Published in final edited form as:
BEOnline. ; 1(1): 16–25.

Ethical and Legal Issues in Biobanking for Genomic Research in Nigeria

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Abstract

The pursuit of genomic research and biobanking has raised concerns and discussions about the ethical and legal implications. Given the specific challenges that surround such enterprise in low and middle income countries, it is pertinent to examine them in the light of the advent of Biobanking and Genomic research in Nigeria. In this paper I discuss the issues and suggest model solutions derived from advanced jurisdictions. These ethical and legal issues are discussed within the context of the legal system of a typical African country whose jurisprudence derives from that of its erstwhile colonial master, the United Kingdom. This includes issues relating to law and human rights, informed consent, native and customary law.

Keywords

Biobanking; Genomic; Research; Nigeria; Law

Introduction

The quest for new knowledge or new approach to the solution of old problems is perhaps the strongest drive in scientific research.[1] For some years now, tissue derived from human bodies, has been stored, distributed and used for therapeutic, educational, forensic and research purposes as an integral part of healthcare service in most Western countries. Gradually such collections have become known under various names such as biobanks, biolibraries, tissue repositories, genetic databases, or DNA banks.[2]

Biobanks come in many different forms, according to the type of samples that are stored and the domain in which they are collected. For example, samples might be derived from a clinical setting, from research projects or from the judiciary domain.[3-6] The data derived from these samples might relate to a given individual (clinical data), to a family (genealogy information or ethnic origin) or to a group (geographical location of a population, or its language).[4] Such data might be collected at the time of sampling or were added to the database at a later date. The collected samples need not be physical, as in the case of mutation databases, which contain only the data plus information on the sample origin and its geographical provenance.[3]

The creation of biobanks of specific biological materials during research has become common practice, for example in Nigeria, most teaching hospitals have tissue collections which are often used for the promotion of biomedical research and this has become a source of worry from the point of view of the law on privacy, data protection, human rights and customary law. Biorepositories and genomic research raise questions about future use of residual tissue, duration of preservation, third party rights to donated samples and security measures which may not have been anticipated at the time the biological materials were collected. Hence, the collection and long term storage of human tissue in Biobanking has

become a source of ethical concern reflecting intersections in genetic research, recent developments in patient rights and increasing commercialization of research.[7]

Biobanking for genomic research in all countries has raised similar ethical issues.[8, 9] The first is the tension that exists between the rights of individuals or groups and the routes towards research progress.[3] The second concern is the need to define what constitutes adequate information to be given to individuals before they consent to deposit their samples in Biobanks for research including potential future unspecified research. The third is the difficulty of reconciling the non-commercial use of human body parts with the growing role of commercial biobanks. Finally, there is a debate over how best to ensure the optimal and transparent use of biobanks while defining the rights of priority of researchers and companies over samples and data.

The paper examines the legal and ethical questions about Biobanking and genomic research within the context of the Nigerian legal system. The areas covered include examination of the various definitions of biobanks, the nature of research on human participants, the development of Biobanking in Nigeria. This study will also examine the ethical questions on the use of stored tissue in genomic research: informed consent, privacy/confidentiality and secondary use of samples.

Governance of Biobanks Biobanking

Medical research has many expectations about the discoveries that may arise from molecular biology. Biobanks play an important role not only in the identification of the causes of diseases in an individual or a group of individuals; but also in the development of diagnostics, therapeutic and preventive methods.[7] Biobanks have the potential to become useful tools for researching common and low prevalence or rare diseases but it seems the existing mechanisms for research oversight is insufficient for providing uniform and encompassing protections for biobanking and genomic research.[10]

Definitions

There are several definitions from the existing framework on biobanking defining biobanks. The Swedish Biobanks Health Act of 2002 defines a biobank as a collection of biological material from one or several human beings collected and stored indefinitely for a specified time and whose origin can be traced to the human or humans from whom it originates.[11] This act uses contradictory terms such as “stored indefinitely for a specified period of time and it does not specify if it is a private or a public body who stores the material.[7]

Additionally, the German National Ethics Council opinion on Biobanks does not make reference to the period of time and it defines biobanks in general terms as collections of specimens of human bodily substances associated or associable, with personal data and information on their donors.[12]

According to the joint paper by the French and German National Ethics Councils of 2nd October 2003, biobanks are privately or publicly maintained bodies for the long-term storage of human bodily substances and for the storage of personal data and information on the donors of these substances.[12] They establish that the bodily substances such as the cells, tissues and blood, as well as DNA, are the physical medium of genetic data.

