

European, Middle Eastern, and African Society for Biopreservation and Biobanking (ESBB). 2012 Conference Session on Biobanking in Emerging Countries

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Introduction

THE EUROPEAN, MIDDLE EASTERN AND AFRICAN SOCIETY for Biopreservation and Biobanking (ESBB) held its second annual conference in Granada, Spain, in 2012. The Society was created to focus on issues of biobanking in the countries of its regional focus. This year, ESBB dedicated two sessions to the issues of Biobanking in Emerging Countries, focusing on countries of the Middle East and Africa. The sessions addressed Progressive Approaches and Inspirational Examples together with Challenges and Opportunities in emerging countries. Here we present a review of the presentations included in these sessions and the discussions that these presentations solicited from the ESBB audience.

Overview

Pasquale deBlasio presented an overview of the challenges of Biobanking in Africa as perceived from Europe.

Africa is rich in variety. It is considered the most biodiverse continent, in addition to being the cradle of mankind. It is the home of many endangered species and has many diverse populations such as Afro-Asiatic; Saharan; Sudanic; Niger-Congo; Khoisan; Indo-European; Malay-Polynesian. As such, it is the ideal location for the creation of biobanks intended to further research, both environmental and medical, as well as biobanks that can support measures to mitigate wildlife extinction and disease transmission. However, the development of a sustainable biobank requires a number

of elements including: institutional commitment; informed consent (ELSI); management and staff; infrastructure and facilities; specimen packing and shipping capability; information technology infrastructure; access to stored materials, and cost recovery policies; national and international harmonization and networking. How and to what degree these elements can be implemented depend on the environment in which the biobank is created. These are challenges for every biobank and more so in emerging countries.

The development and sustainability of a biobank involve a high initial cost, as well as high and continuous running costs. Initial development costs are significant obstacles to establishing new biobanks. International organizations (UN, WHO, foundations, etc.) usually finance research projects, but not infrastructure. H3 Africa (NIH and Wellcome Trust) is financing the realization of biobank infrastructure in Africa. However, all granting initiatives can only be short term. Medium and long-term sustainability is the largest problem. It is vital that institutional and governmental commitment ensures the sustainability of the biobank, but this may be undermined by political instability in emerging countries, and weakened by the difficulty of prioritizing this type of investment among many other unmet needs in biology and healthcare.

Ethical approval is necessary before using biospecimens in international research studies. This approval normally takes the form of an informed consent approved by local ethics committees in Africa. This informed consent delineates the permissions and relationship with the donor. The extent of the "informed consent" must conform to local legislation and it should be as broad as possible to avoid restricting research.

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In developing countries, there may not be local legislation establishing parameters of consent or use of samples and more importantly data. Where there is legislation, it may prohibit the use of samples outside of the territory. In some emerging countries unable to sustain extensive research financially, this is a challenge for collaborations. There may also be different traditions and cultures affecting an individual's interpretation of the consent request. Different social structures where the individual is part of a collective society or community may also affect the concept of individual consent. Even local language differences need to be taken into consideration.

In many aspects, difficulties faced in running a biobank reflect the overall defects in infrastructure, organization, and human resources of the healthcare system, the research infrastructure, and more broadly, of a country.

One of the most important elements of a biobank is managing operations according to specified, written procedures. This requires dedicated staff and management to guarantee the correct functioning of the biobank. In many countries allocating staff is a problem, and in emerging countries where staff may not be available to perform perfunctory tasks, providing sufficient and adequately trained staff may be a challenge.

There is already a considerable shortage of health care professionals, including pathologists, in emerging countries. Additionally, pathology services currently suffer from limited infrastructure (lab equipment, transportation, standardized sample processing). The latter could be improved by financial support, the former only by training new professionals (doctors and technicians) and preventing "brain drain." Since this situation is not restricted to pathology specialists, but extends to all fields of healthcare, one major goal for local governments is to provide facilities for local training and to make local professional activity more attractive.

