



INSTITUTE OF HUMAN VIROLOGY



Biobanks and Genomics – Perspectives from Africa

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Characteristics of African health research environment and their implication for research

- Health indices, resources and access
 - Poor health indices
 - Poor health infrastructure
 - Limited access to good quality health care
- Patterns of diseases and health
 - Persistent communicable diseases
 - Rapidly progressing non-communicable diseases epidemic



Characteristics of African health research environment and their implication for research

- Socio-economic parameters
 - Poverty and rapid transformation in income levels
 - Urbanization – reduced physical activity, changing diet
 - Religion, culture and practices
- Education
 - Low levels of health professionals' knowledge about genomics
 - Low levels of general population's knowledge about health in general and genomics in particular



Biobanks

- Biobanks are now an increasingly common tool of biomedical research throughout the world
- While pathology laboratories in Africa have often stored residual tissue samples from biopsies and autopsies for long periods after primary utilization, and used such tissues in research, the modern concept of biobanks is new to the continent
- A characteristic of most prospective biobanks is that samples and data are collected for long-term future use, not just for a single project
- At the time of establishment of collections of samples and related data, it is not known and it is impossible to anticipate all the studies may eventually use this resource



Genomic research and biobanking in Africa

- Given that African research currently accounts for 2.5% of global health research despite having most of the intractable and emerging health problems, it is important to ensure that biobanking and genomics research are used to effectively contribute to African research enterprise because:
 - Genomics research supported by biobanking offer pathways to new solutions for Africa's old public health problems – HPV DNA testing is better than Pap smear in reducing mortality from cervical cancer - NEJM. 2009; 360: 1385-94



Genomic research and Africa

- Results of genomics research in Africa informs understanding and application of research in other populations - Variation in APOL1 gene may contribute to high rates of kidney disease in African Americans Science. 2010; 329: 841-5
- Genomics research has potential to contribute to reduction in global health inequalities through “an enhanced translational genomics and population sciences agenda” CEBP 2011; 20: 2105 - 14
- Genomics research tends to be a catalyst for system-wide innovation, interest and investment in medical research in general



Genomic research and biobanking in Africa

- Biobanking as part of research in Africa is required because of:
 - Role of Africa in human ancestry
 - Huge genomic, socio-economic, cultural (diet, religion, practices), climatic heterogeneity on the continent and their impact on health and diseases
 - Potential for huge contributions to understanding disease pathways, new approaches to treatment and prevention, drug discovery and pharmacogenomics
 - Widespread use and contribution of genomics research in developed countries



Medical records and health databases

- Most African health care systems are plagued by challenges with recording and maintaining health databases
- Health systems in Africa were traditionally set up and funded to respond to acute illnesses such as infectious diseases and trauma and not to complex diseases that require long term management and follow up
- There has therefore been minimal investment in health databases and medical records
- Recent interventions like PEPFAR led to creation of large databases often targeted to meeting reporting requirements of funding agencies



Controversies - Power disequilibrium at individual level

- Concern about the perceived “value” of the contributions of the individual
 - For example how do we compare the contributions, recognitions and rewards given to
 - (a) Raji – an 11 year old Yoruba boy with Burkitt’s lymphoma whose cells, in 1963, gave rise to the Raji cell line – the first continuous human cell line of hematopoietic origins (Pulvertaft JV. Cytology of Burkitt's tumour (African lymphoma). Lancet 1: 238-240, 1964) with
 - (b) the anonymous Yoruba participant in the first phase of the International HapMap project who genome was one of the first to be completely sequenced and
 - (c). Henrietta Lacks of HeLa⁹ cells fame



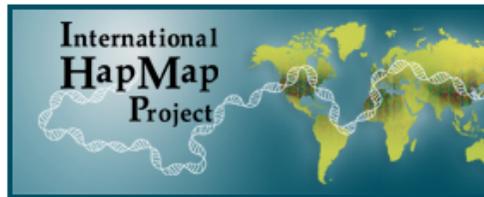


Controversies – diminution of the value assigned to individuals and to community particularly when data is de-identified or anonymized

- Where am I?
- Where are we?

Asepo HapMap ti Gbogbo Agbaye

Ibuso | [Nipa Asepo](#) | [Esi](#) | [Itejade](#) | [Tutorial](#) |



中文 | English | Français | 日本語 | [Yoruba](#)

About the HapMap

- Kinni HapMap?
- Orisun iwon-Jiini (Haplotypes)
- Anfani
- Awon Eya ti a ti se iwadi
- Majeobaje
- Iwe Idarapo mo iwadi
- Community Advisory Groups(CAG)
- Ilana Agbekale Esi Iwadi
- Ilana lilo Esi Iwadi
- Guidelines For Referring to HapMap Populations

Project Information

- [Ibuso](#)
- [HapMap Esi](#)
- [Olukowesi HapMap](#)
- [Alajose HapMap](#)

