

What Are the Biggest Challenges and Opportunities for Biorepositories in the Next Three to Five Years?

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ONE OF THE MAJOR challenges for modern biorepositories is gaining visibility and recognition as professional infrastructures and service providers, in front of national regulatory bodies, institutional review boards (IRB), data protection authorities, research funding organizations, and the diagnostic and pharmaceutical industries. This recognition is necessary to ensure biorepository-specific law texts and IRB and data protection guidelines are drawn up, and to attract public and private funding. All the above elements and especially the last are necessary for long term biorepository sustainability. There are two ways to ensure this:

1. By the development of rules for appropriate public institutional support and funding of biorepositories as long-term research infrastructures (and not as appendices of specific and finite research projects). Such rules can only be based on an objective assessment of each biorepository's organization by an independent third party, in the context of a certification mechanism. The opportunity lying ahead of us now is the development of an appropriate international certification scheme covering all human, animal, plant and microbial resources.
2. By the development of incentives for researchers and industry to use biospecimens from professional biorepositories. One opportunity here is the development of strict publication rules for authors about the disclosure of the origin of biospecimens used in the research studies. A second is the development of new rules for the regulatory approval of *in vitro* diagnostic tests and therapeutic agents, pertaining to the origin of biospecimens used for validation, where an appropriate, general certification mechanism as referred to above would be of immediate relevance.

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OVER THE NEXT 5 years we are likely to see a large increase in biospecimen repositories due to increased publicity and the efforts of Carolyn Compton and the NIH's Office of Biorepositories and Biospecimen Research (OBBR). The biggest challenge to these banks will be the definition of standard operating procedures (SOPs) that optimize collection, without compromising patient safety by compromising the pathologists' ability to provide a complete and comprehensive diagnostic report. Although efforts are underway to produce measures to evaluate tissue quality with respect to RNA and protein integrity for future molecular research and diagnostic testing, these efforts have not yet provided guidelines to shape the collection SOPs. As a result the repositories may be compromised for some assays. However, if we think broadly about collection strategies, and include a range of specimen collection methods in the SOPs (like core needle biopsies or FNAs prior to vessel ligation), there is an opportunity to collect small "control" specimens that may allow larger specimens from the same lesions to be assessed or normalized for pre-analytic changes.

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BIOREPOSITORIES HAVE EVOLVED in many forms to address the diversity of research questions. Looking back at one subset of biorepositories, human research biobanks, these have existed in primitive forms for perhaps 50 years or more without much discussion of needs or challenges, until recently. This is partly because of small scale and complexity of use in research, and public engagement in science. In the late 1980s these factors changed. As a result, first generation biobanks emerged and evolved, that for the most part had designs that were reactive to the simple demands for increased numbers of biospecimens and improved oversight. Research demands have now driven the emergence of second generation biobanks since the early 2000s with improved operational designs to address biospecimen quality through standardized processes and annotation. As biospecimen science highlights the importance of pre-analytical variables, third generation biobanks incorporating annotation of these factors are emerging.

All generations of biobanks face the familiar challenges of improving design with limited resources, and making decisions around predicting the tissue preservation format of the future (as frozen format needs decline, live cell needs re-emerge, and FFPE format needs rise) and the most important biospecimen variables to document. Achieving this balance of offering biospecimens that are linked to current practice and treatment, but at the same time are linked to sufficiently mature outcomes data, is necessary to best serve research in any era.