Biobank workflow has a time-critical element of collection that is measured in minutes, while post acquisition and sample release may be measured in years. These time-critical elements may be more difficult to guarantee in situations in the field, and the ability to collect and document all pre-acquisition information may not always be feasible. Furthermore, transport infrastructure for efficient, rapid, and environmentally controlled transport of fresh and preserved materials may not be in place in emerging countries. This challenge provides an opportunity for innovative approaches, such as a preliminary proof of concept unmanned aerial vehicle designed to facilitate the transportation of microbiological test samples from remote rural clinics to National Health Laboratory Infrastructure and Facilities.¹

Public Perspectives and Perceptions

Michael Igbe addressed the particular issue of Public Perspectives on Biobanking in Nigeria, focusing on biobank informed consent, its content, and how well it is understood by donors being asked to consent for use of their samples and information in noncommunicable disease-related research.

Biological samples such as tissues, blood, and cells are increasingly important tools for research into human diseases and their genetic and physiological causes. A biobank was set up in Nigeria recently to collect samples for research

on noncommunicable diseases. This increased use of biobanking raises several ethical questions which have not been adequately explored in Nigeria.

Against this backdrop, it became pertinent to assess public knowledge, attitude, and willingness to participate in biobanking research and to gain the perspectives of Nigerians on informed consent, confidentiality, secondary use of samples and data over time, return of results and feedback concerning noncommunicable disease research, future research, and specimen and data sharing with other biobanks.² The study used qualitative research methods, and conducted 16 Focus Group Discussions and Key Informant Interviews with members of the general public in Kano, Enugu, Oyo States, and the Federal Capital Territory, Abuja. The study also addressed different religions (Muslim and Christian) and compared different areas and populations.

The results showed that a majority of participants had limited knowledge of biobanking research, but had good knowledge of noncommunicable diseases and were willing to donate their specimens for research. Although they understood that biobanking could have research benefits, they were not aware of all the implications and possible risks involved. While all participants were in favor of storage for future unspecified research, almost half of them wanted the right to re-consent and therefore selected restricted and tiered consent. Those selecting restricted and tiered consent did so in order to receive more feedback from researchers. Most participants permitted access to their medical records provided that confidentiality could be guaranteed, as there was concern for personal discrimination or stigmatization. They also did not mind sharing their samples, provided the research was ethical and did not conflict with their religious convictions.³

Overall, their concerns did not appear to differ from results from surveys conducted in western developed countries, although more in-depth analyses may reveal differences linked to culture and religion. Additionally, there was concern about the use of samples in international research, again for fear of discrimination or stigmatization. Most Nigerians saw an important role for their government in biobanking for research, particularly in safeguarding their interests when samples are shipped and shared with commercial and noncommercial entities.⁴

Pathology Resources

Rupert Langer presented the challenges of Biobanking in Low Resource Settings with regard to pathology requirements and the lack of pathology services.

Cancer in Africa has high mortality rates and has become a serious health problem. Knowledge about epidemiology, pathogenesis, and genetic makeup of cancers in the African population is scarce. This is of high clinical and scientific relevance because many African cancer types differ from their counterparts in the Western world. Moreover, there are significant relationships among infections, other conditions and cancer (including cancers resulting from HIV, HPV) which can only be determined by proper epidemiologic and laboratory (clinical lab and pathology) investigations.

Pathology plays an important role, not only in diagnostics but also in cancer research. However, provision of pathology

services is not sufficient, especially in sub-Saharan Africa. There are few laboratories that can provide constant surgical pathology services, and are sometimes facilitated by supporting programs, which aim to provide aid in diagnostic services, teaching, and improving infrastructure. Even when such services are available, cancer cases often present at late stages, and in many countries in sub-Saharan Africa, cultural norms do not permit surgical intervention at terminal stages of diseases, especially when a major reason is the collection of specimens for cancer research.

