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Business Planning for a Campus-Wide Biobank

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Biobanks are resources that facilitate research. Many biobanks exist around the world, but most tend to focus on a specific disease or research area. BC Children's Hospital and BC Women's Hospital are located on the same campus (Oak Street Campus) in Vancouver, BC, Canada. A campus-wide biobank has been established on the site of these two hospitals to collect specimens and annotated data from children or women seeking medical care at either of the hospitals. Such an initiative requires careful planning and consideration of many factors such as buy in and support of key stakeholders, governance, financial planning, and optimizing specimen collection. We developed a business plan to account for the many aspects associated with integrating the ''BC Children's Hospital BioBank.'' This document describes the approach our business plan took for the implementation of our biobank and the progress, including deviations from the business plan. We also provide a perspective on the current status with a focus on sustainability.

Keywords: business planning, sustainability, biobank

Introduction

Over the last decade, biobanks have become an important infrastructure in research institutes and academic health centers around the world.[1,2] A biobank is defined as ''a facility for the collection, preservation, storage and supply of biological specimens and associated data, which follows standardized operating procedures and provides material for scientific and clinical use.''[1] Many biobanks are project driven and often are operated by a single investigator or researcher, resulting in numerous biobanks across a single institute. A situation such as this was present on our campus with researchers recruiting research participants on an as-needed basis and in some cases establishing their own informal biobanks. We identified several problems with this approach, including (1) high operating costs for single biobanks hampering access to specimens for researchers with minimal funding or without clinical connections; (2) lack of standardization of methods making sharing of specimens between researchers problematic; (3) lack of guardianship for specimens resulting in abandoned collections when principal investigators (PIs) retire or leave the campus; (4) high consent burden for participants resulting in a paternalistic approach through which clinicians make decisions about which studies ''their patients'' were allowed to be approached for, often leading to less connected researchers or researchers with limited funding being excluded. To alleviate these issues, we proposed, as others have,[3,4] that consolidation of these individual biobanks into a single biobank has significant benefits. This approach was supported by institutional management as it was deemed that with good governance, a campus-wide biobank would reduce (if not remove) risks such as breaches of privacy or misuse of specimens.

This article describes the planning, implementation, and operations of a campus-wide biobank with a focus on pediatric and maternal specimens with annotated data for research purposes. Our experiences suggest that creating a business plan before embarking on implementing a large biobank is worthwhile and is beneficial for monitoring the sustainability (financial, operational, legal, and ethical) of the biobank, bearing in mind that adjustments and deviations may occur.

Background and History

In 2013, when the business plan for the campus-wide biobank was developed, the Oak Street Campus in Vancouver,

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BC, Canada, consisted of five separate entities, including two hospitals and three research institutes: BC Children's Hospital (BCCH), BC Women's Hospital (BCWH), BC Children's Hospital Research Institute (BCCHRI), Women's Health Research Institute (WHRI), and BC Mental Health and Addictions Research Institute (BCMHARI). This campus with its reputed research mandate has established numerous biobanks over the years to foster research projects. One such biobank was from the Childhood Cancer and Blood Disorder Research (CCBR) Cluster at the BC Children's Hospital Research Institute (BCCHRI), which was established in 2011 and was the first of its kind on the Oak Street Campus as the specimens were collected under a broad consent for as yet undetermined research studies. There was interest for this concept by clinical and research groups on the campus as it was thought that there was the potential for decreasing operating costs and consent burden and increasing potential use of specimens in the future. We were able to get financial support from the BCCHRI and the WHRI as well as the BC Biolibrary to hire a business plan consultant. It should be noted that the business plan mandate was not to consolidate all existing biobanks but to identify whether the concept of a campus-wide biobank was feasible and what the governance and operational structure would look like.

Methods

A business plan consultant was recruited in December 2012 and discussions started regarding the process of integrating a campus-wide biobank. A biobank business plan development team was established and consisted of the business plan consultant, the Director of the CCBR BioBank, the CCBR BioBank Coordinator, and consultants from the Office of Biobank Education and Research (OBER). The task of the development team was to develop the concepts in regard to biobank governance, management, and operations with advice and input from the research ethics board and Provincial Health Services Authority (PHSA) privacy for compliance in these areas.