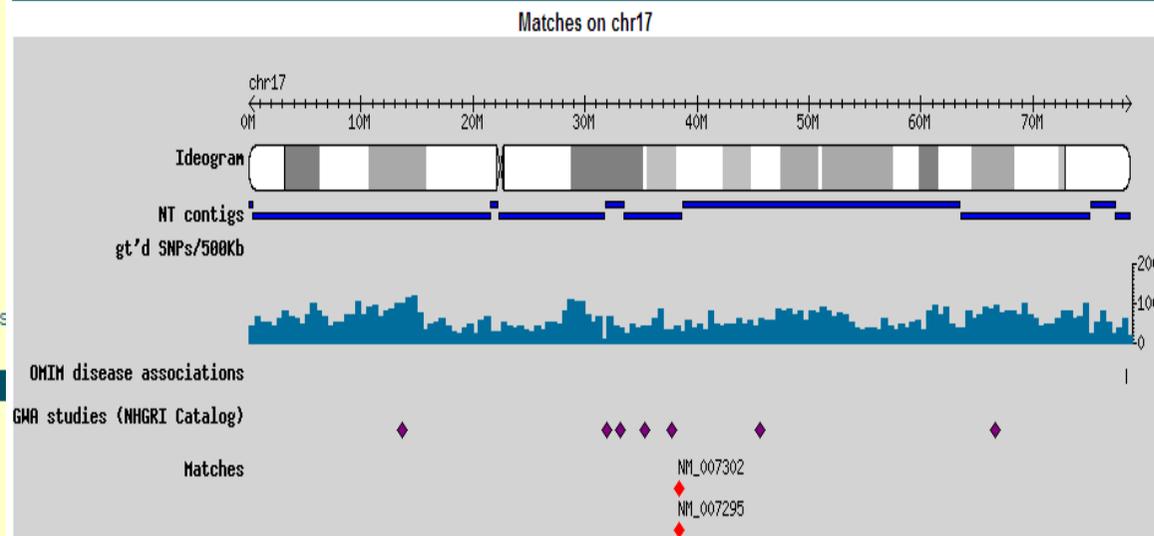
Landmark or Region :

Data Source :

Reports & Analysis :

Population descriptors: YRI: Yoruba in Ibadan, Nigeria, JPT: Japanese in Tokyo, Japan, CHB: Han Chinese in Beijing, China, CEU: CEPH (Utah residents with

The following 2 regions match your request.



Controversies – Trust as the most important ethical basis for participation in research

- Trust – is the commonest reason we found why people participate in genomics research.
- Yet, these are often people who have little trust in their government or political systems
- The manifestation of trust within the research context is highly nuanced
- Significant variations exist between communities in the expression and manifestations of this trust
- Has not received as much or as rigorous an evaluation as required because it is difficult to study objectively



Challenges – Trust and consent

- Majority of the respondents supported the use of broad consent for biobank research, while a significant minority prefer tiered and restricted consent approach because they want to receive feedback on donated samples and would like to know the research that could be done with their specimen in the future
 - *I prefer the tiered consent, but may thereafter give a broad consent if I am given feedback on what has been done with my specimen.* Male Medical Doctor urban B6 – Kano
 - *I would like to be informed before my specimen is used for another research (i.e. tiered consent). Even when I have moved away from my previous location, inquiries should be made at my previous location for my where about.*

Male Spokesperson rural D1 - Enugu

Challenges – Trust and consent

- *Since I would not give broad consent, I will not permit sharing of my specimen. The other group of researchers should approach me for use of my specimens. I will have no objection if you want to take it abroad for analysis, provided other participants allow that.*
Male Community Leader urban B4 – Kano
- *For me there no problem if you share my specimen with other researchers. For example when I was doing my diploma programme, I went to another place to obtain my data and they agreed to share with me. If I have a disease and they want to take my specimen abroad, they should let me know. Though, my reason is to get the information so that I can seek for solution.*
Male Spokesperson rural C14 - FCT



Controversies - Intersection between culture and biobanking

- The banking of body fluids and tissues may raise significant concerns at the intersection of science, religion and culture. Illustrative experience of use of umbilical cord blood for research
 - Certain biological samples have very high and significant cultural values
 - Research and banking of such samples raise significant cultural and ethical concerns in the community





Controversies - Intersection between culture and biobanking

- *Lay opinion about the afterbirth*
 - *Umbilical cord or afterbirth is a dangerous thing to play with in Yoruba land, since it connects the child to the mother, Yoruba believe that how it is handled can change the destiny of a child.*
 - *That is what many pregnant women fear during childbirth and they are eager to collect the umbilical cord and after birth and give it to the father of the child (husbands).*
 - *Yoruba says “ki aye ma fi bi omo mu wa” – (May we not be vulnerable to our enemies through the umbilical cord)*
- *A traditional religion priest*
 - *burning the umbilical cord is best thing to do and it must done when people are not around, may be in the night at a location that is wet, so that that child life’s will be cool and prosperous.*
- *A Senior Nursing Officer*
 - *the importance of the afterbirth is that after a woman has had sex with a man and missed her period, God will put the placenta beside the fetus and this brings about the cordial relationship between mother and child that is responsible for the child’s breath and the child’s feedings*



