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BRIEF REPORT

Sustainability in the Modern Biorepository Environment from the Perspective of the Tissue Procurement Core at the University of Iowa

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A brief overview of biorepository sustainability from the perspective of a federated biorepository system at the University of Iowa Carver College of Medicine is presented. The ongoing evolution of the federation and the efforts to improve efficacy and efficiency are described. The key sustainability factors identified are adaptability, focus, collaboration/networking, and service improvement.

At the University of Iowa (UI) and its academic medical center, University of Iowa Hospitals and Clinics (UIHC), a number of biorepositories have been created over time under the auspices of the Carver College of Medicine (CCOM), the Holden Comprehensive Cancer Center (HCCC) and/or the Institute for Clinical and Translational Science (ICTS). The various repositories were independently created to fulfill separate goals that ranged from highly-focused, targeted collections to population-based, generalized collections. The repositories were funded by multiple mechanisms, but most were financed directly or indirectly by grants from various sources, with some funding coming from institutional sources.

The repositories had no formal interconnections and seldom, if ever, intercommunicated. Few or none were initiated with detailed plans for long-term financial sustainability. As the demand for high quality biomaterials for research rose, the disconnected nature of the existing biorepositories made it challenging to determine what material and data might be available, who had it, and how it could be accessed. The separate biorepositories operated under divergent protocols and IRB authorizations. Multiple subject and biomaterial tracking methods and software products were in use that required maintenance and support. Subjects were sometimes approached by multiple studies with similar goals. Across the biorepositories there was considerable duplication of equipment and effort.

With a vision of moving forward more efficiently, a federation of biorepositories was proposed (Fig. 1) with a common, ''state of the art'' information system at the core that would be interfaced to the medical center clinical database while maintaining ethical and regulatory compliance. Requests by researchers for materials and data would be routed through a common portal. Biomaterials would be encouraged but not required to be housed in a shared secured facility. Authorization for distribution of specimens was retained by the utilization review committee from each repository in order to maintain control by the original expert stakeholders. Most data would either be stored on the shared repository information system or linked via an intermediary data repository derived from the hospital information system.

Subjects must be enrolled into a study on the hospital system to enable the direct interface to the repository system to transfer subject demographic information and to authorize linkage to data in the clinical repository. Converting the vision of the federation plan into a reality has been a major challenge for the past 3+ years. While still an ongoing effort, some of the key elements of the vision are beginning to come to fruition. The common repository information system has been selected and installed. Repositories are now uploading data and implementing the system. The research module has been activated on the hospital system and the interface between the hospital and repository systems has been implemented. The common request portal now consists of a software tool called Iowa Catalog And Research Tracker (ICART) and a staffed service called UIBioshare to assist researchers.

The University of Iowa Tissue Procurement Core (TPC) facility began in 1999 under the Department of Pathology. The original TPC was absorbed by the Carver College of Medicine and converted into a core facility in 2009. The conversion to a CCOM core facility brought with it an increase in financial scrutiny that required more strategic and financial planning. Core operations must look more closely at spending versus revenue. It is critical to realize that services can be contracted out to other institutions or companies if the economics do not support (and the operational requirements do not dictate) the maintenance of an in-house operation. The University of Iowa BioBank (UIBB) was

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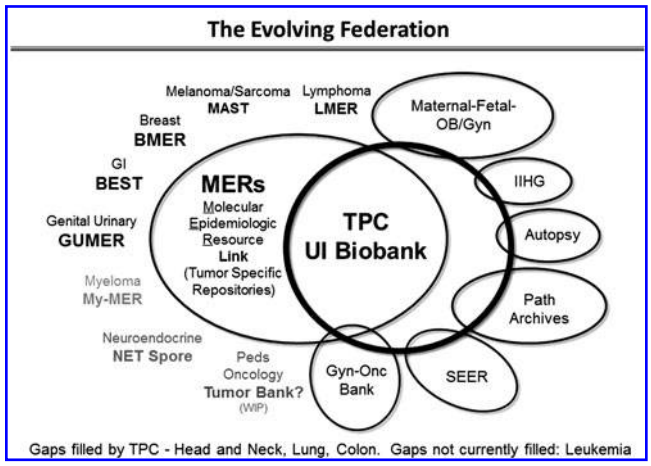

FIG. 1. Venn diagram representation of the federated biorepositories at the University of Iowa. The MERs are administered under the Holden Comprehensive Cancer Center. The other repositories are affiliated with the Carver College of Medicine or the College of Public Health.

initiated under a grant awarded to a researcher within the institution and was absorbed by the TPC in 2013.