The major challenges remain quality and capacity and oversight requirements to serve research. The response to date has mostly centered on “internal core” solutions at the level of biobank design and operation and more recently on “top down” solutions above the level of individual biobanks. The latter serve to identify and disseminate standards and link biobanks, through creation of networks, grids, associations and societies. What has largely been missing is the development of “bottom-up” complimentary solutions to fully meet the challenges. Networks of standardized biobanks only partially address the components of these issues that lie “upstream” of biobanks in the chain of stakeholders. What is needed are new frameworks within regions to connect donors and clinical biospecimen sources and biobanks more effectively. These frameworks are called biolibraries to distinguish them from biobanks and the latter’s core business around targeted accrual, processing, annotation, storage, and determination of release of biospecimens and data for research. The core business of a biolibrary is to develop improved biospecimen collection to serve biobanks across health regions and overcome geographical, jurisdictional and other barriers to biobanking. Biolibraries are needed to focus on processes to collect biospecimens to potentially distribute to biobank users, to connect potential donors associated with these biospecimens with biobanks for consenting, and engagement of the public and patient donors around these processes to develop transparency of purpose and process, enhanced governance models. Biolibraries connect biobanks in a different way from networks. Ultimately both contribute to improved confidence, recognition, and support for biobanking. The latter in particular requires increased recognition of the contribution of biobanks as producers rather than static foundations of research advances and distant value to achieving better health care within society.

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THE KEY TO the impact of biorepositories in next three to five years is the development and application of our discipline: “biosample science.” In any discipline that is emerging, the challenges should be seen as opportunities.

First and foremost, biosample science requires a sound evidence base. We know that to date, this evidence base has been patchy and sometimes contradictory. However, Biobanking and Biomolecular Resources Infrastructure (BBMRI—www.bbMRI.eu) in Europe and the recent launch of the Cancer Human Biobank (CaHUB—<http://biospecimens.cancer.gov/cahub/default.asp>) as a national U.S. initiative (with multinational input) both incorporate systematic approaches to biosample scientific evaluation using multiple research platforms and are likely to be the best and probably the only opportunities the discipline will have in the next five years. The costs of such initiatives are enormous. Funding of our individual biorepositories will continue to be a challenge, and we will all be seeking resource through public and/or private routes. The guarantee for future funding will require as a minimum, the evidence base for “quality, fit-for-purpose” biosamples in our biorepositories.

Biosamples have research value not just as a result of their integrity but also from the clinical data that is associated with them. Advance in information technology (IT) is on the agenda of every healthcare institution and agency. Biorepositories stand to be secondary beneficiaries and it does not appear that we are in a position to influence clinical data IT developments significantly. However advances in biorepository organization, standards, quality management and bioinformatics are within our control and will be expected to gain wide international acceptance and application in the next 3–5 years.

The challenge is a competitive biorepository environment; the opportunity is a shared network.

Over the next five years the regulatory environment is likely to mature and we must ensure that biosample science is engaged in the process. It is now timely for a review of some of the associated ethical issues, for example: consent (opting “in” or “out”), sample ownership and control, sample and data sharing, payment (including defining “not-for-profit”). New technologies such as (adult and fetal) stem cell utilization and rapid whole genetic sequencing provide additional ethical and also legal considerations.

The biggest opportunity can be to engage our patients and the public about what biosample science can mean to them. Today’s biomarker research is tomorrow’s diagnostic test and in a recent article in the *New York Times* a patient shares in the uncertainty of an established tissue diagnostic test, the results of which depend, at least partly, on sample handling (<http://www.nytimes.com/2010/04/20/health/research/20cancer.html?ref=research>).

In the biorepository community, everything we do with human biosamples is ultimately to benefit that subpopulation of the public, the patients. They can be the greatest advocates for biorepositories but they will also want to see the biosample science evidence base.

Some biomarkers of human disease, for example blood pressure or standard radiological response evaluation criteria in solid tumors (RECIST), do not require a patient sample and the major challenge for biorepositories will be when all disease biomarkers can be measured in the patient—the stuff of Dr. “Bones” McCoy in *Star Trek*. But for the foreseeable future and even with the continuing rapid advances in science, medicine, and technology, biorepositories are the appropriate focus for the facilitation and provision of essential *ex-vivo* tools research into human disease.

