

# In My View

*In this opinion section, experts from across the world share a single strongly held view or key idea.*

*Submissions are welcome. Articles should be short, focused, personal and passionate, and may deal with any aspect of laboratory medicine. They can be up to 600 words in length and written in the first person.*

*Contact the editors at [edit@thepathologist.com](mailto:edit@thepathologist.com)*

## Taking the “Bank” out of Biobank

**Users agree that biobanks aren't delivering – but what's wrong, and how can it be fixed?**



*By Vanessa Tumilasci, Project Management and Communications, Trans-Hit Biomarkers Inc., Laval, Canada*

Dominic Allen's article (1), “A Failed Model,” highlights some of the reasons why biobanks are failing to provide the services for which they were designed. From the other side of the table – as users of biobanks, rather than administrators – we agree on many points.

One particular area of concern for us is the number of samples sitting unused in biobanks. Patients who donate tissues for research purposes expect their samples to benefit others in the future. They would likely be unhappy to learn that their samples had not been used – or, in some cases, are even under consideration for disposal! Too many biobanks are still proud to advertise the number of biospecimens they store – but this is an inappropriate measure of how good they really are. Donors provide their samples to biobanks to be used in research, not to be stored for an indeterminate amount of time. The saying “a good biobank is an empty biobank” refers to the continual distribution of collected samples for use in research to improve healthcare. Samples that just sit in a biobank and are not used

do not fulfill their purpose. Hence, the efficiency should be evaluated by ratio: the number of stored specimens relative to the number of used and shared specimens. By that measure, a good biobank would be an empty biobank.

But even the phrase “biobank” itself has pitfalls. Referring to a biorepository of samples as a “bank” conjures up the wrong image. A bank protects your assets from being stolen by others, and eventually, may even help to increase those assets. But is this really what patients want for their samples? In our view, patients deliberately donate their tissues for “the greater good.” They aren't seeking to help only themselves, or one or two others – they want to give all scientists, public and private, the resources needed to move medical research forward.

The other problem with the “bank” concept is that such repositories should not be intended for long-term storage – a specimen's intrinsic scientific value may decrease over time. All in all, the word “biobank” is a poor term; we recommend that those involved in biological specimen storage develop other terminology.

In his keynote address to attendees of the 2017 Global Biobank Week in Stockholm, Gregory Simon, Director of the Biden Cancer Initiative and himself a cancer survivor, suggested the term “trust.” The “bio-trust” receives the samples from the donors in trust that they will be used for the purposes to which the donors have consented. It then distributes the samples to research groups in trust that the samples will be used for the betterment of healthcare and to benefit society as a whole.

Finally, we believe that biospecimens should be accessible to and shared by all scientists, whether public or private. The biotech and pharma industries are certainly among the biggest end-users of such specimens. However, as confirmed by two recent surveys (2,3), the respective requirements and expectations of biobanks and their industry clients are often not

aligned. For instance, 89 percent of companies consider existing collections in academic biobanks to be underutilized and the biobanks themselves unable to respond to their R&D needs.

To maintain the automotive analogy of “A Failed Model,” the technology improvements applied to Formula One cars aren’t reserved only for those specialist vehicles. They help all

automobile manufacturers improve the safety of today’s cars. In a similar vein, the benefits of industry biobanking aren’t just for industry users themselves; in fact, we would say that they are crucial to the ultimate goal of putting the patient first!

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## A Failed Model

**We need biobanks to operate efficiently and successfully – and that means taking a lesson from an unlikely source: the automotive industry**



*Dominic Allen, Chief Operating Officer of the Integrated BioBank of Luxembourg, Luxembourg*

I have to agree with the point made in “Curating Pathology’s Future” (1) that, right now, biobanks are not providing the service they are designed to deliver.

As a member of our Society had the courage to say, “Ours is a failed model.” We are loading biobank freezers with samples that will never be used. What better illustration than the seemingly desperate offer of “samples for free” (2) from a European organization representing a list of prestigious biobanks? In the past, we griped that no one was willing to pay the true value of our samples – and now we have to give them away. What happened?

Medical research in the era of personalized medicine is based on the analysis of samples with clinical data – and, because the associations are often weak, we need these samples in large numbers. TIME’S March 2009 cover feature (3) reinforced this idea by declaring biobanks one of the “10 Ideas Changing the World Right Now.” It was clear to everyone that the more samples were available, the faster research would advance and the healthier we would be. At the same time, there would

be more recognition – and therefore more funding – for biobanks. We had also learnt that the value of a sample goes up with time, because we are able to look back at samples from previously healthy patients, potentially opening the door to discovering predictive biomarkers and heading diseases off at the pass. So, naturally, we launched large population cohorts to amass as many samples as possible. Now there are perhaps 100 million samples in stock in Europe and no one seems to want them – at least, not in numbers that justify the cost of collecting and storing them. Why?

It’s not about the money. The prices are taxpayer-subsidized – and, as any biobanker will tell you, when an impoverished researcher can’t afford to pay for samples, he gets them anyway.

The problem with biobanks is analogous to one that troubles the research world as a whole. Research output is notoriously difficult to evaluate, so funding bodies tend to use simple measures, such as numbers of publications, to evaluate research centers and allocate future funds. It’s no wonder that we now have a tsunami of publications, many of piteous quality. For biobanks, one of the simplest measures of “success” is the number of samples in stock – and we have a biological sample mountain! Number in stock has become the virility symbol of the biobanking

*“When an impoverished researcher can’t afford to pay for samples, he gets them anyway.”*



world: “Mine’s bigger than yours!”

But we are confusing two value models. We need to learn from now-successful industries that, 40 years ago, were where we are now.