In January 2013, a workshop for key biobank stakeholders representing different interests of the Oak Street Campus was held. The objective of the workshop was to determine current biobank inventory, identify the current and future biobanking needs, and discuss a framework of concept, function, and governance. During the workshop, ~45 formal biobanks and/or informal collections of biospecimens were identified on the campus, ranging considerably in size and type of biospecimens (Supplementary Table S1; Supplementary Data are available online at www.liebertpub.com/bio) with the vast majority being project driven. Benefits and key elements of a coordinated biobanking approach were discussed, including standardization, improved collaboration, and decreased cost (Table 1).

A survey was conducted by the biobank business plan development team to address the financial cost of current biobanking activities. Twenty of the biobanks identified in the workshop were surveyed. These 20 were selected as they were research only and had an operating budget, seven biobanks responded. These seven biobanks spent approximately CA$250,000 combined per year on personnel and an additional CA$37,000 on laboratory supplies for a yearly total of CA$287,000.

Table 1. Benefits of a Campus-Wide Biobank as Identified at the Workshop

Key element	*Benefits*
Standardization	SOPs, standardization and quality control
	Paired data, follow-up data
	Best practices applied to collection, storage, and retrieval of biospecimens and patient information
	Improved quality of stored specimens for specialized studies
Consolidation of biobanking	Economy of scale, cost
	Efficiency of Research Ethics Boards (REB)
Funding and use of resources	Increased funding, allows for expansion of grant earning potential
	Increased job creation and training opportunities and efficient staffing
Research	Broader scope of research
	Increased volume, quality, and impact of research on Oak Street Campus
	Efficiency of sample use
	Increased collaboration among clinicians and researchers on the Oak Street Campus
	Increased statistical power
	Shorter time for research and discovery
Patients and families	Increased patient confidence in research
	Decreased consent burden for patients (biobank consent will cover numerous research projects).
	Enhanced ability to rapidly translate new knowledge to improve care

SOP, standard operating procedure.

A review of existing campus-wide biobanks, such as the Mayo Clinic Biobank in the United States,[5] was performed to provide models of best practices for governance, structure, and operations.

Finally, key individuals on the campus, within the health authority and from the university, were consulted about their views on the concept of a campus-wide biobank (Supplementary Table S2). A Business Plan Advisory Committee (Supplementary Table S3) was formed to review and comment on the draft business plan, which included a governance structure (Supplementary Fig. S1), management structure (Supplementary Fig. S2), and a 10-year proposed budget (Table 2). Key elements and the guiding principles of the campus-wide biobank were developed, which included consent, privacy, governance, operations, sustainability, and communications (Table 3). A town hall meeting was held for stakeholders to comment on the proposed business plan. The final business plan was reviewed and approved by the Business Plan Advisory Committee.

Results

Ethics, privacy, and governance

The appointed Director and Manager created ethics application and consent/assent forms. Discussions occurred between the BCCHB and the Children's & Women's Research Ethics Board (C&W REB) to address issues with