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Biggest Challenges

Best practice may not be good enough

CURRENTLY, the emphasis in biospecimen collection is standardization of pre-analytical variables. For example, there is an emphasis on noting and controlling the ischemic time for a tissue being harvested for preservation. An impressive list of factors (principally surgical and pathological) has been identified, and the hypothesis is that controlling and specifying these factors will enable collection of high quality biospecimens. However, it is also possible that even if all of these elements are controlled, we can still end up storing uniformly poor quality samples. This likelihood results from the fact that current methods for processing many biospecimens fail to use best practices common to other fields. For example, plasma is routinely collected and placed in -80°C freezers for storage, principally of protein biomarkers. There is a considerable body of scientific work related to preservation of therapeutic proteins and drugs. None of this knowledge has been translated to the biobanking field and to the preservation of biospecimens such as plasma. A major challenge for the biospecimen community will be to integrate preservation knowledge from other fields to the preservation of biospecimens to improve quality.

Biobanks will be challenged by increasing financial pressures

Collecting and processing biospecimens can be very time consuming and labor intensive. For example, mononuclear cells (MNCs) from patients are one common biospecimen, and a small fraction of these MNC isolates may be thawed and then immortalized using Epstein-Barr virus and then the immortalized cell line frozen (as a future source of DNA). The entire process including isolation of the MNCs, freezing, immortalization and then freezing of the immortalized cell line, is labor intensive, time consuming and as a result, expensive. Capital costs (mechanical freezers or liquid nitrogen storage units) and recurring costs (electricity and/or liquid nitrogen) for long-term storage of biospecimens will continue to grow. Biobanks are also being asked to collect not only an increasing array of biospecimens but biospecimens from representative populations for a given disease/disorder; resulting in further increases in the total number of biospecimens stored.

Biggest Opportunities

The biggest opportunities in biospecimen collection result logically from the challenges described above.

- Scientists involved in biomarker discovery can team with preservation scientists to develop preservation protocols for biospecimens that reflects the state-of-the art in preservation science. These protocols can then be used to accelerate biomarker discovery.
- Technology can be developed to reduce time and labor involved in biospecimen processing and also improve biospecimen quality.

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FIRST, IT IS IMPORTANT to stress that human tissue is donated voluntarily for the purpose of enhancing the understanding of human diseases, and to support the development of safe and effective treatments for those diseases. Donated human tissue should not be considered as being owned by a biorepository, and it must be understood that it would be unethical for it to exist simply as part of a private collection, or to support solely private research. As such, subject to reasonable availability, samples of materials within the biorepository should be readily available to all *bona fide* researchers upon submitting an appropriate request and of course, where necessary, reimbursing appropriate costs of recovery. *Eliminate the concepts of ownership and exclusive availability.*

In view of the diversity not only between, but also within human diseases, some degree of specialization may well be necessary in order to maximize the value of any biorepository. However, this should not encourage the proliferation of multiple limited biorepositories, but rather result in the establishment of a more limited number of organizations, each with a comprehensive content within a specialist area. And in order to maximize the value of biorepository-held materials, there must be a degree of consistency in the way that they are retrieved, processed, stored and transported. Ideally, this should involve the use of generally agreed SOPs. *Maximization of disease coverage and standardization of process.*

In order to recognize the heterogeneity within human diseases, any biorepository must attempt to acquire its samples from as wide a pool as possible, recognizing ethnic, cultural and lifestyle differences. To this end, greater efforts must be made to overcome or compensate for culturally and religiously related reluctance to donate. Furthermore, the value of any biorepository is not limited to the materials held, but is also in the information associated with those materials. Thus, annotation should be as comprehensive as possible, ideally incorporating details on genetic (expression profiling and presence of key gene variants), clinical (diseases and drug history) and other personal (age, gender, lifestyle etc) background. And particularly in the area of genetic profiling, the possible value of advances in genotyping technologies must be reflected in on-going improvements in routine annotation. *More adequate representation of heterogeneity within diseases and donor populations, accompanied by more consistent and comprehensive annotation.*

The value of effective infrastructure to serve all stages, from retrieval, through processing and storage, to delivery to researcher is essential, and again, as far as possible this should follow standardized procedures. And finally, there should be an efficient means of dialogue between researcher and biorepository, to ensure that research requirements are fully understood, and as far as possible, met. *Establishment of consistent standards for all aspects of retrieval, processing, storage and distribution.*