Since the vast majority of biorepositories are embedded within a larger organization or institution,[1] one question arises: ''How should the parent institution define sustainability?''

- Should the definition be full cost recovery of all direct and indirect costs, whether fixed or variable?
- Should some portion of the cost be absorbed by the larger institution (often the fixed and/or capital expenses and/or indirect costs, leaving the direct variable cost of operations to be covered by the revenues generated by the biorepository)?

Since the majority of funding for biorepositories comes from the federal government or from the parent institution[1] (both of which may be shrinking pools), the distinction is critical. The ultimate goal for the TPC was full cost recovery, but there was a realization that full cost recovery would likely be overly ambitious, if not impossible to achieve while maintaining the added goal of minimizing costs to the local researchers. Hence the primary financial goal was informally changed to at least cover variable direct expenses with anything beyond that being considered a bonus.

Financial planning, sometimes including formal business plans, are part of the annual budgetary cycle within the institution but there is substantial variation in the degree of depth and detail to which such plans are required for each operating unit. Financial reports are provided monthly, and budgets and justifications are reviewed annually (at a minimum). For the biorepository, the performance measurements used include consents, collections, distributions, projects, researchers, publications, grants, and other metrics, in addition to expenses and revenues. Funding and support for biorepository operations comes from multiple sources, the CCOM, the HCCC, the ICTS, specific external (mostly federal) contracts/grants (the largest single revenue source for the TPC), internal college and departmental funds, and fees for services rendered to researchers.

The funding/support for the recent implementation of the new common information system came from all three major divisions and represented a multidisciplinary approach involving federated biorepositories residing in numerous departments. Attempting to think outside the traditional healthcare repository box, the federation design included the potential for nonmedical departments such as Archeology, Geology, and Paleontology that may have materials that they wish to catalog and track.

While the business plan for the TPC is very informal, the consideration of how the TPC can strive to attain sustainability is very much a part of planning and a key driver of how the biorepository (and other members of the federation) will move ahead in the future. The fact that the institution maintains the physical plant and fixed assets provides some relief over the long run. But even the requirement to cover variable costs is a significant concern and must be the minimum mandatory requirement for any long term sustainability. Hence the goal has been to focus efforts on areas where the revenue potential is the greatest.

The answer to date has been participation in large scale federal (NIH/NCI) projects such as the TCGA and PDX initiatives. But such projects are limited in number, scope, and funding and will eventually end. So the search is always on for new avenues by which revenue can be generated. Another revenue issue that was evaluated was the fee schedule. Tiered fee schedules were devised and adjusted. Potential tiers included but were not limited to:

- researchers inside vs outside the institution
- academic vs corporate researchers
- cancer center members vs non-members

