

## **RICH DATABASES AND POOR PEOPLE: OPPORTUNITIES FOR DEVELOPING COUNTRIES**

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**Abstract.** The implications of genetics research is fundamentally same and all human beings share same intrinsic value but the world is divided into developing and developed countries based on socio-economic patterns, literacy, legal procedures and also technological developments which are interlinked with these factors. Genetic databases have become crucial for research and therapeutic purposes; and have their own implications and importance for developing countries. They provide opportunities and threats to developing countries and raise dimensions that diversify the ethics of genomics at global level. They call for redressing gap between developed and developing countries and challenge us with the new horizons in genomic debate. This paper raises some of the ethical concerns in establishing databases, issues of governance and implications on the use of genetic databases in the context of developing countries. At present large-scale databases do not exist in developing countries, but in this paper an attempt is made to analyse different types of databases, their application, options for developing countries, opportunities and threats that large-scale genetic database might possess for developing countries.

**Keywords:** genetic databases, developing countries, ethics, economics, regulations

### **1. Introduction**

Technology has been at the heart of human progress since earliest times. There are different perceptions of technology, some people view technology as a reward of development and some people consider technology as a tool for human development. In medicine it serves both; with information technology impinging every aspect of medicine. The increased reliance of medical research on genomics and its interdependence on information technology has given rise to bioinformatics which helps us to understand the complex structures at molecular level, and also holds structures and information about genomes in databases. The implications of genetics research is fundamentally the same and all human beings share same intrinsic value but the world is divided into developing and developed countries

based on socio-economic patterns, literacy, legal procedures and also technological developments which are interlinked with these factors. Using genetic databases has its own implications for developing countries and raises many ethical concerns. At the level of each human being, whether in developing or developed countries, the ethical principles may not change but the availability of resources and the governing structures of countries challenge application of universal ethical principles and balancing ideals.

Genomics is still considered a fruit of developed countries, although there are some notable exceptions of bigger developing countries like Brazil, India, China, Cuba that have made significant progress in genomics. Genetic databases are “add-on” in genomics research and have their own implications and importance to developing countries. They provide opportunities and threats to developing countries and raise dimensions that diversify the ethics of genomics at global level. They have called for redressing the gap between developed and developing countries and challenge us with new horizons in genomics debate. Whether there is a need for creating large-scale genetic databases, their implications on health care, issues of economics and public understanding of genes and genetic technologies are important concerns especially in the context of developing countries given the access to healthcare and awareness about possible alternatives in medicine is limited because of illiteracy and poverty. In this paper I want to consider an overview of broader ethical issues involved in establishing genetic databases, issues of governance and some cultural factors that play an important role in decision-making. Let us first consider some accepted definitions for genetic databases and different kinds of existing genetic databases at international and country level.

## **2. Genetic databases**

Genetic databases are of various kinds and today most of them rely on computational tools. WHO describes genetic databases as “any methodical or systematic collection of data, structured in a fashion that allows accessibility to individually or collective elements of that database by electronic, manual or other means” (WHO 2001). Databases of genomes of many diseases causing micro-organisms other organisms including plants for biological and environmental studies and human beings have been created for research and therapeutic purposes. The HUGO ethics committee in its Statement on Human Genetic Databases adopted the definition “a genomic database is a collection of data arranged in a systematic way so as to be searchable. Genome data can include inter alia sequences, mutations, alleles, polymorphic haplotypes, SNPs and polymorphisms. The work associated with a database includes collecting, curating, storing, validating and preparing specific sets for transmission” (HUGO 2002). There are also bibliographic databases carrying information on the relevant studies done on human genome and large-scale population biobanks for long-term studies. This information is utilised for research in medicine and biology for healthcare and environmental purposes. It can also be said that

without the use of computational tools, the complex structures of genes and genomes would have been difficult to elucidate and interpret. Some of these databases are developed based on a pre-existing large scale, systemised medical and health information of the populations, and for some inspiration has come with the developments in medical technologies and finding interrelationships between health and our environment; here the term environment applies to a broader, holistic meaning.

