# Biobanking During COVID - Challenges and Opportunities Related to Infectious Biospecimens

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**Julie McDowell:**

Pathologists have long been at the forefront of biobanking practices, assuring that biospecimens from patients are properly collected and processed for diagnostic procedures. During the ongoing COVID-19 pandemic, pathologists and laboratory technicians have had to develop and implement new biosafety procedures to protect themselves and patients, and they're also often involved in research into new therapies, explained Dr. Jim Vaught, editor-in-chief of the journal, Biopreservation and Biobanking.

In this CAPcast, Dr. Vaught discusses the special challenges involved in developing protocols to work with biospecimens collected from patients during an infectious disease emergency, as well as the role that biobanks play in the development of COVID vaccines and therapies.

Dr. Vaught, from a historic perspective, how have biobanks been involved in responses to emerging infectious diseases?

**Dr. Jim Vaught:**

Biospecimen issues have long been important factors in handling the response to emerging infectious diseases. The US C D C has maintained a biobank for decades, and is found through analysis of its samples that infectious agents responsible for outbreaks such as the hantavirus and Legionnaires' disease were present years before the epidemics.

As noted in the 2008 report from the US Interagency Working Group on Scientific Collections, tissue samples from the 1918 Spanish influenza pandemic were used to determine that the origin of the virus was related to strains that commonly infected pigs and humans and not of avian origin, as had previously been thought. Studies of the 1918 pandemic and subsequent influenza outbreaks have been instrumental in vaccine research as well. The Ebola outbreak in Africa in 2014 to 2016 presented some unique challenges due to the high infectivity of blood samples. There were also security concerns that Ebola patient samples could be used for bioterrorism purposes.

These issues resulted in a series of meetings in Africa over the past five years to address biobanking during such outbreaks. The Global Emerging Pathogens Treatment Consortium known as G E T, which organizes these conferences, is as noted on their website working with international collaborators with a goal of providing strategic recommendations and establishing infrastructure and research capacity to respond to highly infectious emerging pathogens. In the case of COVID-19, influenza surveillance networks can test samples retroactively to distinguish between influenza and COVID cases. In the early days of the epidemic, there were some confusion between these diagnoses.

**Julie McDowell:**

Now, how has the international biobanking community responded to the pandemic?

**Dr. Jim Vaught:**

A recent article by Henderson et al in the journal Bio Preservation and Biobanking asked biobanking experts from North and South America, the Middle East, Asia, Africa, and Europe, to share their experiences during the pandemic. As is apparent from the reported experiences, the sweep of the pandemic across the globe has affected and continues to disrupt healthcare and biobank operations.

Many of the experts reported the interruption of care for patients in noncommunicable diseases and elective procedures, whereas testing care and treatment of COVID-19 patients were ramped up in their facilities. Several of the facilities redeployed staff from biobank operations towards collection and testing of samples taken from suspected infected patients. Most of the biobank experts noted that their operations were not prepared for this type and level of disruption on an operational and financial level. Biobank collections were halted in some countries or regions, whereas operations were moved to merely maintenance mode.

Supply chains for critical supplies and services were delayed or completely disrupted. Human resources were affected either by being unavailable due to the virus or being used in a different capacity within their organizations. Some biobanks were able to engage their operations in support of COVID-19 research by collecting, processing, and storage of patient samples and data for current research and for future use. Specific protocols were activated if available or modified to manage infectious or potentially infectious biospecimens based on standard precautions. A consensus is noted in that all the biobanks used or are using the COVID-19 pandemic as a learning experience for their staff and to modify their operational and business plans for future pandemics and crises.

**Julie McDowell:**

What are some of the biosafety considerations for biobanks during the pandemic?

**Dr. Jim Vaught:**

COVID-19 presents some unique issues in the biobanking world. The vast scope of the pandemic with over 50 million cases globally as of November, means that laboratories and biobanks are likely to be handling many samples involved in developing diagnostics and vaccines. The US CDC has published guidelines for handling COVID-19 samples. Some biobanks have developed their own guidelines, usually based on those of the CDC. For example, the University of California-San Francisco has published guidance for its biobank, which are publicly available. The CDC'S guidance regarding handling, storage, processing, and transport is as follows. The handling of specimens obtained from patients not known or suspected to be infected with a novel coronavirus SARS-CoV-2 does not require additional precautions beyond the use of standard universal precautions. Patients with known or suspected SARS-CoV-2 infection require the use of personal protective equipment for sample collection and handling.