Table 2. BCCHB Financial Projections Synopsis, Years 1–10/2013–2023

		July 2013–March 2014	*April 2014–March 2015*	*April 2015–March 2016*	*April 2016–March 2017*	*April 2017–March 2018*	*April 2018–March 2019*	*April 2019–March 2020*	*April 2020–March 2021*	*April 2021–March 2022*	*April 2022–March 2023*	
		Year 1	*Year 2*	*Year 3*	*Year 4*	*Year 5*	*Year 6*	*Year 7*	*Year 8*	*Year 9*	*Year 10*	*Total*
1	Revenue											
2	BC Children's Hospital Foundation	980,000	250,000	230,000	265,000	290,000	230,000	190,000	127,000	78,000	20,000	2,660,000
3	Services	0	16,000	35,000	70,000	100,000	140,000	190,000	250,000	325,000	400,000	1,526,000
4	Research institutions	0	0	0	10,000	20,000	20,000	20,000	25,000	25,000	25,000	145,000
5	Grants (CIHR, CFI)	0	25,000	50,000	250,000	25,000	25,000	150,000	150,000	50,000	50,000	775,000
6	In-kind (1)	40,000	55,000	55,000	55,000	65,000	65,000	65,000	70,000	70,000	70,000	610,000
7	Total	1,020,000	346,000	370,000	650,000	500,000	480,000	615,000	622,000	548,000	565,000	5,716,000
8	Expenses											
9	Operating—personnel subtotal #1	182,000	241,000	291,000	365,000	377,000	384,000	413,000	413,000	448,000	460,000	3,574,000
10	Operating—laboratory subtotal #2	22,000	26,000	26,000	29,000	34,200	34,700	36,700	36,700	36,700	38,700	320,700
11	Operating—administrative subtotal #3	72,500	49,500	31,000	32,000	28,000	34,200	34,200	34,200	31,700	31,700	379,000
12	Capital—laboratory equipment subtotal #4	637,000	8,500	0	194,000	34,000	0	100,000	100,000	0	0	1,073,500
13	Capital—administrative subtotal #5	105,000	20,000	20,000	27,500	25,000	25,000	30,000	37,500	30,000	30,000	350,000
14	Operating total	1,018,500	345,000	368,000	647,500	498,200	477,900	613,900	621,400	546,400	560,400	5,697,200
15	Year-end balance	1,500	1,000	2,000	2,500	1,800	2,100	1,100	600	1,600	4,600	18,800

Services include fees for the release of biospecimens for research projects, provision of freezer storage for BCCHRI, consenting, processing of biospecimens, and clinical data collection. In-kind resources include personnel support from BCCHRI for facilities, IT, communications, and financial advice. All funds are in Canadian dollars.

BCCHB, British Columbia Children's Hospital Biobank; BCCHRI, BC Children's Hospital Research Institute.

Table 3. Key Elements, Issues, and Guiding Principles of a Campus-Wide Biobank as Determined in the Business Plan

Key element	*Issues*	*Guiding principles*
Consent	Getting the right type of consent from patients and/or their families is critical to the long-term value of the biospecimen.	The BCCHB will set guidelines for patient consent that will be followed for all biospecimens to be collected and stored in its facilities. Guidelines include, but are not limited to, (a) First contact with patient for sample is the primary care provider (physician or nurse). (b) Biobank specially trained consent personnel will obtain either a broad consent or a specific consent. (c) Permission to contact for future research may also be included in the consent form.
Privacy	Patient and family privacy needs to be protected at all times.	The BCCHB will complete and maintain the PHSA—privacy impact assessment at all times. The BCCHB will follow specific SOPs to protect patient privacy and maintain confidentiality of all patient information.
Governance	To be a valuable resource for all researchers on the Oak Street site, the BCCHB needs to be a fair, transparent, and equitable organization.	The BCCHB Management and Operations will be overseen by a multidisciplinary and multidepartment group of individuals who will ensure transparent, fair, and equitable processes are established and followed for the benefit of all clinicians, researchers, patients, and families.
Operations	The collection, storage, and retrieval of biospecimens and patient information need to be efficient and effective to provide the best resource for research projects.	The BCCHB will strive for the efficiency of its operations and will use best practices for all of its management and operations. It will maintain a transparent and an iterative process with its stakeholders to ensure long-term involvement and ownership by all key individuals. Biospecimens will be forwarded to the biobank only after sufficient sample for all necessary clinical tests, and their quality assurance, have been collected. The clinical evaluation of a specimen is the highest priority and will not be compromised due to obtaining a biospecimen for biobanking.
Sustainability	Biobanks are costly ventures and maintaining their viability requires carefully ongoing financial planning and execution.	The BCCHB will begin planning for its long-term sustainability at the end of year 1 of its operations with a multipronged strategy. The execution of the sustainability plan will begin in year 2.
Communications	Public, patient, and family support is critical to the success of the biobank. Long-term buy-in by clinicians and researchers is also critical to success.	The BCCHB will develop a comprehensive communication plan that uses a variety of external and internal tactics.

regard to assent, consent, and reconsent of children, families, and young adults. Incidental findings were also addressed and continue to be discussed as more guidelines become available worldwide. The BCCHB uses ''broad consent''[6] and reconsent of participants at the age of majority (ethical issues in pediatric biobanking are described in a manuscript in preparation).