Many specimens that are processed and reviewed in African pathology laboratories represent malignant cases. The departmental archives contain formalin-fixed paraffin-embedded (FFPE) tissues that can be prepared without expensive reagents or equipment and may be a great resource for tissue-based cancer research. One of the most crucial issues in tissue-based research is the quality of the specimens. Current existing infrastructure allows standard diagnostic staining. The application of further molecular analyses, however, is hampered by the lack of standardization of pre-analytic tissue-handling parameters (variable fixation times, unclear fixation agents, etc.), which is now known to be one of the most important factors affecting feasibility and reliability of results from tissue-based science⁵.

A basic approach for improving biobanking infrastructure in low resource settings (e.g., in sub-Saharan Africa) should encompass three main points:⁶

A) Structuring and standardization of tissue processing would also allow FFPE tissue to be used for scientific projects. Moreover, alternative fixation agents have recently been developed⁷ that show advantages over current FFPE tissue processing in the field of molecular diagnostics, inducing less degradation of molecular features, and may offer reasonable alternatives for robust tissue preservation. This could prove invaluable in emerging countries, where infrastructure conditions (e.g., inconsistent power supplies, natural events like storms, and floods) require inventive and innovative strategies and technologies that take into account the local conditions.

B) Establishing clinical data banks that are complementary to the collection of tissue, in order to collect, store, protect, and retrieve the corresponding pertinent clinical information (patient data, clinical and laboratory findings, e.g., HIV status) and are of great scientific relevance.

C) Consideration of ethical issues for the use of tissue (informed consent, and respect of cultural aspects) is of high importance. Formal collaboration and communication with ethics committees and regulatory bodies should be regarded as mandatory.

Effective Sampling

Muntaser Ibrahim discussed the challenges of biobanking in populations of effective size.

Evidence of recent evolution and expansion of humans from an East African birthplace indicates Africa as the reservoir of the bulk of human traits and their underlying variations, which makes the documentation and future analysis of these variations all the more interesting. Creating a biobank of such human "biodiversity" is its own incentive. Its documentation, however, creates exceptional challenges, including the practicability of profiling, storing, and pro-

cessing of a large number of tissue samples representative of the genetic structure of populations. The economics of maintaining large repositories in underdeveloped countries that lack the necessary means and resources including viable health systems is also a challenge. A preliminary estimate of a representative biobank sample size in East Africa is around 10 million samples, which would take into account the actual population size of East Africa.

Populations of pronounced genetic variation such as those in Africa also pose additional and often unique challenges to genome analysis. In addition to the various challenges of allele calling, there are questions on the frequency of rare and common variants, low linkage disequilibrium, with associated implications for trait mapping and pertinence to ontological applications that are now increasingly perceived as individualized.

Such unique features of genetic structure are valuable for addressing the current paradox where, on one hand, current genome analyses are based on the assumption that human populations are genetically close enough to overcome sampling effects and other evolutionary forces, while on the other hand, there is the premise of early human divergence (i.e., early enough to allow for current genotypic differences to appear and explain phenotypic differences).

Both of those seemingly contrasting assumptions may in fact be tested in a large effective size of the original human gene pool in East Africa. This group is now believed to have spent a substantial period of "in situ evolution" in the same area prior to the exodus of a small subset of humans out of Africa, leading to the formation of the current world continental populations that are the primary subjects of current genome analysis.⁸

Networking

Bonginkosi Duma addressed the challenges and opportunities of biobank networking in Africa.

Africa's rich biodiversity and diverse human, animal, and plant populations place it in a position to develop a unique biobanking infrastructure by networking the continent's facilities. The continent has untapped resources that can be used in healthcare, conservation, environment, and biotechnologies to derive benefits for society. Africa's biodiversity represents a unique opportunity to generate a strong mass of scientific expertise. Biosciences are recognized as the driving force behind the next wave of scientific and technological advances. A biorepository is necessary for securing components of biodiversity and a necessary infrastructure for contributing to the new "bio-economy."