The National Health and Medical council of Australia in its Biobank information paper of 2010, defined biobanks as large collections of human biological materials (biospecimens) linked to relevant personal and health information (which may include health records, family history, lifestyle and genetic information) and held specifically for use in health and medical

research.[13] Their objective is to provide a resource for researchers to use to advance our understanding of human health and disease. Biobanks are seen as increasingly important to research especially in two broad areas: understanding the risk factors that underlie complex diseases, and translating biomedical research into real improvements in health care, especially through advances in pharmacogenomics and personalized medicine, to minimize adverse drug reactions and match drugs more effectively to the patient.

It has been argued that the wide use of 'biobank' or similar terminology across all types of tissue and information collections creates difficulties, as the different types of collections and databases raise different scientific, technological, ethical, legal, and social considerations.[13] From the foregoing it can be observed that even the definition of a biobank is not uniform even though several sets of international guidelines have been developed regarding various aspects of collection storage and secondary use of biological specimens. Even the European Union lacks an overreaching and encompassing regulatory system which is creating challenges to the widespread use of specimen.[14]

A number of international guidelines have been developed over the years and some countries have passed legislations governing biobanks e.g. Iceland Norway and Sweden.[14] The United States Cohort Study Report notes that:

> "In some cases, the biobank is directly linked to a study with a predetermined goal, such as identifying genes causing specific disease. In others, the biobank literally serves as a repository of genetic material, patient exposure data, and medical history information that is available as a resource to researchers who request samples for the study of a particular disease. The characteristics of biobanks, such as participant population, age, size, ethnicity, and environmental exposures, vary widely."[13]

Genomic Research on Human Subjects in Nigeria

Nigeria is a multi-ethnic, multi-cultural country with population estimated at 170 million in 2012. The population growth rate of 2.53 percent per annum is one of the highest in Africa, with 40 percent of the population under 15 years of age. Fifty percent of the people live in rural areas. Life expectancy at birth is currently estimated at 52 years for both sexes; while maternal mortality ratio is 840 per 100,000 live births; infant mortality rate is 74.36 per 1000.[15]

There exist in Nigeria many clinical databases that store human data and some genetic information but do not store human biospecimens. These therefore differ based on the foregoing definitions of a biobank.[15] An example of such a database is the cancer registry that exists in many hospitals in Nigeria.

The phase 1 of the International Haplotype Mapping Project (the Hap Map Project), a collaboration between the United States, the United Kingdom, Japan, Nigeria, China and Canada is an example of a Biobank that involves Nigerian samples. Subsequent phases involved other African populations. Its aims were to identify the variations in the genome of donated germ line DNA in order to support research on disease etiology, population history and pharmacogenomics. While the donated cells were immortalized, the sample size is very small, there were no associated phenotypic information and donated samples were anonymized.[16] The only large scale biobank established in Nigeria is that created in 2011 by the institute of Human Virology in Abuja.

Ethical Issues in Biobanking Informed Consent

Consent is a fundamental principle in modern medical ethics and biomedical research; this was explicitly established in the Nuremberg Code[17] and Declaration of Helsinki.[18] The principle of consent is closely related to the principle of autonomy and the affirmation of human rights and respect for human dignity.[19, 20]

Generally, in most Western societies, consent is framed as a very individualistic notion yet in genomic research there is potential for a participant's family and possibly other members of communities to which the research participant belongs to be impacted by an individual's participation in research.[13, 21]

In Nigeria, informed consent before surgery is a part of preoperative routine as a matter of hospital policy, legal requirement and ethical obligation.[22] Consent is usually obtained in the immediate preoperative period in many places.[23-25] It is also obtained for structured interviews[26] and information leaflets in other disciplines.

A recent review of the subject showed that the body of literature on informed consent and genomic research is not robust.[27] For example in surgical practice, the principle behind consent for surgery is essentially the same in most hospitals but the emphasis placed on it and the process of obtaining it varies from place to place.[22]

Consent practices have been found to be influenced by factors such as the level of education, extended family system, urbanization, religious practices, and available health care financing options.[28] In other words consent may be shared or given especially for married couples in Nigeria.