The history of storing information in databases is not new. Details of enigmatic biological processes and structures of cellular molecules had been stored in different ways in writing and as physical models. In medicine, medical registers carrying information about patients have existed for a long time now. Family genetic registers have been in practice for over thirty years, for example Register for the Ascertainment and Prevention of Inherited Disease in Edinburgh to offer member of the families with a history of genetic disorder active counselling; and a register centred at the University of Utah in USA was based on the family register of the Mormon Church to identify the individuals with dominant hypercholesterolemia (Modell et al 2001). Such register services have been extremely beneficial to individuals, families and society. These registers are also a kind of genetic databases and have been made with a tunnel vision of serving future generations.

Today most of the biomedical research depends on computational tools and most of the generated information is stored in computer based genetic databases. The new generation of genetic databases is very different in its size scope and format since they are fundamental genome sequence based, faster and precise. Many of them are population-based. There are various types of modern genetic databases: information databases, nucleic acid sequences and protein databases, etc. Given that genomics has become the basis of life sciences, these genetic databases are crucial for research and therapeutic purposes. They have become unavoidable in genomics research. Their impact on genomics research and overall implications on individual human beings and communities are enormous, and many ethical concerns are raised on their use, reliability, confidentiality of personal information and broader issues of regulations and governance of databases at national and international level.

Different kinds of databases available worldwide enable the developing countries to make their own choice, and also get inspiration for critical analysis on investments for biomedical research and future healthcare to people. Large populations, poverty, and health are intricate ethical concerns and access to them is a parallel question for developing countries. In country like India, with over a billion people and approximately 35% of the population living below US\$ 2 per day, economics plays a major role in daily lives of people. In such countries genomic knowledge might be expensive to produce and its implementations at public level is even more challenging. What options can developing countries consider, especially in terms of financial investments is a critical issue not only for national governance structures, but it is also an ethical challenge in terms of providing universal healthcare and equity to all. Some economic implications and opportunities especially with regard to creating genetic databases are discussed below.

### **3. Economic viability of genetic databases**

Developing countries are not only economically poor but also information-poor. Genomics knowledge is expensive and that is why much of it is created in the West. It is also the reason why applied research has been centred in developing countries whereas basic research has been more extensive in developed regions of the world. Genetic databases provide huge opportunity to developing countries with their information about genomics to pursue their own research agendas and create their own knowledge banks. In this scenario genetic databases could be of immense importance for developing countries. The existing databases should be in the public domain and available either freely or at minimal costs.

Sequencing genomes and deciphering different genes require massive investments to set up appropriate laboratory environments and human skill, and it is also an ethical concern for many developing countries whether to invest in genomics research or whether to provide essential healthcare services to people. It has been argued that bioinformatics approach to invest in genomics is far less expensive, requiring only initial training, access to computers and internet. A large amount of information is available through internet and requires substantially less investments to develop computational tools for understanding the existing sequenced genomes than it is to sequence genomes (Pongor and Landsman 1999). Genetic databases in public domain provide new opportunities for developing countries to get access to a large amount of available information and gain deeper knowledge at the basic research level. Technological innovation is an essential tool for growth and development. It would help the developing countries to advance their own research methodologies and therapies for some of the serious diseases causing millions of deaths, for example thalassaemia and sickle cell anaemia. Recognising the instrumental value of genetic databases, developing countries like India and China have invested millions of dollars in bioinformatics approach and have succeeded in genomics research.

The existing databases are beneficial also as models to create their own databases and computational tools for analysing and managing information in new ways. This could be of immense importance because of the genetic diversity found in big developing countries; for instance there are approximately 300 ethnic groups in India alone offering excellent opportunities to create databases for understanding correlations of genetic diversity for cultural and anthropological studies, let alone for biomedical research. Such investments might be necessary to reduce the dependency on the West and exchange of information at local and global level in the spirit of equity and reliability of factual knowledge ( Bhardwaj and Macer 2003).

Many small developing countries or geographical areas, especially those on the Pacific islands also present desirable opportunities for the development of such databases when the population is relatively genetically homogenous due to limited migration in the area and from founder effects. Such databases could prove crucial for population-based studies. However, with huge costs involved, any such attempt that might serve to redistribute resources and the social balance in general

should be examined carefully. These databases vary to the extent to which the data in them remain individually identifiable, though individual data are typically made non-identifiable to the users of the databases (WHO 2002).