In order to achieve all this, it will almost certainly be necessary to establish an overall authority to approve standards and to accredit biorepositories, to ensure that adequate levels of performance and value are offered and maintained. *Establishment of an overall authority to set and maintain standards, and to provide biorepository accreditation.*

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Key Messages

- Open access to well- annotated samples and the challenges that poses to sustainability
- Open access to well- annotated samples and the privacy challenges
- Challenges are magnified due to increasing amounts of data of unknown quality

The field of biobanking is expanding rapidly. Powerful resources are being developed, and we must be able to maintain and sustain them. Data capture has increased by many magnitudes, and there is the potential for data to be entered from multiple digital sources (e.g., EHRs, PHRs, online patient questionnaires, provider-entered data, and medical devices and instrumentation). The influx of large amounts of data from multiple sources has the potential to increase the knowledge-base and utility of samples. To truly leverage the potential of these data sources, we must be able to connect them and integrate them with the biorepository. Siloed data will not further our research endeavors, and increased amounts of data are not enough. It is essential that these collections are appropriately curated and annotated. Missing, ambiguous, or misleading data sources will not only stall research, but in a worst-case scenario, can result in incorrect conclusions. We must accurately capture the necessary data points, focusing on controlled vocabularies and standards. We may also need to focus on specific areas of collection, such as pre-analytic variables, that may influence sample integrity.

Open access of these well-annotated collections will be key to moving research forward. However there are great challenges to sustaining open access to these well-annotated sample collections. Who will govern and steward the samples over the long-term? Who will ensure fiscal sustainability? How can we encourage the collection of data that maps to a standard for cross-study and cross-condition research? Privacy concerns will also emerge as participants are becoming more engaged in the research process. Participants have begun to ask, how will my data and samples be used? Can I be identified? How will decisions be made about future use? Protocols must be in place to adequately address these privacy concerns. Creating sustainable models that support open access to well-annotated collections and address participant privacy concerns are vital for continued advancement of the biobanking field.

Only when we all share our toys, and put as much information and resources into the precompetitive space, will we really make a dent in the challenges. This means we must find ways to build shared infrastructure systems, essentially uber-registries and biobanks. These should allow many models to be networked, and be standards based, in a learning system that encourages rapid iterative improvements.

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SPEAKING FROM THE POINT of a cancer biobank the biggest challenge is unfortunately finding financial certainty. While researchers wish to have access to high quality samples with detailed clinical annotation very few are prepared, or indeed able, to contribute even a small fraction toward the costs incurred in procuring these. Governments and funding agencies have for the most part failed to take a strategic approach that would lead to sustainability of resources which are increasingly being understood to underpin biomedical research. It is not a question of just handing out money though, it must be done to maximize benefit and perhaps it is time to review whether large scale external biobanks are the best method to obtain samples for some types of disease.

For cancer I believe that the major untapped resource is the routine pathology practice. However, a lack of real engagement by researchers to understand the needs of hard pressed pathology services coupled with no money available to provide incentives for them to co-operate, means that the largest biorepositories of human tissue lie largely unused. Pathology laboratories are ultimately a key player in delivering new medicines through molecular diagnostics and their place in underpinning the initial research needs to be better understood and ways to engage with them need to be developed.

Another area of concern is the very conservative interpretations of human research ethics guidelines that beleaguer biobanks and researchers. While no one would argue that ethical consideration of the intended work is unnecessary, the time has come to ask whether the present, largely adversarial system, really delivers a useful service. Given that most consumer groups demand that the research gets done, it is perhaps time to move to an opt in system that sees consent for research included on every consent to treatment document. Our experience of this in a busy colorectal cancer service suggests that there are no good reasons not to do it. Indeed, one may argue that this should be regarded as the standard of care since we don't have a "cure" for cancer yet.

Perhaps when patients and researchers get together to place into perspective the real risk of harm, mitigated by the enormous and obvious benefits of the research, and build a system that is ethical by design we can dispense with an autocratic and bureaucratic ethics framework that only pretends to protect people but in reality causes very real harm by its wasteful requirements. One can only dream....