An African Biobank Network would help secure and manage collections of biomaterials representative of Africa's human, animal, plant, and microbial genetic resources, for biodiversity conservation, human health, and biotechnology development. These would benefit the African people in terms of health and heredity, and would allow for more effective engagement with continental and international research communities.

This endeavor, however, faces a great number of challenges. Individually, many African countries and communities do not consider biobanking a priority for funding and development, and therefore devote no or few resources for biorepository development, security, and sustainability. This

leaves collections across the continent in which many valuable samples remain unused by the broader research community. Taken together, the African continent is not only biologically diverse, but also culturally, linguistically, religiously, and administratively diverse, and this creates huge obstacles to the establishment of shared and common infrastructures, or for harmonization of practices in the various aspects of biobanking operations.

The creation of an African Network is critical to address fundamental issues in the development of biobanking, in particular policies for the creation and management of biobanks and agreements for biospecimen and data sharing. The network could focus on issues of education and training; policy, legislation, regulations; human resources development; technology transfer and infrastructure development. The development of a continental network of biobanks in Africa would foster relationships for future cooperation with biobank members on the continent, and would provide facilities to integrate human tissue biobanks with those of Enviro-Bio repositories. A case in point is the South African Biobank Network that plans to integrate universities, forensic laboratories, clinical trial laboratories, and researchers of the nine provinces. It could be extended to other African countries in the Southern African Development Communities of Botswana, Zambia, Mozambique, Angola, Swaziland, and Lesotho, and later to other countries in Africa such as Ghana, Nigeria, Libya, and Egypt.

The way forward depends on fostering collaborations at national levels through Departments of Health, Departments of Agriculture, and Departments of Environmental Affairs.

Sample Provision and Sharing

The following discussion regarding the provision of samples arose from questions from the audience

One of the most critical issues for biobanking in emerging countries is the provision and sharing of samples. Samples must be shared to achieve the numbers required for statistically relevant research. However, this has been an issue in emerging countries where foreign researchers have collected and/or taken samples for research but did not involve, acknowledge, or provide results to the sample-providing institute. This has resulted in reticence in sharing samples with countries outside of the continental region of collection and even among neighboring countries.⁹

An example is that of the Saudi government, which is investing heavily in developing research infrastructure. Their policy is to provide facilities to conduct research within the kingdom. Only when facilities are not available can samples be sent abroad, and in such cases, collaborators must follow the kingdom's policies. In countries that cannot afford to create such research facilities and know-how, biobanking of materials must have policies to govern the provision and sharing of samples to guarantee a return of investment in terms of collaboration, training, data sharing, and/or acknowledgement.

Examples of successfully established and ongoing projects

The following sections list examples of successfully established biobank projects which were presented at two sessions. They cover various areas of biobanking such as non-neoplastic

(diabetes mellitus) and neoplastic (cancer) human diseases, or themes involving ecology/environment (biodiversity).

Biobanking for Diabetes

Khalid Siddiqui presented the successful creation of a bio-bank in Saudi Arabia for diabetes studies.

Diabetes is an illness that affects 100 million people. Type 2 diabetes mellitus is most prevalent in a high temperature zone that spreads from North Africa through the Middle East and Japan. In the Middle East, the frequency of metabolic syndrome is higher and the numbers are increasing at a rapid pace.

One of the research aims of the Saudi Diabetes Bio-Bank is to investigate whether this prevalence is attributable to genetic, nutritional, or cultural factors. Many environmental changes have taken place in the Kingdom of Saudi Arabia over the last 60 years, especially in lifestyle and diet. Currently, Saudi Arabia has very high rates of diabetes and obesity. In coming years these conditions will reach epidemic levels.