One of the fundamental global ethical concerns at individual-level participation in genetic databases is informed consent. The informed consent procedures need to be properly drawn and evaluated; databases need to be carefully defined and scrutinised given that the controversies involved around sample collections and their use in genetics research have been debated worldwide. Although globally debated whether it is just a legal doctrine, the concept of informed consent is also a big ethical concern for developing countries because of the complications of social hierarchy at the level of a nuclear family, community and still prevalent paternal attitudes to medicine where doctor is above the patient. The Harvard Anhui controversy reflects a few similar issues. As Xiomei Zhai puts it, Chinese ethics is based on duty and following the elders and authorities even in medicine when compared to Western rights of an individual approach (Zhai 2003). It is also seen in many other Asian cultures. It is one of the crucial factors in informed consent, where the concept of a duty is more dominant than a right to choose for oneself. There are also issues of language barriers and public understanding of genomics.

In a survey conducted by Hitchcock in 1994, respondents among Asians and in the United States, were asked about personal and societal values that were “critically important to the people in your country”. The top six values chosen by Asians included; (i) orderly society, (ii) social harmony, (iii) accountability of public officials, (iv) openness to new ideas, (v) freedom of expression, and (vi) respect for authority. In contrast, the top six values chosen by respondents from the United States included (i) freedom of expression, (ii) personal freedom, (iii) rights of the individual, (iv) open debate, (v) thinking of oneself, (vi) accountability of public officials. Given the diversity of Asian cultures, although they cannot be conclusive regarding the differences in ethical values of East and West, they do highlight some of the social and cultural values that play an important role in the decision-making among people.

#### **4. Selection and choice of databases**

There are different kinds of databases available and all are meant for specific purposes. There are population biobanks, information databases, experimental databases, sequenced genome databases of other organisms, specialised sequence databases like ribosomal database and immunogenetics databases and protein sequence databases. One of the issues that scientists and researchers in developing countries may encounter is the choice of databases. Researchers in the developing countries have dilemmas on the kind of database that is easily accessible, affordable but also vital for research, and can render beneficial outcomes at research level and the results of which can be applicable to medical care at population level. There is a need to categorise research priorities so that minimum resources could be allocated

for better outcomes. Unexpected ethical concerns may arise during the process of specifying the kind of data and their levels of accuracy and precision. Selection and choice is also conditioned by historical, social and cultural factors, so there is a need for careful examination in specifying research protocols especially for human genetic databases.

Genetic databases would be helpful especially for studying some tropical and infectious diseases in developing countries, for example malaria or leptospirosis. Sequencing of microbial DNA and their databases would be helpful for possible target vaccines. The recent sequencing of malaria genome done entirely in the first world's well equipped labs seems difficult to transfer to the countries in the South for epidemiological studies and also accessibility in terms of propriety technology (Hide 2001). However, such research is critical in understanding the biology of the disease. Other existing databases of several disease causing micro-organisms could be useful in applied research in developing countries to produce and test "home-grown" drugs. Genetic databases of some human genetic sequences carrying information about specific disease causing genes prevalent in developing countries would also be useful in understanding patterns of diseases and the influence of social and environmental factors.

At the same time databases like a population biobank provide huge opportunities to study patterns of health in a population on a large scale. Such biobanks might even be beneficial to understand genetic diversity in many developing countries of the world and causes of illness. However, they require large investments and robust health management systems which are lacking in developing countries. Secondly, large-scale population based genetic databases are feasible where there are national health care systems, but even big developing countries like India do not have a national health care system (Nature Genetics 2003). Still, small genetic databases may be created at local levels for specific purposes which could be centrally monitored at national level. Partial sequenced databases can be created and utilized for genomics research. There are also examples of medical registers and health records maintained in many developed countries that might prove beneficial in studying health patterns in developing countries and require substantially less investments. Although many scientists expect that human genetic databases will yield useful information, there are ethical concerns raised whether massive costs would justify the returns and what the optimal design and size of the databases should be. Efforts need to be taken for maintenance and follow-up of these databases which involve additional investments.