Once collected, biospecimens should be moved to a Biocept level two or higher laboratory, and all specimen containers known or suspected of containing the SARS-CoV-2 virus should only be processed using a class two biological safety cabinet (for example, a HEPA filter). Aerosol-generating or droplet-generating procedures should primarily only be performed in either a certified class two biological safety cabinet or with the use of PVE as well as other physical barriers to reduce exposure risk. Isolation of the virus itself and cell culture and characterization of antivirals in SARS-CoV-2 culture should be performed only in laboratories that are at least in biosafety level three or BSL-3.

**Julie McDowell:**

What are the additional considerations for handling COVID-19 specimens and the major sources of practices developed, especially for such samples?

**Dr. Jim Vaught:**

As noted in response to the previous question, biosafety is a major consideration for biobank working with COVID-19 specimens. However, biobanks have been required to review their procedures for all aspects of sample handling, including collection, processing, storage, and distribution. Standards for the collection and sharing of data are also important.

To address these issues, biobanks have relied on prior experience in working with highly infectious specimens and referring to previously developed guidelines and best practices. The CDC, World Health Organization, [inaudible], and the International Organization of Standardization or ISO, are among the primary resources for best practices and standards. The publisher of Biopreservation and Biobanking, Marianne Liebert Incorporated, has made articles related to the current pandemic freely available. These articles address issues such as the allocation of equipment, economic impact, and other scientific and logistical topics. Also, a US NIH COVID-19 scientific interest group has been organized where interested parties can join in an online discussion and exchange information about research and resources.

An article in Biopreservation and Biobanking from the Louis Pasteur Hospital biobank in Nice, France, outlined how they reorganized facilities to protect personnel and to keep COVID-19 samples separated from the general biobank collections based on is per best practices and local French guidelines. Only the sampling and storage of blood specimens from positive COVID-19 patients were performed in these facilities, which excluded other collections. The facilities have three separate spaces, one with a desk for reception and registration of the samples, another with an airlock connected to a chamber isolated from the laboratory, and one corresponding to the laboratory itself for preparation of blood derived products and for storage of sampling tubes.

**Julie McDowell:**

Finally, Dr. Vaught, what are some of the biobanking considerations in the development and distribution of COVID-19 vaccines and other therapies?

**Dr. Jim Vaught:**

Many critical questions remain unanswered in relation to SARS-CoV-2 and COVID-19. It seems likely that many of these mysteries will only be further elucidated via the availability of high quality, large scale collection, storage, and analysis of patient specimens. Biobanks have played an important role in understanding prior disease outbreaks as well, and in the development of vaccines and novel therapeutics. In the case of vaccines, once they're developed, the logistical issues involved in distributing and storing the vaccine vials are critical. At least one of the approved vaccines requires shipping and storage at minus 80 degrees Celsius while another requires only refrigerator temperatures about five degrees Celsius. In any case, this cold chain process is familiar to biobanks, which are often required to handle samples and strict temperature requirements. However, it should be noted that small and regional clinical centers may not have access to the alter freezers needed for some of the potential vaccines.

Note that the Biomedical Advanced Research and Development Authority, BARDA, within the Department of Health and Human Services, has awarded a contract to provide centralized biobanking services for COVID-19 clinical specimens. Moreover, the development of novel therapeutic strategies, diagnostic assays, and vaccines will necessitate reliance upon patient biospecimens. One of the research needs for the development of vaccines has been the genetic sequencing of the virus.

In response to the needs of virus sequence data from the research community, the China National Gene Bank or CNGB established a virus portal through strategic cooperation with the global initiative on sharing all influenza data known as GISAID. Two vaccines have been approved by the FDA during December of 2020. The role of biobanks will continue to be important as COVID-19 cases rise while therapeutic solutions are developed and implemented in 2021.

**Julie McDowell:**

Thank you, Dr. Vaught. For more resources related to biobanking and bio repository, including the CAP Biorepository Accreditation Program, please visit cap.org and search for biorepositories.

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