Biobanks have a duty to address privacy to minimize the ''risk of privacy breaches and to mitigate data misuse.''[7] To review and document the privacy impact of the BCCHB on potential participants, a consultant was hired to complete a privacy impact assessment (PIA) with a specific focus on privacy, privacy risk mitigation, and safeguards, both technical and operational. A quality management system manual was developed, which includes policies and standard operating procedures to guide the governance and operations of the BCCHB. This manual was reviewed during the PIA consultation. BCCHB policies were based on the Canadian Tissue Repository Network (CTRNet)[8]-recommended policies and best practices provided by the International Society for Biological and Environmental Repositories (ISBER).[9] These policies were modified to accommodate the needs of the BCCHB. Specifications of the BCCHB database were also addressed. The PIA was reviewed and approved by appropriate specialists at PHSA and will be reviewed and updated when necessary to ensure compliance with privacy policies in British Columbia.

Transparent governance with robust oversight is key to the success of biobanks[10,11] as it helps to ensure public trust as well as trust of researchers as fair access to specimens and data is ensured. The BCCHB governance structure was determined by the Business Plan Development Team and is composed of four different committees as described in the Supplementary Data (Supplementary Fig. S1).

Operations, facilities, management, and staff

To fulfill our mandate and serve all research on the Oak Street Campus, the BCCHB offers two different biobanking approaches. The ''general biobanking'' approach involves collecting, processing, and storing high value specimens for as yet undetermined research studies. The value of specimens is determined by the Biospecimen Advisory Committee. The biobank is the custodian of the specimens and annotated data. Researchers with ethics approval for their research can apply to obtain specimens. A cost recovery fee is charged to the researcher on retrieval of the specimens to assist with the sustainability of the BCCHB.

The second approach is investigator driven. In these cases, PIs can request specific services from the BCCHB as per an established agreement with associated fees. These services may include consenting, collection, processing or storing of biospecimens, clinical data collection, pathology reviews, and xenograft expansions. In this situation, the PI is the custodian of the specimens and data. The PI is encouraged to obtain a general BCCHB consent in addition to the study-specific consent, so that after the study closes, the remaining specimens can be transferred to the ''general'' biobank allowing the BCCHB to increase its specimen collection. The study PI needs his/her own study REB approval before the BCCHB can support their collection.

The BCCHB has created two facilities: a processing facility and a storage facility. An integrated facility design (IFD), based on LEAN processes,[12,13] was performed to accommodate the BCCHB processing laboratory within the clinical laboratory at BCCH. The IFD aims to develop a functional space with efficiency at the core of the design and this design process decreased the overall cost of BCCHB renovations. The storage facility is located in the BCCHRI.

Significant staff resources are necessary to ensure the daily operations of the BCCHB, including obtaining patient consent, biospecimen collection, and processing, storage, retrieval, and data collection (Supplementary Fig. S2). These operations need to be well integrated into everyday hospital activities while not interfering with patient care. In addition to an administrative and laboratory manager, the business plan proposed to include staff such as laboratory technicians, database technicians, consent staff, finance and administrative assistant, and a bioinformatics specialist.

Sustainability

Biobanks must consider operational, financial, legal, and ethical sustainability. The operational sustainability of the BCCHB is assessed on a yearly basis when the key performance indicators (KPIs) (Table 4) are summarized in the annual report, which can be viewed online.[14] The evaluation of biobanks is important for assessing the biobank's performance. Indicators that might be beneficial to assess are quality of specimens and data, activity of the biobank, scientific productivity, or external dissemination and communication by the biobank.[15] Our KPIs (Table 4) represent all of these areas and are used to monitor our performance over time. It should be noted that KPIs may not reflect the true operational value of biobanks in the early stages of development, as it will take several years to build up inventory and trust with participants and researchers.

