# Emerging Markets and Technologies in Biobanking

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**Becca Battisfore:**

Welcome to the latest edition of the College of American Pathologists' CAPcasts. I'm Becca Battisfore, a content specialist with the CAP. In this episode, I'll be talking with Dr. Jim Vaught about the new era of biobanking. Before we get into the questions, let's learn more about our guest. Dr. Vaught, please tell our listeners a little about yourself.

**Dr. Jim Vaught:**

Okay. I've been involved in the field of biobanking for about 25 years. My most recent full-time job was at the National Cancer Institute as Chief of the Bio Repositories and Biospecimen Research Branch. I've also been the editor of the journal Biopreservation & Biobanking for 10 years. I retired in December 2022 from that, and now I do a little bit of consulting and I serve on some advisory boards and I'm on the CAP Biorepository Accreditation Committee.

**Becca Battisfore:**

Great. So biobanking of human biospecimens has a long history. In the last two decades, a number of best practices have been developed, resulting in better-quality specimens, and we're now entering an era where new markets and technologies will result in new approaches to collecting, processing, and storing these samples. So I'm so glad to have you on the podcast today so we can talk about what's on the horizon. But first, let's start with the basics. How would you define biobanking and its importance in biomedical research?

**Dr. Jim Vaught:**

Biobanking, in terms of human biomedical research, involves the collection, processing, storage, and dissemination of biological specimens. Such specimens may include blood and blood products, urine, tissue, and specimen derivatives, such as nucleic acids. Any of the processes involved in biobanking may introduce factors that result in suboptimal quality of samples. The field of biospecimen research is devoted to studying, for example, variables that may affect the quality of samples. Some of these variables are the time between collection of samples until they're processed by a pathologist or technician, the temperature at which samples are processed and stored, drugs the patient may have taken prior to surgery, and many other such factors. Since biobanking is critical to the success of translational research and precision medicine, paying attention to the quality of samples is important to the ultimate success of any research program.

**Becca Battisfore:**

What is the importance of continuously developing new technologies in biobanking?

**Dr. Jim Vaught:**

Initially, biobanking generally involved pathologists collecting blood and tissue samples from patients and using the samples for diagnostic purposes. Over time, with the consent of the patients, pathologists and other researchers began to use samples to, for example, engage in studies into cancer biomarkers. Over the past decades, biobanking and biospecimen research have become more multidisciplinary. Now, epidemiologists, clinical researchers, molecular biologists, clinical chemists, and other specialists are engaged in biobanking and associated laboratory and clinical activities.

Although biobanking initially involved collection of blood and tissue, over time, many new specimen types have been introduced. These include, for example, saliva, hair samples to study drug exposure, toenails, ocular samples, circulating cell-free DNA, circulating tumor cells, and others. Note that, in addition to human specimens, environmental samples such as air and dust are often used in epidemiology studies to examine exposure to environmental contaminants. As new samples are identified, they require research into methods to collect, process, and store them under optimal conditions. The methods involved in collecting blood and tissue samples are often not adequate for newly identified specimen types. Such methods are published in various biobanking, pathology, epidemiology, and clinical chemistry journals.

**Becca Battisfore:**

Now let's talk about new developments and what's on the horizon. Can you share some examples of emerging markets and technologies in biobanking?

**Dr. Jim Vaught:**

The journal Biopreservation & Biobanking introduced a new emerging markets and technology section and an editorial in 2020 and published a special issue on these topics in October 2022. I'll discuss some of the topics introduced in those articles. Biobanking research has resulted in a new generation of technologies geared at providing direct-to-consumer solutions in emerging markets across the globe. Examples include services to help you better understand your wellness, personalized biome products, targeted marketing campaigns, new data security infrastructure, and much more. Direct-to-consumer genetic testing, such as 23andMe and AncestryDNA, provides people access to their genetic information without necessarily involving a healthcare provider or a health insurance company in the process. In the near future, biospecimen collection will be involved in integrative wellness monitoring, complete health production based on genetics and environment, old genome sequencing as early as six weeks into pregnancy, comprehensive molecular monitoring for many diseases and therapies, and point-of-care testing in doctor's offices, clinics, hospitals, and medical centers.

