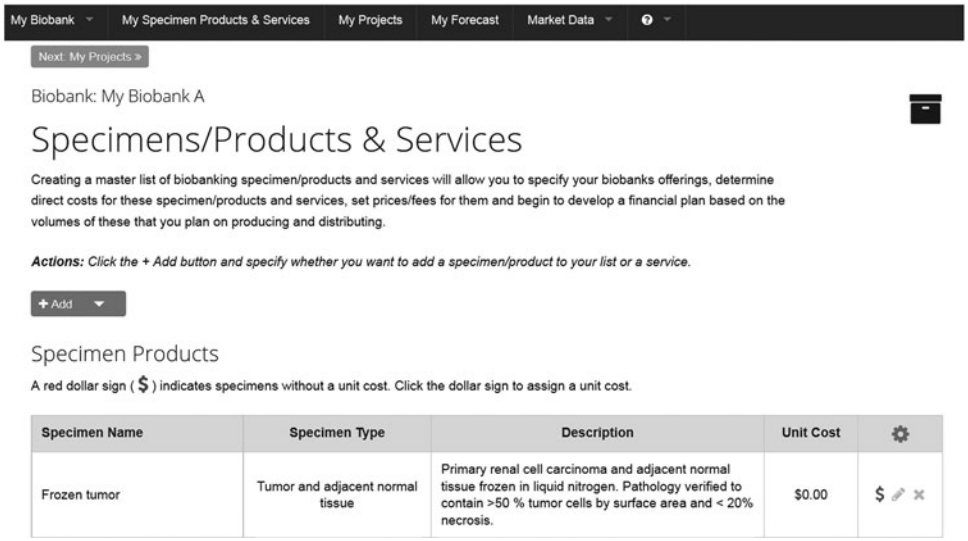

FIG. 6. My Biobank Specimens, Products and Services (module 2). Users of the BEMT can enter specific data related to the biospecimens, products, and services the user's biobank offers. In this example, the user has entered data related to a specific biospecimen type. The user can go on to enter specific cost information to build a cost profile and define unit costs to guide cost recovery decisions.

biobank at a specified quantity and a cost recovery fee (or price) based on the cost of a single product or service offered. In this module, users can review projects, add new ones, remove completed projects, and set fees or prices for each specimen, product, or service utilized in the project. Following the completion of My Projects, the BEMT user can develop custom fee schedules and project forecasts.

My Forecast. My Forecast (step #7) allows an individual to add projects to the forecast, specify the quantity of specimens or services, and calculate the anticipated price and cost increases over 3 years. The forecast will also determine net loss and profit associated with cost-recovery from specimens, products, and services distributed. Specifying the unit costs for each single product and/or service offered will automatically complete portions of the forecast.

Discussion

Historically, many human research biobanks were smaller biorepositories located in hospitals and academic medical centers supported by departmental funding mechanisms.[15] Many biobanks today primarily function as ''fee for service'' core facilities offering a variety of specialized services and managing collections of biospecimens ranging in the thousands to millions of samples and are located in hospitals, academic centers, institutions, corporate entities, and government agencies.[15–17] Start-up costs for biobanks can require millions of dollars up front to purchase equipment and supplies, build or buy informatics systems, and provide salaries for trained personnel and health care professionals.[5]

The challenge for many of these biobanks is that dedicated long-term funding is often not available, leaving biobanks largely dependent on the flow of short-term grant funding, institutional sponsorship, philanthropic donations, and/or the influx of project-related capital to fund operational costs for their biobank.[18] Conversely, in order to fulfill the increasing demands for biospecimens for basic and translational research, biobanks typically spend years accruing, managing, and storing specific biospecimen types and associated data and must remain viable for decades to come during the accrual process.[6] Traditional models of biobank funding become more challenging to secure in tight economic conditions. Sound business models that include cost-reimbursement strategies, such as the implementation of cost recovery fees, have been proven to increase resources for ongoing operations and decrease reliance on public funding.[5]

The BEMT is designed to provide a greater understanding of the costs involved in biobanking and increase the transparency of market data related to cost and pricing. It is especially important for biobanks to be transparent in regards to calculating user fees and to ensure that the fees applied reflects the total costs associated with the services utilized in collecting, handling and processing biospecimens (e.g., processing, pathological review, annotation, storage, and distribution).