Financial sustainability of the BCCHB was projected in our business plan, which included a 10-year financial forecast. The BCCHB operates on a financial year of April 1–March 31. Table 2 reflects the financial planning defined by the business plan. As a result of the timing of the allocation of start-up funds, year 1 started on July 1, 2013, and ran

Table 4. Yearly Key Performance Indicators for the BCCHB

	Key performance indicators	*January 1, 2015–December 31, 2015*	*January 1, 2016–October 1, 2016*
1	No. of participants recruited	215 (BC Children's)[a] 145 (BC Women's)[b]	181 (BC Children's)[a] 64 (BC Women's)[b]
2	No. of requests for specimens from general biobank	2	6
3	No. of PI-driven research projects supported	14	19[c]
4	No. of aliquots released from general biobank	32	409
5	Sample QC (two methods)		
	(i) Mononuclear cells (post-thawing)		
	Recovery	71%[d]	87%[d]
	Viability	75%[d]	88%[d]
	(ii) DNA A260/280	1.85	1.89
	A260/230	2.05	2.18
6	No. of successful grants for BCCHB-specific projects	1	2
7	No. of successful grants that proposed using BCCHB specimens/data	1	1
8	No. of publications with BCCHB specimens/data	0	2
9	No. of publications/conference presentations and participation in working groups by BCCHB staff	6	7

[a]Approximately 18 participants per month stayed stable.
[b]BC Women's Hospital consent form changed to request many more specimen types, some prospectively and some retrospectively. This has resulted in an increased number of specimens per pregnancy but a lower recruitment rate, presumably due to level of commitment.
[c]Eleven services from previous year are carried over from previous year. Three projects from 2015 were completed by 2016.
[d]QC data improved as a function of the mean of specimens released. Increasing the number of specimens released increased the accuracy of the mean.
PI, principal investigators.

until March 31, 2014 (9 months as opposed to a full year). However, BCCHB operations did not start until January 2015 (end of year 2 as per Table 2). Financial planning is based on initial start-up funds provided by the BC Children's Hospital Foundation, with a gradual increase in proposed income through PI-driven services, general biobank applications, and grants. The utilization of start-up funds decreases as income from services and grants increases. Note that although the total start-up funds were received in 2013, they are reflected as projected income over a 10-year period (Table 2). This results in a low year-end balance (Table 2, line 15) each year. After a 10-year period, the BCCHB has planned to be financially independent (Table 2), which is an ambitious goal. It should be taken into account that a significant amount of grant money needs to be secured as income to allow financial sustainability of the BCCHB. Financial sustainability through cost recovery alone is predicted to be insufficient as has been shown by others.[16]

Legal and ethical sustainability is addressed via the PIA (previously described) and yearly renewals with the REB.

Database

Biobanks require a Laboratory Integrated Management System (LIMS) for their operations. A suitable LIMS or database capable of storing specimen inventory as well as participant information in a secure manner is crucial for the performance and sustainability of a biobank. Key components of a database include specimen inventory management, mechanisms to import and export clinical data, audit trails, and a high performing query tool. We selected four databases that could potentially fulfill the needs of the BCCHB database requirements: TissueMetrix,[17] CAISIS,[18] CaTissue,[19] now known as Open Specimen and Advanced Tissue Management (ATiM)[20] (Supplementary Table S4). As it was anticipated that the BCCHB database would require regular customizations and updates as the biobank evolved, ATiM was chosen. The BCCHB database is continually evolving and we have a dedicated team for the required customizations.

Discussion

The idea of institutional, campus-wide, or hospital-integrated biobanks is becoming more common. The Health Science Alliance Biobank in Australia has implemented an institutional biobank that has been well received.[21] Although there were initial concerns about the biobank impacting workload and compromising patient care, these concerns have been overcome by effective and ethical biobank processes. We have discovered that the same principles are true for the BCCHB. The Oak Street Campus is currently undergoing significant restructuring with a mandate to further integrate clinical research into the clinical care provided on campus. The success of the BCCHB has been recognized by key players in the leadership of the campus hospitals and research institutes, and discussions to incorporate the BCCHB as a core facility have started.

