BIOPRESERVATION AND BIOBANKING
Volume 10, Number 5, 2012

DOI: 10.1089/bio.2012.0017

Fee-For-Service as a Business Model of Growing Importance: The Academic Biobank Experience

Sandra A. McDonald,[1] Kara Sommerkamp,[2] Maureen Egan-Palmer,[2] Karen Kharasch,[2] and Victoria Holtschlag[1]

Biorepositories offer tremendous scientific value to a wide variety of customer groups (academic, commercial, industrial) in their ability to deliver a centralized, standardized service model, encompassing both biospecimen storage and related laboratory services. Generally, the scientific expertise and economies of scale that are offered in centralized, properly resourced research biobanks has yielded value that has been well-recognized by universities, pharmaceutical companies, and other sponsoring institutions. However, like many facets of the economy, biobanks have been under increasing cost pressure in recent years. This has been a particular problem in the academic arena, where direct support from grant sources (both governmental and philanthropic) typically now is more difficult to secure, or provides reduced financial support, relative to previous years. One way to address this challenge is to establish or enhance a well-defined fee-for-service model which is properly calibrated to cover operational costs while still offering competitive value to users. In this model, customers are never charged for the biospecimens themselves, but rather for the laboratory services associated with them. Good communication practices, proper assessment of value, implementation of best practices, and a sound business plan are all needed for this initiative to succeed. Here we summarize our experiences at Washington University School of Medicine in the expectation they will be useful to others.

Introduction

With the advent of sophisticated biomedical research technologies that can unlock the molecular mysteries of disease, and the recognition that diseased and normal tissue and biofluid specimens provide an invaluable substrate for such inquiries, biorepositories have become a key resource in recent years within many academic, commercial, governmental, and pharmaceutical institutions. The science of biobanking has recently seen prominent recognition in the lay media,[1] and arguments for its scientific merit and resource justifications are well recognized.[2]

Institutional banks have grown in part from the value (including economy-of-scale) that is provided when many customers are served by centralized hub-and-spoke models, instead of by small banks located within departments or individual laboratories. The economic advantages of centralization have, in fact, been advocated on a very large scale model.[2] Centralized banks offer more efficient use of personnel, space, and resources, and allow the use of uniform processes and policies across all biospecimen-related activities, including those required by regulatory or advisory bodies. Also, such banks create a neutral entity for the coordinated distribution of resources while protecting patient privacy, and they can preserve biospecimens and data beyond the tenure of individual investigators or studies. For academic institutions, biobanks serve as a readily accessible resource to support pilot studies and other endeavors that can lead to grant funding, both internal and extramural.

The traditional role of biobanks, particularly academic ones, has included support for basic and translational research. As such, they were traditionally viewed as site-based resources for their institutions or departments, and thus could often receive financial support from sources not requiring a fee-for-service approach. One example is support from academic departments; often pathology departments have administratively housed biobanks, since the specimen accruals and subject matter/expertise are naturally relevant to these departments' missions. Other examples are philanthropic sources, and governmental grants such as those periodically offered through the Office of Biorepositories and Biospecimen Research.[3] The challenge to this traditional model is that the current difficult economic climate, and the competitive nature of the biobanking field, has reduced or

[1]Department of Pathology and Immunology, and [2]Siteman Cancer Center, Washington University Medical Center, St. Louis, Missouri.

curtailed many of these sources, or made them more difficult to secure. In the meantime, the operating costs for biobanks continue to grow, with reagents, equipment, ongoing maintenance, and salaries all being examples of significant "overhead" expenses. And so, increasingly biobanks must operate as business enterprises as well as scientific laboratories—operating on the cutting edge of business philosophy, collecting sufficient revenues for their value-added services, and strategically apportioning and investing their financial resources. Despite its importance, relatively little has been written regarding evolving financial strategies for biorepositories.

Like any good business, biorepositories offer a valuable product, which they market to consumers and encourage them to pay for. Also as with other businesses, that product may have to compete with alternatives on the open market—such as commercial tissue vendors, and investigators' option to create their own bank. For a sustainable financial model, the value of offered services—and the revenue they generate—combined with non-fee-for-service money (i.e., grants or departmental support), should at least equal the expenses involved. A good fee-for-service schedule helps meet this standard, while also providing customers a sense of fairness and value. A fee-for-service schedule also typically is more flexible (especially relative to grant or philanthropic support) in adapting to changes in the cost of doing business, whether anticipated or not.