Transparency in user fee assessment can illustrate to the users of the biobank and potential funding sources what the true costs are for the biospecimens collected and anticipated project related expenditures. Such assessments are often incomplete and omit some of the costly labor and materials involved with collection of biospecimens and associated data.[6] The BEMT is designed to address these issues and help the user account for the total cost of biobanking.

Project-based cost recovery can be a significant source of funding. Once costs are calculated, the BEMT can be used to generate a forecast to anticipate revenue for each project for up to three years. An important consideration in achieving a financially sustainable biobank in the long term is the development of a strategic business plan.[5,19] The plan can highlight the efforts taken on by the biobank to remain financially sustainable, including the percentage of funding from a variety of different funding sources and cost recovery user fees. Cost recovery user fees can provide revenue to sustain variable costs associated with collecting, processing and distributing biospecimens, to supplement multi-year funding for start-up operations and incurred fixed costs (e.g., biobank personnel, infrastructure costs).[19]

Cost and outcomes data in biobanking are often lacking, and cost recovery user fees can provide an invaluable metric by which the products and services offered by the biobank can be accurately and effectively measured.[5] It is important to note that the recognition and understanding of the true cost and value of a biobank's resources is essential information for investigators, funders (i.e., from government,

institutional, commercial and private charitable organizations), and patient groups in the context of securing long-term sustainable funding support.

Relevance of findings. The purpose of the BEMT survey was to gain a greater understanding of the economic considerations involved in initiating, operating, and maintaining a biobank, and to inform the design of the BEMT. The findings of this survey provide significant insight into the economic activities of biobanks, particularly for sources of funds and revenue, biobank spending and operating expenditures, allocation of management activities, and percent of costs recovered. Data from the survey indicate that fees recovered from biobank operations represented the greatest source of funding for the biobanks surveyed, followed by government/non-profit grants and start-up funds (Fig. 1A). Based on the responses collected in the survey data, a variety of funding sources are brought in to fund biobank operations.

In a previous study, six biobanks that comprise the Canadian Tumor Repository Network (CTRNet) biorepository nodes were similarly asked to report the relative contribution of financial sources of funding across the CTRNet nodes.[16] Their results indicated that use of specific sources of funding (e.g., funding by host institution, government grants, and charitable foundation support) varied tremendously across the CTRNet nodes. User fees as a source of funding across the CTRNet nodes were reported to be 2%–25%. The CTRNet study and the current study both indicate that biobanks are obtaining funding from a variety of funding sources and that user fees are a key source of funding for a majority of biobanks surveyed.

With regard to operational expenditures, survey respondents reported that most, if not all, of their biobank start-up funds were utilized in purchasing initial pieces of equipment, inventory management systems, space planning, and construction. From these data, biobanks should consider infrastructure as a major expense in year one of their operational budgets. Beyond year two of biobank operations, respondents reported that 59% of the operational expenditure is spent on employee payroll. These data are similar to the survey data reported by Clément et al.[6] in which 60%–80% of a biobank's costs was attributed to employing biobank professionals. The purchase of supplies, additional pieces of equipment, and maintenance were relatively small expenditures after payroll in year two and beyond. However, these expenditures may increase over time as the accrual rate increases, projects are initiated, and new technologies are brought into the biobank.

The survey data indicated that biobanks obtained more than half of their operational revenue from internal end users and other academic institutions. This is not surprising since many of the biobanks are established to assist internal end users and other academic collaborators. The data further reveal that after building inventory, providing specimens and services, and performing administrative, maintenance, and quality management activities, very little time remains available for biobank managers to engage in biobank-related promotional activities (Fig. 1B).