The organized collection of blood (for DNA) and serum with all medical information from Saudi populations will provide a means for the Saudi Diabetes Genome Study to conduct studies using the human genome map. The main goals of the Saudi biobank are to increase the quality of patient care and accelerate the impact of research on such care. This translates into the specific objectives of encouraging the donation of specimens, educating the public about potential advances from the study of biological materials, enabling the biorepository community to collaborate in implementing best practices and novel approaches, and enabling researchers to quantify disease incidences in various populations and subpopulations.

The Saudi Diabetes biobank project is a large-scale study of the combined effects of genes, environment, and lifestyle on common diseases of adult life. It will recruit a group of 200,000 subjects from different regions of the Kingdom. The collected records from participants will form the initial Saudi Diabetes biobank database.

Strategies and procedures for prioritization of access to samples, and for scheduling access to newly collected data will be determined by the University Diabetes Centre and Institutional Review Board (IRB) of King Saud University.

Convincing people to participate in such research remains difficult due to ethical and cultural issues that also compromise the creation of the biobank.¹⁰

Biobanking for Cancer

Maher A. Sughayer presented the progressive approaches used to establish a Cancer Biobank in a Developing Country as was recently done in Jordan.

The King Hussein Cancer Center (KHCC) in Jordan is the only stand-alone comprehensive cancer center in the Middle East. It was established in 2002 with the primary goal of providing state-of-the-art patient care in the diagnosis and management of cancer. The hospital has been accredited by the Joint Commission International (JCI) and its pathology department is accredited by the College of American Pathologists (CAP).¹¹

The strategic plan of KHCC emphasizes the importance of initiating basic and clinical research alongside continued excellence in patient care. Until now, research at KHCC has

been mainly clinical and descriptive. To keep pace with the current advances in medical sciences and to contribute to and collaborate with the world's research community, the decision was made to foster basic and translational research in addition to clinical research. To take advantage of the large number of cancer patients willing to donate their tissues, a biobank (KHCCBIO) was established at the KHCC to serve as a nucleus for the research infrastructure.

Such an ambitious goal requires resources including funding, expertise, and training. Active networking was utilized to identify and connect with international partners, which led to a successful joint application for funding from the European Union Framework Program 7 (FP7). This funding is dedicated to help establish a biobank in Jordan and build its capacity. The biobank will be set up in compliance with ISO, EU, and FDA quality guidelines.

The Thoracic Oncology Group at Trinity College Dublin (TCD) under Professor Ken O'Byrne, the EU-certified tissue establishment Biostor Ireland, and Accelopment, a management company from Switzerland, are partners in the funded project. An international advisory committee was established with experts from the biobanking field, made up of members from Europe, USA, and the Middle East. This committee will assist in the establishment of KHCCBIO. The KHCCBIO bank was conceived to create a world-class, ISO-accredited Biobanking system for KHCC, Jordan, and the region. The KHCCBIO mission is to advance research into the diagnosis and treatment of cancer and to make personalized medicine available. Through development of KHCC's research infrastructure, the aim is to increase the center's scope and visibility and improve its competitiveness throughout the European and international biomedical science arena. Platforms will be established for future knowledge transfer and collaborative research. Staff exchanges, seminars, and conferences focused on cancer will be developed through partnerships between European and Middle Eastern organizations for future collaboration.

The project has included ethical aspects since its inception. The Institutional Review Board (IRB) is a standing committee established at KHCC in 2003. It aims at protecting the rights and welfare of human research subjects recruited as potential biomaterial candidates and who are asked to participate in research conducted at KHCC.

Biobanking for Ecology

Patrick Sluss presented the progressive approach to establishing a Biorepository to support ecological and environmental studies in Southern Africa.

The aim is to establish a longitudinal repository of annotated genomic nucleic acids from impacted ecosystems in Southern Africa. Collection sites were selected where documentable major ecological, environmental, and socioeconomic changes are currently on-going and projected to intensify. Specifically, ecosystems rapidly losing biodiversity due to climate change and human activities will be studied. This aim is not simply to collect DNA and related biological material.