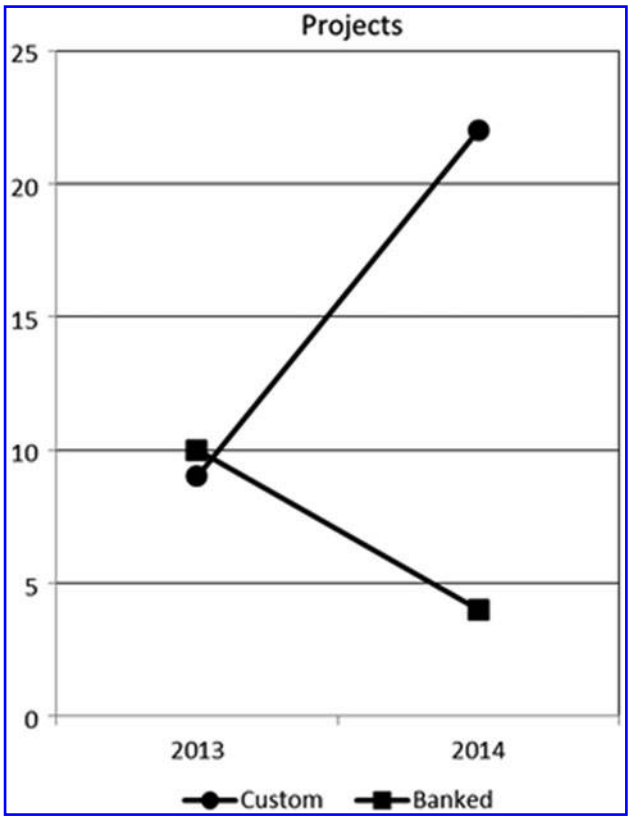

FIG. 2. Supported research projects categorized by custom (prospective) versus banked (retrospective). The trend has been toward custom projects where prospective collections (often fresh biomaterials) are required. There has been a corresponding decline in utilization of retrospective studies utilizing banked (usually frozen) biomaterials. The data for 2015 to date continues to support the same trends.

Cost reduction efforts have focused on the division of duties across the federation to reduce inefficiencies and duplication of efforts, equipment and supplies. Some examples include:

- creation of a centralized freezer farm
- creation of expert core facilities for specialized specimen processing
- establishment of protocols for the tissue procurement core to coordinate biomaterial collection, storage and distribution
- elimination of the duplicate consenting between the UIBB/TPC and the Molecular Epidemiologic Resources (MERs)

Considering how to market services and exploring new ventures are required features of any business planning for the biorepository. Perhaps the most important element is the ability to adapt. One key example of adaptation was changing the culture and establishing processes to allow the consideration of collaboration with compatible external clinical research organizations (CROs)—private specimen consolidators who contract with researchers in academic or commercial institutions to provide biomaterials, data and other services.

Previously the TPC could only work with internal researchers or occasionally collaborators at other academic institutions. In a large academic institution there is considerable inertia to overcome to initiate change in thinking and practices. Keeping an eye on the horizon for opportunities and working early and hard to remove institutional challenges that can delay or sidetrack the rapid response to a new opportunity can help pave the way to sustainability.

For the TPC, this meant discussions with the necessary administrators to gain conceptual approval and considerable work with the legal arm of the institution to craft material transfer agreement language that could be used as a template for different outside partners. Both processes took time to accomplish. Another venture under consideration is joining one or more networks of similar institutions to share information about existing resources that can enhance/expand access by researchers at all of the member institutions to a larger pool of material and data.

One way that the evaluation of metrics and the planning process has resulted in change was the realization that biomaterial requests utilizing retrospective (banked) population based collections were decreasing while prospective (custom) collections with highly specific specimen requirements were rapidly increasing (Fig. 2) The data reinforced the need for a change in focus away from ''collecting everything you possibly can in hopes of getting what you need'' to ''only going after things you know someone needs and you know you can get.'' For the new approach to be successful, staying in tune with the needs and trends of the research community (both locally and globally) is important.

Understanding the population of subjects that your repository has access to and how the diagnostics and therapies are changing for that population are other key indicators that can signal the need to adapt. For instance, dramatic changes in imaging and screening techniques have allowed for earlier detection of lung, breast, and other cancers, resulting in earlier treatment and significantly reduced tumor size at time of resection. Changing therapies and treatment regimens have also resulted in changes in the viability of tumors and sometimes negated the need for resection surgery.

Decreased tumor size and viability has impacted the ability to collect fresh frozen material via the Surgical Pathology Department. To meet clinical requirements, many tumors are entirely processed to formalin-fixed paraffin-embedded (FFPE) blocks in the Pathology Department where access to them falls under a more complicated set of regulations and processes. Researchers may need to be educated about what can and cannot be done using FFPE and guided toward the correct access process when the Pathology archive is not directly part of the repository. Building bridges and communication channels between traditional repository operations and the clinical departments greatly helps. One of many ways the TPC has been building bridges is via partial funding of a pathology assistant line in the Surgical Pathology lab since the operation is key to successful collection. Factors such as these should become considerations in business planning.

By remaining agile, focusing on the best opportunities, looking for new revenue options, collaborating with other repositories, and improving services, the TPC has managed to grow distributions and increase revenues from nearly nothing to better than variable cost recovery. Achieving and maintaining sustainability will require continuous effort and continuous evolution of the business plan.

Author Disclosure Statement

No conflicting financial interests exist.

Reference

1. Henderson GE, Cadigan RJ, Edwards TP, et al. Characterizing biobank organizations in the U.S.: Results from a national survey. Genome Med 2013;5:3.

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