The respondents self-reporting regarding the use of cost recovery in the BEMT survey is consistent with the survey results reported by the CTRNet biobank survey.[16] Both surveys indicate that 70% of the biobankers surveyed practice cost recovery through the application of cost recovery fees. Roughly half of the respondents to both surveys reported that they recover 25% or less of their costs. These results indicate that, although many biobanks practice cost recovery through the use of cost recovery user fees, their cost recovery schemes recover only a fraction of the operational costs they incur when collecting, processing, and storing biospecimens.

As increasing numbers of high quality biospecimens are required to meet the demands of translational research, it will be essential for biobanks to remain financially viable, partially through recovering as much of their costs as possible by the application of a variety of funding sources and user fees that reflect the total costs involved in providing the specimens. To better meet research needs, biobanks should regularly engage in long-term financial planning activities in which the total costs involved in providing biospecimens are determined and balanced with funding sources that are clearly defined to recover operational, labor and infrastructure costs. It is especially important that end users and potential funders are fully aware of the total costs involved in providing high quality biospecimens and associated annotation, to justify implementation of user fees that more appropriately reflect the complete costs involved in providing biospecimens for basic and clinical research.

A thorough consideration and understanding of the costs involved in obtaining specimens for research would also encourage end users to more accurately estimate the scope of their studies, the anticipated costs, and the funding required to support such studies. Establishing accurate user fees that take into consideration the total costs associated with collecting the biospecimen, understanding the costs associated with operating and maintaining a biobank, and effective financial planning that considers current and future expenditures should serve to enable long-term sustainability for biobanks and increase the availability of high-quality biospecimens for research.

Limitations

The survey has some limitations in addition to being self-reported data. The list of potential participants was designed to capture a broad representation of the biobank community nationally and internationally and include representation from a variety of different types of biobanks. The geographical representation indicates that nearly half of the respondents were from North America and Europe. This may be due to the observation that a greater number of biobanks from North America and Europe could be identified as potential participants, while considerably fewer biobanks could be identified in Africa and South America. We also observed fewer respondents from countries where English was not the primary language. In addition, the demographic data indicates that a majority of the respondents were from biobanks located in academic medical centers, community based hospitals, and independent research laboratories. Fewer respondents were from biotech/pharma.

Feedback from some of these potential participants indicated that due to proprietary constraints they were not able to participate in the survey. Thus, the cost and pricing data collected is largely reflective of that seen in academic medical centers and community based hospitals based in North America, Europe, Australia, New Zealand, Asia, and the Middle East, and to a lesser degree from biobanks located in Africa and South America.

Some respondents were not able to complete all the sections of the survey. The survey respondent's ability to

complete the survey was observed to be largely dependent on six common variables: 1) level of regular participation in cost accounting, hands-on biospecimen project management, and service development; 2) baseline understanding of cost analyses; 3) thoroughness of self-reporting; 4) quality of the data received based on due diligence in cost accounting; 5) real time access to cost data; and 6) historical knowledge of the biobank's finances.

It was not possible to evaluate the degree to which these confounders impacted the content and/or quality of the information reported. Some participants noted that they did not have access to historical cost data provided by previous biobank management, real-time access to current operational, and/or financial data required to answer all of the questions or sufficient time to address all the questions in the survey during the survey period.

Conclusion

The BEMT is a novel, publically available web-based financial planning tool for biobanks. The design of the tool was informed by the results of a market-based survey that aims to provide a greater understanding of the costs involved in initiating, operating and maintaining a biobank. In addition, the BEMT was developed to enable a thorough cost analysis and calculation of cost recovery user fees that accurately reflects the direct and indirect costs associated with the collection, processing, storage, and distribution of biospecimens for basic and clinical research. Understanding biobanking costs and proactive financial planning should lead to greater biobank sustainability and meet the challenge of providing an accessible supply of high quality human biospecimens necessary for the translational research that will enable transformative patient care.

Acknowledgments

We would like to thank all of the individuals who graciously participated in the BEMT survey as well as those who provided initial testing and feedback on the tool. We also wish to thank Steve Hunter for expert data analysis and assistance with the figures, Sailaja Mareedu for her assistance with the password/login functionality, and David Tabor for release and deployment support.