The biorepository at Washington University School of Medicine, also known as the Tissue Procurement Core (TPC), derives its specimens from a wide variety of clinical trials and collection protocols. Given the long-standing history of support from the Siteman Cancer Center at Washington University Medical Center, the TPC focuses on oncology. The TPC supports a wide variety of translational and other research programs at the School of Medicine on a request-driven basis, and in addition to storing and distributing tissues and biofluids, it also provides an array of laboratory services. Many banking protocols interfacing with the TPC are investigator-driven, but the TPC maintains its own Institutional Review Board (IRB)-approved general collection protocol using discarded tissue from surgical pathology,[4] which is used to fill some requests. Reflective of its roles, the TPC is organized into processing, molecular, and histology divisions, with storage as a centralized "hub" function. During fiscal year 2010–2011, the repository accessioned 34,863 specimens and disbursed 11,936 specimens for 85 different internal research programs or protocols. Requests are initiated by the use of an online request form which investigators must complete,[5] and which facilitates subsequent billing. Typically, requesting investigators are expected to pay fee-for-service charges out of their research funding, which can have a variety of origins, some internal (i.e., institutionally sponsored) and some external.

As direct grant sources to the TPC have become less prominent as a way of supporting it relative to ongoing "overhead" expenses, in response the Core has throroughly examined each aspect of its business. Importantly, in this model, users are never charged for the biospecimens themselves, but rather for the laboratory services associated with them. A key approach used was to examine each labor-consuming or expense-incurring part of the overall workflow, determining whether such components

- offered a readily apparent value to the customer, for which that customer would be willing to pay;
- were not value-added from the customer's point of view (i.e., something they would not specifically be willing to pay for) but still were necessary aspects of running the business, or
- were not value-added from either the customer or the business point of view and should be eliminated.

Items in the first category were considered prime candidates for inclusion in a fee-for-service mechanism, and the methodology for that is described in this article. An important aspect of our strategy was that some items in the second category could potentially be moved to the first category, and thus eligible to support the revenue stream, if persuasive communications were able change to customers' willingness to pay for them. An example described further on is storage, which through communications to the user community at our institution, was "re-framed" as a value-added, specialized service that justified the imposition of charges.

We describe here the process of building a good fee-for-service approach into our financial plan. How adaptable our approach is for other banks depends on their setting, their areas of focus, and the nature of their customer base. Also, nonacademic banks (e.g., pharmaceutical industry) may require a different model by virtue of having distinct objectives, and a different payer system. Nevertheless, we think our approach is useful as a general measure to address an increasingly challenging financial environment. For banks already using fee-for-service, we provide recommendations for revenue enhancement. For banks not yet using this approach, our experience may be useful in its implementation.

Discussion

There were several value-added categories of activity that were prime candidates for inclusion in a fee-for-service schedule (Table 1): storage, accessioning and disbursal, laboratory procedures, and pathology review. For each of these, proper analysis and cost-accounting required us to evaluate the relative contributions of three key cost components (Table 2): reagents/consumables, depreciation, and labor.

Reagents and consumables pertain to those items, both chemical (e.g., xylene, Ficoll-Paque Plus™ reagent) and material (e.g., plastic tubes, slides) which are necessary to perform requested tasks. The quantities and costs needed for such items should be scaled to reflect the expected overall volume and trends of activity, after which it is fairly straightforward to calculate cost on a per-procedure basis, and build this amount into the quoted fee for that procedure.

The second component of the cost analysis is infrastructure, which accounts for the large capital equipment needed to do a given procedure in a given laboratory area, and in so doing, builds needed capital equipment into the cost-recovery model. Charges for infrastructure thus vary across different laboratory workflows; for example, costs for frozen sections will be influenced by cryostats, whereas those for blood processing procedures will pertain to centrifuges and freezers. In addition, the cost of service contracts may also be included in building the infrastructure component. The laboratory must assure compliance with applicable government regulations (e.g., U.S. Office of Management and Budget Circular A-21 and A-133), and therefore, laboratories must work in partnership with their university administration.