The first model is that of vintage wine, which appreciates in value over time. Cohort samples, too, appreciate over time. But what proportion of samples and data used for research actually need to be longitudinal? Five percent? Ten? We are fusing the vintage wine model with the conviction that more is better to justify building up massive stocks of samples, most of which do not need to be aged. We mix up the need to have longitudinal samples – true for a small fraction of research – with the need to have a large stock from which to satisfy any specific demand. We delude ourselves that, if only we could have enough in store, we could supply all demand from stock. We fail to see that there are so many variables in a sample that, to have one that corresponds to a specific need, we must have hundreds or even thousands in store. And the delusion suits us, as it justifies the need for massive inventories and comforts our funding bodies on the road to approving big budgets.

That brings me to the second model: cars. Some readers will remember the good old 1960s and forecourts full of new cars for sale. You went to the garage, looked for the car you wanted, rarely found the combination of model, color, engine, and options you had hoped for, and bought a compromise. When did you last see a forecourt full of cars for sale? Every automobile manufacturer has now adopted the Toyota revolution of the 1970s and there is, to a first approximation, no more stock. Instead, you get the car you really want in a matter of weeks, made to order.

Stock is waste. It costs money to store; it degrades; it becomes obsolete; and it is discounted or discarded. It’s often the result of processes with high setup costs and times. And stock in a process provides a buffer that

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masks operational inefficiencies and poor quality. Eliminating stock, producing to order, delivering when needed: this is basic manufacturing good practice. But what is its relation to biobanking?

All signs point to the same problem. Storing samples costs money; samples degrade at  $-80^{\circ}\text{C}$  and FFPE tissue samples at room temperature; they certainly become obsolete (who wants old samples without pre-analytical data?); and we are already seeing discounting and discarding of collections. Setting up ethics and Data Protection Authority approvals, sponsor, PI, clinicians, contracts, CRF, collection kits, LIMS and logistics can take a year. Longitudinal cohorts will remain a “vintage wine” business, but they represent a minority of the samples actually needed for today’s research. It’s time to look at the two models we use for collecting non-longitudinal samples – “open collection” and “project collection” – and see how we can do better.

In the open collection model, we store samples today hoping they will correspond to tomorrow’s needs. It provides the advantage of samples immediately available to researchers, but suffers from the same crippling disadvantages as the 1960s car manufacturing model and most biobanking today – uncontrolled stocks. Researchers seldom get exactly the samples they want; biobanks have high

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*“In our zero-growth research budget world, the choice is to collect smarter or not collect at all.”*

storage costs and high levels of waste. And there is a further hidden cost: the cycle from production to client feedback is long and the voice of the customer faint. If we produce stock today, it might be years before customers tell us that our quality does not correspond to their needs. If, in a few years, the focus of medical research moves to metabolomics and proteomics, we will simply throw away today's stocks as not fit for purpose.

The project collection model, in which we collect to order for specific research work, should produce the samples needed, but involves high setup costs and long lead times. Nonetheless, this is the way the whole biobanking business needs to evolve. So how can we dramatically reduce the setup times and costs of this model? And how can we collect fast enough to avoid delaying research? The answer lies in trusted collection networks and broad, ongoing ethics approval. The goal is to form small, flexible, ad hoc groups of biobanks for each sample request, based on the type of sample and the difficulty of collection. Biobanks should build up their own networks – preferably local – of others with ethics approvals, similar validated protocols, compatible quality standards and quality control, common data items, pre-agreed Material Transfer Agreement formats and pricing structures, and solid personal relations.

This is not a model suitable for centralization. Requests will continue to come to biobanks, and the responsibility to deliver will always lie with a biobanking institution. Clients want to deal with the “factory,” not the intermediary, and prefer a single contact point. The model provides for this: one lead biobank (which is compensated for project management) establishes the precise need, checks the feasibility in its network, takes on the contract, establishes the ad hoc collection group, coordinates the project, and provides the point of contact. It's a self-organizing system that can start tomorrow. Each biobank establishes its own network and independently markets its own capabilities. Quality standards between biobanks will naturally converge as clients preferentially do business with those offering the price and quality they require, and eventually, international bodies will formalize these standards for the benefit of all.

The “vintage wine” collection model has a different challenge. By definition, population cohorts generate stock – but we can improve the depressingly low utilization rates by reducing the stock needed to provide a given number of samples, rather than by artificially boosting usage rates. One way to do this is to focus cohorts on specific disease domains and enrich enrolment by consciously biasing recruitment towards those with risk factors. This may be anathema to “no-hypothesis” epidemiologists, but in our zero-growth research budget world, the choice is to collect smarter or not collect at all.

To criticize the current collection model is not to question the importance of biobanks – just as criticizing car manufacturing practice is not questioning the importance of the automotive industry. Biobanks are indispensable to medical research and they need to be funded. The evaluation criteria on which to base

funding remain a challenge – but at least let us replace number in stock with number distributed, or ratio of stock to distributed, and introduce a way to measure service.

Let us conclude with a thought experiment. If there are 100 million samples in stock in Europe, and medical research projects each consume 100 samples, take three man-years, produce two publications and cost €500,000, then using up the samples would require a million research projects, occupy three million man-years, generate two million publications, and cost €500 billion. Don't ask who would read – let alone peer review – those publications, but at least the funding bodies would be happy and the funds would continue to flow!

*A note on biobanking and business: This “In My View” article uses business vocabulary and logic for the simple reason that we are dealing with an exchange in which some parties supply products and services others wish to use, money changes hands, and the user has choice. This is the definition of a competitive marketplace. But we must remember that the object of the exchange is personal biological material donated by altruistic individuals and covered by legal and ethical constraints. The use of business language in no way detracts from this – but for everyone's good, we need to identify and use the operating model that most efficiently matches supply with demand and reasonably covers costs. Medical research depends on it, and business language can help deliver it.*

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