The mission of the BCCHB is to provide a comprehensive service for the collection, processing, storage, rapid access, and retrieval of biospecimens and clinical information for research projects using a professional and compassionate approach to patient consenting that adheres to the highest standards of research ethics and patient privacy. Observing such a mandate and maintaining sustainability is not an easy task for biobanks and this will be further discussed below.

Implementation of business plan

At the time of creating our business plan, most existing biobanks were disease specific. Therefore, feedback at our initial business planning workshop and the individual interviews we conducted were important to guiding the models we developed for governance, structure, and operations.

As previously mentioned, the Business Plan Advisory Committee developed the concept of dividing the initial start-up funds over a 10-year period and seeking additional funds from other avenues, both from granting agencies (discussed further below) and fees for service. The financial model is based on the prediction that increased reputation of the BCCHB will lead to increased income through fee for service and subsequently utilize less start-up funds.

It has taken 2 years to plan and implement the BCCHB, and the business plan has been critical to guide the BCCHB to its current state. The BCCHB is now in its second year of operations (Table 2, financial year 4). Of the 45 biobanks originally identified on our campus, 13 are no longer in existence either because they have ''closed'' as a result of the services provided by the BCCHB or because they have come under the governance of the BCCHB in some manner. At this time, we collect specimens for general biobanking and support $\sim$19 PI-driven research projects from a variety of disciplines. Income is generated on a cost recovery basis, which includes direct costs, 20% overhead fee (to partially account for the cost of equipment service contracts and replacement, air conditioning, electricity and computer services among others), and a 10% administration fee. In the past year (year 3), income from services to PIs has been 30% greater than anticipated (Table 5, see line 3). This is promising, but we need to ensure that the general biobanking arm is further developed, promoted, and utilized. To encourage usage, the BCCHB will release specimens to national and international researchers, including industry, assuming all regulations are fulfilled. However local researchers have priority and are provided access to specimens at a discounted rate to stimulate research on our campus. Our costing model reflects the type of organization receiving specimens and whether any in kind contributions have been made.

At the time of entering year four of operations, the financial status of the BCCHB is on track as predicted (Table 5, year 3, line 15.). The operating capital in year 2 (Table 5, line 12) is significantly higher than predicted but this is offset by the low operating capital spent in year 1, and is due to the timing associated with invoicing for initial purchases and renovations. A major challenge for the coming years is acquiring supplementary grants, as biobanks are often not eligible for research grants for basic operations.[22,23] This element of our planning may have to be reconsidered.

Ethical considerations

Ethical sustainability is very important and our biobank emphasizes education, information, and transparency. Unfortunately, we have not been able to significantly reduce

Table 5. Predicted and Actual Expenditure for Year 1–3 of BCCHB Operations

Line #		*Predicted year 1—2013/2014*	*Actual year 1—2013/2014*	*Predicted year 2—2014/2015*	*Actual year 2—2014/2015*	*Predicted year 3—2015/2016*	*Actual year 3—2015/2016*
1	Income						
2	BC Children's Hospital Foundation	2,660,000	2,660,000	1,671,500	2,517,827	1,387,500	1,719,133
3	Services	—	—	16,000	17,555	35,000	48,536
4	Other revenue				2,594		4,043
5	Research institutions	—	—	—	—	—	—
6	Grants	—	—	25,000	—	50,000	—
7	Total	2,660,000	2,660,000	1,712,500	2,537,976	1,472,500	1,771,712
8	Expenses						
9	Operating—personnel	182,000	85,380	241,000	174,200	291,000	391,789
10	Operating—laboratory	22,000	1,128	26,000	16,236	26,000	36,018
11	Operating—administrative	72,500	54,198	49,500	43,895	31,000	16,960
12	Operating—capital	637,000	1,464	8,500	572,913	—	31,861
13	Capital—administrative	75,000	—	—	11,599	—	2174
14	Operating total	988,500	142,170	325,000	818,843	348,000	478,802
15	Year-end balance	1,671,500	2,517,827	1,387,500	1,719,133	1,124,500	1,292,908

All funds are in Canadian Dollars.

consent burden or the number of specimen collections from patients, critical to the ethical component of our mandate. However, the presence of the BCCHB has improved access to specimens for researchers who previously did not have access. Provisions for the custodianship of the specimens have been created with the REB and legal representatives of our institution in the event of Director relocation or other similar events. In this scenario, all specimens and data in the BCCHB are to remain on campus under the guardianship of the leadership on site. To allow for continued buy-in from participants, we continue to actively educate and inform the public about all aspects of biobanking. Transparency to all stakeholders of the biobank, including participants and researchers, is a key component for sustainability of any biobank. It will take patience and trust to change the mentality among researchers and physicians, but our KPIs (Table 4) suggest that services of the BCCHB are increasingly utilized.