The need for consent for research on humans cannot be over emphasized, several international guidelines some of which Nigeria is signatory to also recognize the need for informed consent in research and medical practice.[29]

In Nigeria, where a substantial part of biomedical research is conducted by medical practitioners, the conduct and behavior of physicians is also guided by the Code of Medical Ethics of the Medical and Dental Council of Nigeria.[30] This position has been affirmed by the Supreme Court of Nigeria in the case of Medical and Dental Disciplinary Tribunal v. Okonkwo the Nigerian Supreme Court ruled that: ‘The patient's consent is paramount… (accordingly) the patient's relationship (with the doctor) is based on consensus. It follows that the choice of an adult patient of sound mind to refuse informed consent, barring state intervention through judicial process, leaves the practitioner helpless to impose a treatment.’[31]

Consent under Customary Law of Southern Nigeria Customary Law in Nigeria

The Supreme Court of Nigeria in Kharie Zaidan v Fatima Khalil Mohssen defined customary law as “a system of law not being the common law of England and not being a law enacted by a competent legislature in Nigeria, but which is enforceable and binding within Nigeria as between parties subject to its sway”.[32] Law on the other hand has been defined by Black in its generic sense as “a body of rules of action or conduct prescribed by controlling authority and having binding legal force”.[33]

T.O. Elias, a foremost Nigerian jurist has also defined customary law as “a body of rules which are recognized as obligatory by its members on the principles of their social imperative”. He also refers to customary law as a social contract, an accepted behavior

which the vast majority of its members regard as absolutely necessary for the common weal.[34]

As a social contract, it is not every aspect of the social contract theory that fits the definition of customary law. The aspect of social contract theory that posits the principle of an individual submitting some of their powers of decision making to an authority such as the government, community leader or family head describes one of the main tenets of customary law.

However for conduct to be considered as accepted behavior and therefore a part of customary law it must consist of "norms the violation of which calls for the employment of sanctions which directly affects the property, person or status of the offender".[35] For customary law to be a valid in any community it must be accepted by the community. Customary law has been referred to by the courts as "a mirror of accepted usage" which cannot be decreed or legislated into existence but must crystallize into an accepted custom".[36] For a custom or social conduct to attain the status of customary law, such custom or conduct must not only be acceptable but also enforceable and its breach would also be visited with sanctions.

Against this brief back ground, the principle of informed consent can be assimilated from the various aspects of customary law, and practice of southern Nigeria where this principle is utilized. For instance, consent is required under customary law in many areas; notable of which are the areas of land as well as marriage.

Where sale of family land is to be undertaken, it is imperative that the consent of members of the family be obtained. Under Yoruba customary law for instance, consent does not imply unanimity of decision by all members. It has been held to be sufficient if consent is given on behalf of members of the family by the head and principal members of the family.[37] Validity of customary law is derived from a proper source or a competent authority which gives it the stamp of enforceability. These authorities include the king or paramount ruler, the people's assembly, arbitral bodies or the head of the family.

It follows therefore by analogy that the law recognizes that in circumstances where it is impracticable to obtain unanimous consent of a group who possess a joint identifiable interest in a subject matter (for this purpose) research, the courts will accept the consent of the head of the group and principal members as indicative of consent of all.

It can be argued that whereas consent to economic transaction such as sale of family land does not carry risk of personal harm, research participation does and it is easy to see a Head giving consent to activities that he is not at risk from. This is arguable however under the theory of social contract; individuals give up their sovereignty to a sovereign ruler in this case the head of family. Under the terms of this contract people repose their rights in the head of family in exchange for the guarantee of the collective preservation and security of their individual lives.

In local communities, the need for an institution or governing body is recognized and respected, there persons that hold the right to make decision for and on behalf of others. By logical extension, informed consent under customary law would imply that there is a source of authority that can decide on genomic research. The role of the individual from whom samples are collected cannot be underestimated; autonomy is one of the central principles of research ethics; which suggests that individuals should decide what happens to their bodies. The social contract theory under customary law implies that this right has been given to an authority.

Conclusion

In this context, biobanks will play an important role not only in the identification of the causes of diseases in an individual or a group of individuals; but also in the development of diagnosis, and in the application of therapeutic and preventive methods. Biobanks can become useful tools for researching common and low prevalence or rare diseases.

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