The special issue highlighted the varied scientific innovations within biobanking and provided insights on several aspects. In terms of collection and preservation of samples, novel devices have been developed, such as a small ultra-freezer constructed using a 3D printer. These are aimed at optimizing sample preservation from diverse biospecimens regarding sample cold chain and analysis. Examples include complete end-to-end sample management solutions that standardize processes, promote industry academic partnerships for full bioanalysis, as well as the emergence of a just-in-time biobanking model. Further advances are described in genomics and biobanking, the computational decision support of biobanking governance, and in the light-assisted drying of nucleic acid nanoparticles. Finally, a new subject is the decarbonization of biobanking. Examples of ways in which biobanking can reduce its carbon footprint are presented.

**Becca Battisfore:**

So given the current interest in artificial intelligence, how is AI being incorporated into biobanking practices right now and how will it in the future?

**Dr. Jim Vaught:**

An editorial in the journal Biopreservation & Biobanking entitled Readiness for Artificial Intelligence in Biobanking in April 2023 covered this topic. The editorial is freely available. I'm going to discuss some points made in that article and others.

AI has become integrated into medical and scientific practices, and AI program to screen for diabetic retinopathy by interpreting clinical images was successfully implemented in Thailand. A deep learning system was developed to interpret patients' images. The results showed that the deep learning system was equal to or better than retina specialist interpretations of the same images in terms of accuracy, sensitivity, and specificity. A survey of AI implementation published in the journal Diagnostics found that machine learning models can accurately assess an individual's risk and track the progression of COVID-19 disease. Machine learning models can be used to predict the risk of COVID-19 at various stages. Machine learning models may also predict hospitalization and ICU admissions based on COVID-19 risk. Machine learning models have also been used to estimate mortality risk and confirm cases based on COVID-19 samples obtained from the UK Biobank.

Some AI screening programs no longer require human oversight of clinical diagnosis. AI can decipher hidden patterns in data, build predictive models, and deliver actionable recommendations. AI will likely have significant positive impacts with the overall outcome of increasing specimen data utilization, greater repository sustainability, and increased speed of scientific discovery. AI has the potential to impact all areas of biobanking, from recruiting donors, improving biobank operations, developing educational and training materials for new biobankers, increasing sample use, improving data annotation, and faster deposition of ethically protected data. AI can draft text for consent documents and standard operating procedures. AI can also have an impact on accelerating the availability and analysis for large data sets, such as in the case of whole genomic sequencing.

**Becca Battisfore:**

What challenges or potential risks are there in integrating AI into biobanking?

**Dr. Jim Vaught:**

Data bias and AI parallels the traditional computer science concepts of garbage in, garbage out, in which inaccurate, erroneous, or absent input, these defaults are garbage output data, including actionable reports or decisions. Large, complex data sets are difficult to analyze. Developing AI models to analyze such data is not easy and usually requires human intervention to assure, the AI results are accurate. Although AI, as noted above, is expected to be useful in developing consent documents and standard operating procedures called SOPs, careful analysis will be needed to assure the resulting documents can be used as is. SOPs are often evidence-based, meaning that data has previously been published for the new procedure. Any AI model will need to be capable of locating any needed information and incorporating it into the new SOP. So generally, any AI model will need to be carefully vetted by biobankers, clinicians, and other researchers before widespread implementation.

**Becca Battisfore:**

So as we wrap up, is there anything else you would like listeners to know about biobanking or any resources besides the editorials you shared that you'd like to share for listeners to learn more about this topic?

**Dr. Jim Vaught:**

Over the past two decades, biobanking and biospecimen research have become recognized as complex scientific endeavors. The need to produce high-quality specimens for research collaborations has resulted in multiple best practices published by the International Society of Biological and Environmental Repositories called ISBER, the US National Cancer Institute, and other organizations. Such best practices outline recommendations for all aspects of biospecimen collection, processing, storage and distribution, quality management, information technology, and the ethical and regulatory aspects of biobanking. Such recommendations need to be constantly reviewed and updated as necessary based on new sample types and current research. The topics covered in this podcast are meant to highlight the need for biobankers and researchers to stay up-to-date. Besides the editorials that I mentioned, there are references to the National Library of Medicine survey about AI and biobanking and a study from Thailand about the retinopathy screening. Those references will be made available to you.

**Becca Battisfore:**

Great. Yes, I will include those with the episode. So I want to thank you, Dr. Vaught, for joining the podcast to talk about biobanking. And I want to thank you all for listening to this CAPcast. We'll have a link to the CAP's Biorepository Accreditation Program and the resources mentioned along with this episode in the show notes. For more information about the CAP, visit cap.org.