Performance

Good governance and management help to define the roles and responsibilities of the biobank and staff associated with the BCCHB, ensuring awareness of best practices and ethical conduct. We have high recruitment rates and positive relationships with patients and healthcare staff. To further our knowledge with regard to patient's opinions about the BCCHB, we have conducted surveys among our participants with favorable responses, suggesting that our participants have trust in the mission of the BCCHB as well as the BCCHB staff and operations.[24,25] Overall, we have built a reputation for the BCCHB of a good quality and transparent biobank with high participation rates.

The PI-driven arm of our operations has not only given rise to income but has also served as a marketing strategy. While PIs maintain some level of control, they have become aware of the benefits of the BCCHB such as the recruitment and consenting of participants, high-quality specimens, secure storage, and easy access. This has resulted in word of mouth advertising and increased use of the BCCHB by other PIs. In addition, some PIs have now chosen to use the general biobank for their future studies.

Deviations and contingency

Staffing costs remain the highest cost to the BCCHB. We had not foreseen the extent of the need to program and customize the BCCHB database. To allow the hiring of a database programmer, we reduced management staffing after completion of the processing laboratory. In the business planning phase it was projected that the BCCHB would need a 0.5 full-time employee (FTE) bioinformatics specialist, and that a 0.5 FTE database technician would be provided in kind by the research institute. The research institute felt that they could not support ATiM in kind and the 0.5 FTE budgeted for the bioinformatics specialist was not sufficient to maintain the database at the level required for our biobank. The administrative manager now manages all staff and operations and a senior laboratory technician oversees daily laboratory activities.

Contingency planning is a key component of sustainability for all biobanks. Unforeseen circumstances such as natural disaster or financial disaster must be considered and planned for. Although there is no set percentage recommended as a contingency for biobanks, the BCCHB chose to allocate $20,000–$30,000 of their budget per year

to a contingency fund for operating costs in the event of unforeseen circumstances. An emergency preparedness plan has been developed to help plan for natural disaster and reduce the extent of loss of specimens, damage to facilities, and loss of income. Contingency plans for all aspects of the biobank should be part of the overall governance plan and should address the handling and disposition of biospecimens in case of loss of management, termination of funding, depletion of biospecimens, and/or discontinuation of participation by human research participants. In the unfortunate event of closure of the BCCHB, the REB and the Biobank Oversight Committee will meet to determine what should happen to the specimens and data that are held within the BCCHB. BCCHB participants will be informed of the decision and will be given options with regard to the handling of their specimens and data.

Conclusion

As others have previously stated, business planning for biobanks is critical[2,26,27] for the start up of a biobank. For new biobanks, the time and patience to develop an adequate specimen and data inventory as well as trust with potential biobank users are needed. In the last 6 months, there has been a significant increase in awareness and use of the BCCHB as shown by the number of specimen requests. The framework that the business plan has provided is invaluable and despite deviations, it allows us to assess our mandates and financial situation and adapt, plan for, and address unexpected situations. We are confident that the BCCHB can become a key player in the provision of biospecimens for national and international research projects.

Currently, there is no systemic approach to rate biobanks.[15] However, there is growing discussion that specimens should only be used in research when obtained from a reputable biobank, and that to standardize biobanks there is a need for accreditation.[28] The BCCHB is a registered and certified biobank under the CTRNet program.[29] The registration portion of this program is soon to be a requirement for biobanks across the province of British Columbia, Canada. CTRNet certification is a requirement to obtain funding from several health research funders in Canada.

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Author Disclosure Statement

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