Controversies – Sharing of biological samples

- Sample export and ownership
 - Research participants often express concern about transfer of samples to specific countries and use in specific types of research
 - *My consent has to be obtained again before you share my specimen with other researchers. I am a health worker I know what am heading to.* - Male Medical Doctor urban D9 - Enugu
 - *You can share my specimen with other researchers, I do not have problem with that. You may also take the samples to others countries as long as it is not used for human cloning and things that Christianity will frown at.* Female Pharmacist Urban D18 - Enugu



Controversies – feedback of results

- Participants in general wanted some form of feedback. Where the results of the research is likely to be related to heritable treatable or untreatable serious illness, participants strongly favoured return of results
 - *I need feedback on my result. Since I will give you my specimen on trust, I will require feedback, and if it is not done I will be worried.*
Male Traditionalist and previous research participant urban A8
 - *It is important for me to know, if the biobank discover something serious about my health, they should let me know.*
Female Pharmacist Urban D18 – Enugu
 - *I should be given counselling before am given any feedback. It should involve pre-counselling.* Male Medical Doctor urban D9 - Enugu



Controversies – Impact of religion

- Christians and Muslims alike wanted their religion to be taken account of with respect to how their donated samples are used.
 - *Anything related to health, my Muslim religion is not against it.* Female Pharmacy Technician/spokesperson urban B3 - Kano
 - *Like I mentioned before, the samples may be used for unethical practices such as human cloning which will interfere with my Christian belief. Uncertainty on this and limited knowledge on the religious implication on my action can make me change my mind of participating in the research.* Female Pharmacist Urban D18 - Enugu



Controversies – Impact of religion

- *My concern is that they may use the biobank for something that will not please God, for example occultism. From the research, those that did not know they had disease will get to know it. It may be HIV/AIDS and it will affect them psychologically. I will feel bad if they keep our specimens without carrying out research on them, because I believe they will get back to one of us as a feedback if they carry out research on our specimen. If there's segregation whereby they give some people feedback and I am not given I will not be happy.*
- Male Spokesperson rural C14 - FCT





Controversies – Impact of genomic research and biobanking on ethnicity

- Information on ethnicity may
 - Raise specter of discrimination and stigmatization against individuals or communities
 - Engender a sense of pride and accomplishment
- The people of Aba-Alamu for example were proud of their contribution to the HapMap because
 - It reflected restored ethnic leadership and pride in education and science
 - They were contributing to de-stigmatization of Nigerians
 - They were contributing to the health and prosperity of African Americans
 - They were contributing meaningfully to global advancement in health and science



Controversies – Use of health records

- Many respondents do not have any concerns about use of information from their medical records because they believe they had nothing to hide.
- The main concern was the general issue of donors' anonymity when information is being made available in the public domain.
- However confidentiality was considered a significant issue. Respondents felt that if they are not confident about the procedures in place to respect participants' confidentiality they may withdraw participation.
- Respondents believed that if information is properly encoded or encrypted it will not be accessible to people unauthorized.



Relevant sections of Nigerian Health Law

- In 2014, Nigeria enacted a law whose purpose is to “provide a framework for the regulation, development and management of a national health system and set standards for rendering health services in the federation, and for related matters”
- In many parts this law is similar to laws passed in South Africa, and Sudan, and possibly other African countries
- This law established the National Health Research Ethics Committee and contains several sections that deal with health records and databases



Relevant sections of Nigerian Health Law

- All information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment is confidential
- The person in charge of a health establishment who is in possession of a user's health records shall set up control measures to prevent unauthorised access to those records and to the storage facility in which, or system by which, records are kept.



Relevant sections of Nigerian Health Law

- Any person who—
 - (a) fails to perform a duty imposed on them under subsection (1);
 - (b) falsifies any record by adding to or deleting or changing any information contained in that record;
 - (c) creates, changes or destroys a record without authority to do so;
 - (d) fails to create or change a record when properly required to do so;
 - (e) provides false information with the intent that it be included in a record;
 - (f) without authority, copies any part of a record;



Relevant sections of Nigerian Health Law

- (g) without authority, connects the personal identification elements of a user's record with any element of that record that concerns the user's condition, treatment or history;
- (h) gains unauthorised access to a record or record-keeping system, including intercepting information being transmitted from one person, or one part of a record-keeping system, to another;
- (i) without authority, connects any part of a computer or other electronic system on which records are kept to— (i) any other computer or other electronic system; or (ii) any terminal or other installation connected to or forming part of any other computer or other electronic system; or



Relevant sections of Nigerian Health Law

- without authority, modifies or impairs the operation of—(i) any part of the operating system of a computer or other electronic system on which a user's records are kept; or (ii) any part of the programme used to record, store, retrieve or display information on a computer or other electronic system on which a user's records are kept, commits an offence and is liable on conviction to imprisonment for a period not exceeding two years or to a fine of N250,000.00 or both a fine and such imprisonment.



NHREC guidance on biobanks and materials transfer agreements - <http://nhrec.net/nhrec/>

- National code for health research ethics
 - Sub-codes dealing with other aspects of health research
- Forms for registration of ethics committees and biobanks
- Prototype documents
- Access to educational materials and guidance documents





Browser: nhrec.net

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