Funding: This project has been funded in whole or in part with federal funds from the American Recovery and Reinvestment Act (ARRA) from the Biorepositories and Biospecimen Research Branch at the National Cancer Institute, National Institutes of Health.

Author Disclosure Statement

No conflicting financial interests exist.

References

1. Hamburg MA, Collins FS. The path to personalized medicine. N Eng J Med 2010;363:301–304.
2. Aldridge S. Biobanking emerging as a key growth area. Present challenges and future benefits addressed. Genet Engineer Biotech News (GEN) 2005;25:1–2.
3. Vaught J. Economics: The neglected ''omics'' of niobanking. Biopreserv Biobank 2013;11:259.
4. Rogers J, Carolin T, Vaught J, Compton C. Biobankonomics: A taxonomy for evaluating the economic benefits of standardized centralized human biobanking for translational research. J Natl Cancer Inst Monogr 2011;2011:32–38.
5. Vaught J, Rogers J, Carolin T, Compton C. Biobankonomics: Developing a sustainable business model approach for the formation of a human tissue biobank. J Natl Cancer Inst Monogr 2011;2011:24–31.
6. Clément B, Yuille M, Zaltoukal K, et al. Public biobanks: Calculation and recovery of costs. Sci Transl Med 2014; 6:261fs245.
7. Betsou F, Rimm DL, Watson PH, et al. What are the biggest challenges and opportunities for biorepositories in the next three to five years? Biopreserv Biobank 2010;8:81–88.
8. Puchois PM, Miranda LB, Van Gool A. The cardinal role of biobanks and human biospecimen collections in biomarker validation: Issues impeding impact of biomarker research outcomes. Royal Soc Chem 2013;73–110.
9. Park O, Cho S, Shin SY, Park JS, Kim JW, Han BG. A strategic plan for the second phase (2013–2015) of the Korea biobank project. Osong Public Health Res Persp 2013;4:107–116.
10. International Society for Biological and Environmental Repositories (ISBER). 2012 Best Practices for Repositories: Collection, Storage, Retrieval, And Distribution of Biological Materials for Research. Biopreserv Biobank 2012;10:79–161.
11. National Institutes of Health, National Cancer Institute (NCI), Biorepositories and Biospecimen Research Branch (BBRB). NCI Best Practices for Biospecimen Resources 2011; http://biospecimens.cancer.gov/practices/. Last accessed 15 October 2015.
12. Cadigan RJ, Lassiter D, Haldeman K, Conlon I, Reavely E, Henderson GE. Neglected ethical issues in biobank management: Results from a U.S. study. Life Sci Soc Policy 2013;9:1.
13. Watson PH, Nussbeck SY, Carter C, et al. A framework for biobank sustainability. Biopreserv Biobank 2014;12:60–68.
14. Matzke L, Dee S, Bartlett J, et al. A practical tool for modeling biospecimen user fees. Biopreserv Biobank 2014;12:234–239.
15. McDonald SA, Sommerkamp K, Egan-Palmer M, Kharasch K, Holtschlag V. Fee-for-service as a business model of growing importance: The academic biobank experience. Biopreserv Biobank 2012;10:421–425.
16. Barnes RO, Schacter B, Kodeeswaran S, Committee CTM, Watson PH. Funding sources for Canadian biorepositories: The role of user fees and strategies to help fill the gap. Biopreserv Biobank 2014;12:300–305.
17. Kozlakidis Z, Mant C, Cason J. Bridging the financial gap through providing contract services: A model for publicly funded clinical biobanks. Biopreserv Biobank 2012;10: 357–360.
18. Dorsey ER, de Roulet J, Thompson JP, et al. Funding of US biomedical research, 2003–2008. JAMA 2010;303:137–143.
19. Bromley RL. Financial stability in biobanking: Unique challenges for disease-focused foundations and patient advocacy organizations. Biopreserv Biobank. 2014;12:294–299.

Address correspondence to:
Helen M. Moore, Ph.D.
National Cancer Institute
9609 Medical Center Dr.,3W 428
Rockville, MD 20850-9728

E-mail: moorehe@mail.nih.gov