Finally, a proper consideration of how to deliver the fruits of research in an equitable and fair manner must be undertaken in the very near future. There are substantial community concerns that researchers and in particular large pharmaceutical companies will make a buck out of their altruistic donation. Such public perceptions can snowball into considerable anti-research sentiment and we ignore this at our peril.

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WE ARE CURRENTLY in an “age of the biobank” resulting from opportunities presented by advances in science (particularly the focus on biomarkers and personalized/stratified medicine), enabling technologies, policy, funding, ethics and regulation. Despite this, significant challenges remain and jeopardize the ability of research using human biospecimens to make the impact it should.

Of the many challenges, perhaps the greatest because the solutions are less clear, is biobanking economics. Funders of biobanks (public or commercial) still have a clouded view of how much it costs to run a useful, successful and sustainable biobank. Lack of long-term investment; talk of unachievable concepts such as full cost-recovery and self-sustainability; and, a poor appreciation of the costs and the prices that need to be charged to users of the banks, continue to have damaging effects. Perhaps it will fall to places that are brave and rich, willing to invest sufficiently and for the long term, and who are willing to recognize that the returns on their investment are unlikely to be measurable in financial terms *directly* related to the biobank, who will make the greatest contribution long term.

Another challenge is to ensure that the biospecimens used in research are fit for purpose and the data generated from their analysis represent the biology of the sample/donor rather than artifact or confounding factors introduced during the pre-analytical phase. The problem is that the evidence base—published or unpublished—on the factors that critically affect sample integrity to the extent that they produce misleading results is thin. Instead, we do things because: we always have; a respected colleague advocated that approach; a technology vendor convinced us to do so; or because it was a financially affordable method. These are not approaches that can be maintained or they will result in wastage of many research \$s, £s or €s and lead to inappropriate conclusions that may endanger patients or provide missed opportunities on the back of erroneous research data. The opportunity—“*biospecimen science*.” This is highlighted in the United States by the National Cancer Institute’s Office of Biorepositories and Biospecimen Research (OBBR) and in a more limited fashion in Europe via the SPIDIA program. We need more biospecimen science and the challenge is how to fund, organize and produce a more robust knowledge base.

Biorepositories are only successful where people are willing to donate their samples and personal information. Indeed, donors can provide the powerful “push” required to solve some of the challenges. However, it is rare for biobanks to have anything other than rudimentary patient and public involvement programs. As a result, we do not harness the power of the donors nor do we work with the legitimacy of their full support, although we presume some legitimacy by obtaining their consent. We also do not maintain their connection with the biobanks or the research using the biobanks and we rarely communicate with donors in anything like a transparent and accountable way. The opportunity—better and more inclusive models of patient and public involvement.

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FOR BIOBANKS, in the near and long term the biggest challenges and opportunities are in many ways one and the same. Both involve the field's ability not only to continue to dramatically advance, but to harness its full potential via innovation to ensure actualization of impact. Towards this pathway a few key things will be incredibly important in fostering success: voluntary adaptation related to necessary cultural changes to further cement and centralize appropriate infrastructure either in instituting center of excellence/biological resource center, core facility and/or integrated biobank network models (in conjunction with tools to aide inter-operability, formal induction and evolution towards best in tandem with integration of evidence based practice preparation) as well as incorporation of biobusiness activities (i.e., cost recovery implementation and fit for purpose resource organization and resource evaluation). The ability for biobanks to embrace the changing perspective of viewing the biospecimen as a potential work product and provide focus on the life cycle, related process chain, and related pipeline planning will be hugely beneficial.

Post implementation, these key steps will then contribute to foster viability as well as long term sustainability while providing equitable return on investment. The collaborative theory will then be put to the test as biobanks transition from their current pre-competitive to the future competitive yet potentially collaborative environment. It will therefore be essential to demonstrate the "value add" of utilizing network tools, strategic alliances and private-public partnerships through proof of concepts pilots that offer shared equity and methodologies that categorize and aggregate sample collections, enhance overall quality of biospecimens and associated data and expedite collaboration aimed at discoveries which will ensure real time practice of molecular and personalized medicine such as those related to biomarker validation.