Table 1. Value-added Categories of Activity for Inclusion in a Fee-for-Service Schedule

Item	*Description*	*Examples and Comments*
Accessioning and Disbursal	Taking in new specimens, and later disbursing them to requesting investigators, are procedures needing both time and expertise, involving chain-of-custody measures, computer entry, and communication practices.	Accessioning and disbursal have specific charges on the fee schedule. Mostly these are labor-based charges, with a small reagents and consumables component for disbursal.
Laboratory Services	Collectively, these services form TPC's most visible and recognized core of value in its scientific mission, and thus they represent items which investigators readily identify with, and show willingness to pay for. Specific services are itemized on the fee schedule for customers to see and choose from.	Plasma, serum, and Ficoll processing, cytospins, tissue processing and frozen and paraffin section preparation, and DNA and RNA preparation and analysis. Most lab services have the full triad of labor, infrastructure, and reagents/consumables costs underlying them.
Pathology Review	This is an essential component of the lab, given the focus on neoplastic disease, and the frequent use of tissues and tissue-based procedures in addressing investigator needs.	This is handled as a specialized labor charge, with a per-slide pathology review fee. Less commonly, a pathology consultation fee can apply. Such fees can be waived in certain circumstances (see main text).
Storage	This charge applies only to specimens stored under liquid nitrogen vapor, and to investigator-sponsored protocols, and is assessed annually based on the number of post-processing ampules needing storage (not necessarily the number of tubes or samples originally submitted).	Calculating an accurate storage charge requires the factoring of the cost of purchasing and maintaining the freezers, and the continual resupply of LN_2 required.

Recharge centers at Washington University (i.e., units which charge other units at the institution for goods or services) recover the nonsubsidized, direct costs, and such recharge centers with less than $250,000 in annual billings do not include equipment depreciation in the billing rates.

For those laboratories that are able to include depreciation, building an accurate infrastructure charge can be done by dividing the purchase cost by the estimated lifespan for the equipment (say, 10 years for a mechanical −80°C freezer), and then dividing that figure by the number of tests expected to be run on that equipment within the same timeframe. The calculations' accuracy could be further sharpened by building inflation expectations, and maintenance and repair estimates, into the figures. An obvious infrastructure cost is long-term specimen storage, which is considered further on. However, infrastructure expenses also underlie many other laboratory activities.

Labor, the third basic cost component, is influenced by the institutional rate of pay (salary and benefits), the skill level and personnel education/ training (and thus the pay rate) needed for a given procedure, and the person-hours needed to accomplish a task. Therefore, labor costs vary greatly across laboratories and across various tasks within the laboratory.

Storage

The majority of TPC specimens, and the ones with the greatest potential utility for translational research, are those stored under liquid nitrogen (LN_2) vapor (approximately

Table 2. Underlying Cost Components for Each Value-added Laboratory Workflow

Item	*Description*	*Examples*
Reagents and Consumables	Items, both chemical and material, which are necessary to perform requested tasks.	Xylene, Ficoll-Paque Plus™ reagent (chemical); Eppendorf tubes and packaging equipment (material).
Infrastructure	Large capital equipment and service contracts needed to do a given procedure in a given laboratory area. Charges for infrastructure vary across different laboratory workflows.	Cryostats and microtomes (histology); centrifuges (processing), freezers (storage).
Labor	Influenced by overall rates of pay (salary and benefits), the skill level and personnel education/ training (and thus the pay rate) needed for a given procedure, and the person-hours needed to accomplish a task. Labor costs vary greatly across laboratories and across various tasks within the laboratory.	Ficoll processing and laser capture microscopy (very labor intensive); basic cell processing (less labor intensive).

–120°C). Currently, TPC's storage inventory uses 21 LN_2 vapor freezers, and ongoing tissue procurements and accessions require that a new LN_2 freezer be purchased about every 5–6 months. Associated expenses are high: a typical 30,000-vial-capacity LN_2 vapor freezer costs approximately $30,000–$35,000 new, with an annual LN_2 resupply cost of around $3,000. Despite these significant expenses, prior to 2011, TPC had not specifically billed for, or attempted to recover, storage costs through a fee-for-service mechanism.