Besides these practical concerns, there are also social issues. In many developing countries, society is divided into classes and castes that are inherent and strongly imbedded in the culture. In that respect, genetic databases also pose a possible threat of discrimination, also in the name of genes. In countries like India where there is a caste system still very much prevalent in society, the dangers of genetic discrimination may add to the existing divide in society. At a global level, this may also be used as a possible argument for discrimination between the poor nations, where biodiversity and genetic diversity have many times been exploited

in the name of research. The philosopher Allan Wood remarks that, “proper respect for others is violated when we treat their vulnerabilities as opportunities to advance our own interests or projects. It is degrading to have your own weaknesses taken advantage of, and dishonourable to use the weakness of others for your own ends” (Wood 1995). It is very important to harmonise and standardize the use and applications of genetic databases, but process and formulation of policies and frameworks need to be carefully evaluated on their global implications. Therefore the type of information revealed in the public domain will be a crucial factor to evaluate the large-scale databases.

### **5. Accessibility and digital divide**

Global inequity is not a new issue, but it is of central importance. Global inequity also exists in the form of information inequity, which is fundamentally related to the issue of accessibility. The need for a free flow of data and the fair and equitable distribution of benefits from research was again emphasised in the Statement on Human Genomic Databases by HUGO ethics committee (HUGO 2002). Even with the costs of communications plunging, the “digital divide” is conspicuous between North and South. At the level of general connectivity, even today less than 2% Asians and less than 0.5 % Africans use internet compared to more than 40% Americans, although trends are rapidly changing (World Bank 2001). In most of the developing countries, there exists an information problem and knowledge gap, for which there are several reasons. Ethical concern of accessibility to genetic databases is interlinked to legal obstacles and infrastructural hurdles.

The World Bank figure shows that internet still excludes half of the world, although global expenditure on information technology is expected to be in trillions in 2004. This situation is unacceptable in promoting the use of genetic databases in developing countries. The lack of basic infrastructure facilities and virtual connectivity is a handicap for development and today internet is the biggest and fastest source of information to people. Digital connectivity has become the basic way to faster and latest information, which is crucial for genomics research today. Figures show that even the free access to databases in public domain, the number of hits from developing countries is very low, although some governments have made an effort to establish world-class set-ups for research purposes (Thambisetty 2002). For example, the number of hits from UK and US researchers to the Ensembl database on average is 59, 951.6 hits/week and 49420.0 hits/week, compared to India’s and China’s 230.2 hits/week and 111.02 hits/ week (Welcome Trust 2001). Although some of these databases are freely and openly accessible, but still have intellectual property rights which in itself is an ethical concern. Whether knowledge should be a property or a right of a person or an institution, because they have resources to create knowledge is an ethical concern, based on the current global economic trend where basic medicine is becoming a luxury for millions of people suffering from diseases, malnutrition and hunger.

In order to allow for maximum research potential, we should allow all interested parties free access to genetic databases. However, accessibility issue has become more complicated with a push by commercial interests to create private databases. Private sector is competitive and time is essence. Access to the fastest and latest information in genomics is crucial for patents and monopoly. Stringent laws at international level have not been sufficient to tackle the situation. Although access to public genetic databases is free, many of the databases are rapidly becoming outdated because of the competitiveness in the private sector, the ad hoc costs involved and the continued input needed from both biological and computational perspectives. Today many databases carrying nucleic acid sequences are not updated regularly since the focus is shifting more on proteomics and protein databases. Some of the public domain databases have also made restricted use on the new databases because of the private sector, although discount fees have been granted for academic institutions and developing countries (Ellis and Kalumbi 1998). There are general fears about such free databases at present in developed countries. This could have a severe impact on the overall research and competitiveness of the developing countries. How can developing countries make better choices to get access to public genetic databases? How can information management be utilised as capacity building for the poor nations of the world that are resource poor?