Taxonomic (classification and physical description of the individual donor) and functional (exact collection location and climatic, behavioral, ecological, and human socioeconomic conditions) information associated with each specimen will be preserved. Longitudinally collected genetic

material, fully annotated with respect to taxonomy and functional characteristics, will provide international scientists unique opportunities to study multiple dimensions of biodiversity. Annotated materials will be distributed to multidisciplinary, multi-national investigators. Both currently active investigators and new investigators, especially those among under-represented groups that may lack adequate resources, will be able to participate. Data assessing changes in gene expression and population genetic diversity, in the context of documented ecological change, are predicted to significantly expand our understanding of the bilateral interplay between ecological and evolutionary processes. Such new knowledge will have long-term, local and global impacts on human society at large.

Environmental changes in Southern Africa (Zambezi River: Namibia, Botswana, Zimbabwe, Zambia) are predicted to be significant and negatively impact biodiversity both directly and indirectly. These changes will also have consequences on human needs particularly as population grows in these areas.

Plans are in place to establish biorepositories to support wildlife studies associated with understanding and managing the dynamic environmental changes taking place in Southern Africa.

Three studies illustrate how the planned biorepositories will support studies of the ecological aspects of biodiversity and of changing patterns of disease transmission (malaria and sleeping sickness) associated with climate change. The role of biorepositories in these studies were: 1) to capture current genetic elements of biodiversity as a baseline; 2) to monitor changes in biodiversity longitudinally; 3) to provide materials for identifying molecular mechanisms of evolution [adaptation to environmental change, extinction resilience]; and 4) to support analyses that will identify molecular mechanisms of disease resistance and transmission.

The current status of these studies after 3 years of development includes the following accomplishments:

- Establishment of partnerships with US universities to support funding applications and educational efforts; both local and "study abroad" students.
- Establishment of partnerships with international investigators interested in utilizing biomaterials and who can provide expertise locally.
- Establishment of partnerships with local environmental groups, universities and government agencies.

In conclusion, more wildlife biorepositories are urgently needed throughout the world to provide the materials needed for longitudinal studies of genotype and phenotype changes associated with human impact and environmental changes.

Conclusion

Biobanking in emerging countries is an important and unmet need. Biobanking in these countries represents an opportunity to provide unique biospecimens to global scientific and healthcare communities. Access to annotated and curated specimens, from both the diverse human populations and from animals in ecologically impacted areas in these countries, will support new knowledge that can benefit both the country of origin and the world. However, biobanking in emerging countries presents unique challenges as well.

The two sessions on biobanking in emerging countries provided the audience with general considerations on these challenges, and with illustrations of how some endeavors have tried to address these issues. All biobanks face economic challenges, and their sustainability depends on the scale of services that they provide to users and "customers," as well as on the uniqueness and quality of the biological materials and associated information that they distribute.

Economic challenges are likely to be, at the very least, as difficult in emerging countries as in western countries, as they face enormous needs to build or improve healthcare and research infrastructures, not to mention the basic needs of their populations.

Particular challenges lie in the creation of adequate infrastructure for collection, processing, conservation, and transportation of biomaterials. Although the creation of such infrastructure should take advantage of already available tried and tested solutions to ensure the same high standards developed in other countries, these solutions may need to be revised based on specific conditions to ensure the same applicability. The challenge and opportunity is to adapt these solutions or find new solutions that can meet approved standards and produce acceptable results in the varying conditions found in emerging countries.

Equally important, but not unique to emerging countries is the challenge of establishing biobank networks and multidisciplinary collaborations to take advantage of advances in technology and analytical methods for large scale biospecimen collection applications. Nowadays, statistically significant biomarkers and genetic studies are only possible by pooling resources from different biobanks. However, the success of these studies requires effective networking and collaboration across disciplines.

These challenges can be overcome but will require scientific cooperation and resources, both financial and technical. This is where cooperation between African countries and their European counterparts may provide mutual benefits.

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