In 2011 our laboratory implemented such a charge for investigator-initiated studies (i.e., where specimens are banked and financed under the protocol of a specific investigator) which is assessed on an annual, per-ampule basis. From the investigator's point of view, this means that, based on the number of post-processing ampules needing storage (not necessarily the number of tubes or samples originally submitted), they are assessed charges for all their specimens occupying liquid nitrogen storage on a given date each year. The exact date was largely an arbitrary choice, but it was communicated in advance to the user community. Calculating the correct storage charge (i.e., the one sufficient to meet cost-recovery objectives) required the TPC to factor both the cost of maintaining the freezers, and the continuous resupply of LN_2 needed. Our current policy is that no storage charges are assessed for paraffin blocks, slides, or any other materials not kept under LN_2 vapor. Investigators can elect to avoid future storage charges by releasing their samples into the previously described TPC's general protocol,[4] as long as appropriate regulatory conditions are met, or by requesting the transfer of samples to another bank.

Accessioning and Disbursal

Taking new specimens into the laboratory, and disbursing them to requesting investigators, are procedures which involve both time and expertise, requiring chain-of-custody measures, computer entry, and communication efforts. These processes are reflected as specific charges on TPC's fee schedule. The per-specimen accessioning fee is calculated purely as a labor charge; its disbursal counterpart similarly is mostly a labor one, but does have a small reagents-and-consumables component to account for materials needed for the transfer of deliverables to investigators. Neither charge includes an infrastructure component in the cost calculations.

Laboratory services

Collectively, these services form TPC's most visible and recognized core of value, and thus represent items which investigators usually readily identify with, and show willingness to pay for. Numerous services are offered by the TPC which are listed specifically on a fee schedule. This schedule is posted on the laboratory's website, and shared with investigators (often at the time of initial consultation), and is updated at least annually. Offered services include plasma, serum, and Ficoll processing, cytospins, tissue processing

Table 3. Recommendations for a Successful Fee-for-Service Approach

Recommendation	*Considerations*
An outreach program (which could feature seminars, phone calls, or face-to-face meetings) should be established which acquaint the potential user base with the functions and value of the biobank. Also, new fee schedules should be sent to investigators well in advance, along with an explanation for the changes.	As with any business, it is important to establish and maintain good communications with the user base. The more proactive and value-driven those communications are, the better. If an academic setting, the potential value of the bank as a scientific resource to support grant proposals can be stressed.
All external benefits yielded from biobank services (such as grants or publications that result at least partially from biobank resources), should be periodically summarized and communicated.	Biorepository users, institutional or grant support sources, and other stakeholders may justifiably demand an accounting of benefit and quality in return for the costs incurred, and so impact metrics may be needed.
Quality and accreditation standards (as relevant) should be maintained and communicated to the user base and to stakeholders.	Besides good customer service, good quality assurance procedures help ensure support for a fee-for-service mechanism. The new College of American Pathologists (CAP) biobank accreditation program, once broadly implemented, could potentially serve as a quality standard for resource investments and service-based fees.[7,8]
Fee-for-service subsidies for certain institutional or other affiliations can be offered, as a way to incentivize requests from those sources, or to comply with institutional or philanthropic support.	The applicability of this recommendation will of course depend a great deal on the nature of the biobank, but it might promote business and enhance revenues long-term.
Financial support (i.e., defraying certain costs) may be considered for investigators conducting early "pilot" studies intended to secure subsequent grant opportunities. Such investigators may be those with the lease initial financial resources but good long-term potential.	The applicability of this recommendation will of course depend a great deal on the situation, but it might promote business and enhance revenues long-term, given the potential benefit of investing in early meritorious studies where financial barriers are initially present.
The biobank may wish to designate a given employee within its groups, and devote a segment of that person's time exclusively to billing and revenue activities.	This point will depend heavily on the size, complexity, and resources of the bank. However, it may be a good idea, given that efficient billing and revenue collection must underpin any successful business enterprise.

and frozen and paraffin section preparation, and DNA and RNA preparation and analysis. Most laboratory procedures have labor, reagents-and-consumables, and service contract cost components built into the calculated fee, which is then displayed in appropriate delivery units (per mL, per item, or per cell count). A specialized laboratory service offered by the TPC is laser capture microscopy (LCM). For this procedure, TPC assesses an hourly charge for use of the LCM instrument, and charges for needed items (stain sets and transfer caps).