It will also be crucially important to disseminate experiential lessons learned and scientific data across scientific and professional transboundary disciplines to create a fully operational evidence based environment. This ability to achieve a transboundary educational, yet functional environment will succeed in reducing lags, roadblocks and related impediments that currently exist and may naturally occur along this pathway. In accordance with evolving biospecimen science, an additional challenge will be quantifying current "catch phrases" i.e., specimen integrity, benchmark specimens, and quality marker reference ranges. Ideally these should then all be implemented back into the process chain and biospecimen lifecycle management process ... All the while, this management process should be protected by solid vocal public and private stakeholder support secured by prospective integration of appropriate policy and governance structures, which I believe will be the biggest challenge and opportunity of all.

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THERE ARE SO MANY big challenges facing the broad range of biorepositories and it is hard to say which are the biggest. At one end of the spectrum, there is the holy grail of cryobiology, which is to be able to store cells and tissue at low temperatures without any long-term effects on their integrity, function and viability. Then there is the need to define evidence-based standards and identify biomarkers of decay in biospecimen research. There is the need for well-trained staff to run repositories and provide high quality samples. There is the need for well-equipped, environmentally-friendly biorepositories with long-term funding. There is the need for harmonization and networking to allow sharing of samples. There is the need for legal and ethical frameworks that will protect the interests of donors and facilitate exchange of samples. And there is also the need for outreach efforts to ensure continuing public support.

As with the challenges, there are also many opportunities. However, there is one big opportunity that stands out. That is the opportunity for all subgroups of the biobanking community to work together in a coordinated and effective manner, in order to overcome shared challenges. This will allow us to avoid duplication of effort, to share resources including samples, equipment and brainpower and to progress more rapidly. To achieve this end, we need good communication. Much has been achieved through societies, networks and other organizations in biobanking, which provide various communications *fora* including face-to-face and virtual meetings. However, a very real problem is that these multiple organizations can easily become multiple silos. To avoid this happening, the different organizations must take every opportunity to communicate and work together. One approach would be to have a single journal that is shared by the whole biobanking community, making it

possible for information and ideas to spread rapidly between our different subgroups. This journal, *Biopreservation and Biobanking*, has the potential to serve this purpose.

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TRADITIONAL BIOREPOSITORIES may benefit from emerging “commercial biobanks,” which offer economical, off-site, highly controlled, and monitored storage facilities for all types of biological matter, including cryogenic storage of living material. Biotechnology and biopharma industries also stand to benefit considerably from such services. The biotech/biopharma sector relies extensively on the maintenance and preservation of cell lines or tissues as feedstocks, expression systems, cytotoxicity platforms, or in the case of biological therapeutics, finished products. Off-site storage of products in facilities that are equipped with the appropriate redundancies to avoid damaging thermal excursions that impact cellular function can help protect these valuable assets. The horror stories of expensive therapeutics that have been discarded or inappropriately administered due to a misstep in the cold chain are certainly far too numerous for us to continue with the status quo. The challenges associated with storage and delivery of cells and tissues in industrial biotechnology settings represent good opportunities for new business models and revenue streams for commercial biobanks.

While the current environment provides excellent opportunities for companies in the biobanking business, and continued growth is expected to parallel growth in existing and emerging biotechnology markets, future cost trends need to be considered. Cryopreservation has enabled the maintenance of cell function during storage and distribution of biological products, but even with expertly monitored storage and transport, and the associated economics of scale, the add-on cost of cryogenic storage remains an issue. To remain competitive as markets saturate, commercial biobanks should aggressively pursue opportunities that reduce the cost of biobanking. For long-term commercial viability it will be increasingly important to explore biobanking modalities that are less energy-intensive and to continuously invest in high-efficiency storage devices and infrastructure as these technologies advance. This is especially true as the United States and other countries enact climate change policies that are likely to affect the future cost of electricity, and inevitably the cost structure of commercial biobanks.

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