Pathology review

Pathology review is an essential component of the TPC, given its focus on neoplastic disease, and the frequent use of tissues and tissue-based procedures in addressing investigator needs. From an accounting standpoint, this is handled as a specialized labor charge, with a per-slide pathology review fee (commonly done for quality assurance purposes when tissue specimens, or molecular products derived from tissues, are disbursed), or an hourly consultation fee. Such charges can be waived in some instances where the pathologist receives grant support or manuscript authorship. Besides the obvious accounting benefits, these types of charges highlight the value that pathologists bring to biorepositories, and the appropriateness of expecting compensation in exchange for that value.[6,7]

Recommendations for implementation

Table 3 summarizes our recommendations for implementing a fee-for-service mechanism successfully, once the right structure has been set using the steps in the Discussion section.

One overarching consideration should be mentioned: The "inertia" factor—loosely defined here as the tendency to resist new ways of doing business, especially when they involve charging for items formerly regarded as "free"—has been an occasional but significant obstacle to adaptation and change. To alleviate this, the best approach for us has been persuasive, data-driven, and scientifically motivated advocacy for the new model, made by biorepository staff to its users. The point to be stressed is that biospecimen science is a valuable resource that can and should price its services according to a sound financial model. Banks also should periodically evaluate new technologies and services that could enhance the laboratory's scientific excellence and provide new sources of revenue.

Conclusion

Biorepositories operate under an increasingly challenging financial environment, requiring effective cost-recovery procedures and other business-savvy approaches designed to promote biobanking value, and elicit needed financial support from customers and stakeholders. The recommendations presented here for implementing a fee-for-service approach could lead to a more viable business plan for many biobanks, with greater revenues.

Acknowledgments

The authors wish to acknowledge the Siteman Cancer Center (Grant #P30 CA91842) and the Institute for Clinical and Translational Science (Grant #UL1RR024992) at Washington University Medical Center, which has partially funded the biorepository at Washington University School of Medicine.

Author Disclosure Statement

No competing financial interests exist.

References

1. Park A. Biobanks—10 ideas changing the world right now http://www.time.com/time/specials/packages/article/0,28804,1884779_1884782_1884766,00.html. Last accessed 15 February 2012.
2. 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* 2011;42:32–38.
3. http://www.biospecimens.cancer.gov/default.asp. Last accessed 20 February 2012.
4. McDonald SA, Chernock RD, Leach TA, Kahn AA, Yip JH, Rossi J, Pfeifer JD. Procurement of human tissues for research banking in the surgical pathology laboratory: Prioritization practices at Washington University Medical Center. *Biopreserv Biobank* 2011;9:245–251.
5. McDonald SA, Ryan BJ, Brink A, Holtschlag VL. Automated web-based request mechanism for workflow enhancement in an academic customer-focused biorepository. *Biopreserv Biobank* 2012;10:48–54.
6. McDonald SA. Principles of research tissue banking and specimen evaluation from the pathologist's perspective. *Biopreserv Biobank* 2010;8:197–2010.
7. McDonald SA, Watson MA, Rossi J, Becker CM, Jaques DJ, Pfeifer JD. A new paradigm for biospecimen banking in the personalized medicine era. *Am J Clin Pathol* 2011;136:679–684.
8. http://www.cap.org/apps/cap.portal?_nfpb=true&_pageLabel=accreditation. Last accessed 20 February 2012.

Address correspondence to:
Sandra A. McDonald, M.D.
Laboratory for Translational Pathology
Department of Pathology and Immunology
Washington University School of Medicine
660 Euclid Ave., Box 8118
St. Louis, MO 63110

E-mail: smcdonald@path.wustl.edu