The availability of updated information also gives new ideas for innovative and improved research designs and new paradigms to existing methodologies. Human intelligence has no geographical or economic boundaries, but it could be developed with availability of information. Access to genetic databases would not only be crucial for better biomedical research environment and infrastructure but also for human resources development in developing countries. However, at the level of ordinary public, which is the key to creating genetic databases, volunteer blood donation has been very limited due to the lack of understanding and ignorance about the concept of “genes” its interrelationship with environment and the lifestyle. As mentioned earlier, the paternalistic ideology in the practice of medicine, may be negatively used as coercion where participants are ignorant about their rights. In such circumstances, the responsibility of the researchers and doctors involved is higher – they must guarantee a fair and honest approach to the research and health-care. The way the information is delivered and disseminated may be crucial not only because of the public ignorance but also the very general issue of language. Language is important not only for conveying information to people but also in taking informed consent, given that proper informed consent ideally means that the participants are aware of what they are participating in, its pros and cons and their rights.

## **6. Integrating bioinformatics in academics and public awareness of genetics**

Modern genetic databases use bioinformatics for all purposes, from storing of databases, annotation, curing and other purposes. Bioinformatics involves funda-



mental understanding of biology and computer sciences. These two fields are still taught as separate subjects in many developing countries. The first challenge is to integrate bioinformatics in the curriculum at university level. The issue is more complicated since university staff and science managers are often not yet familiar with the bioinformatics to be able to fully understand and exploit the genetic databases in research. There is a need for skilful training at fundamental graduate level education. This is essential to capacity-building in poor nations of the world. Genomic databases as “public goods” in this context are crucial since the raw genome databases in public domain could be utilised in teachings at universities to graduates and undergraduates. Accessibility alone is not enough, there is a need to strengthen the skills by generating human resources in order to understand and harness genomics using bioinformatics.

At present there are very few research centres in the developing countries that provide some access to international genetic databases and have joint collaborations at international level, for example International Center for Biotechnology and Genetic Engineering (ICGEB) and European Molecular Biology Network (EMBN) and a few others that have included participation from China, India, South Africa and Argentina. Such collaborations have contributed greatly to the success in genomics research in these countries and joint participations and collaborations are based on ethical principles of solidarity, equity and benefit sharing, which are giving new ethical frameworks to genomics research (Chadwick and Berg 2001). However, more investments in human resources are needed to expand the use of genetic databases, and retaining knowledge in the public domain by establishing research groups, specializing in genetics research and the use of computational tools and software technologies used in modern genetic databases in the developing countries.

In the majority of developing countries, people are aware of neither the intricacies of the genetics nor its bioethics. Many times geneticists do not come in direct contact with the people/ patients and they are confined to biological materials, laboratory and the environment. The humane approach is limited to legal procedures of filling up informed consent forms and ethical committee approval. Hence there is a need for a direct contact of patients/ participants for better understanding ethical problems involved and an increase in public awareness about genetics. Although there is a concept of “blood” in societies, the general understanding is based on class and castes in India, and the ordinary public is still not aware of “genes” and what is their role in deciding some of our attributes as human beings.

## **7. Research funding and technology transfer**

Today, genetic databases and the use of bioinformatics cannot be disregarded by any country intending to retain up-to-date biotechnology and biomedical research. Many governments of the big developing countries such as China, Brazil and India have also done significant funding for genomics research, and done well

at international level. However, it is still very little when compared to research funding for genomics in the developed world. The genomics research spending by public and non profit funding agencies in the year 2000 in the US was \$ 627 million, UK \$ 244 million, Japan \$ 353 million compared to developing countries like China \$ 14 million, Korea \$ 8 million (World of Funding for genomics research 2002).

Many databases in the current use were not specially conceived or designed as databases, but grew products to expedite particular pieces of research. To keep public databases operational, they need to be regularly updated as knowledge in its area of expertise grows to best meet the needs of users' community by applying new softwares and sophisticated database management systems. Management and operational expenses of keeping genetic databases alone cost more than US\$ 200,000 (Ellis and Kalumbi 1999). The growing trend of bioinformatics and widening magnitude in genomics has led to the creation of novel large-scale databases that need massive investments. Given the costs involved, large-scale databases might not be a suitable choice for the developing countries.

Rapid technological progression in genomics has made a deep impact on restructuring resources and stressed the need for rethinking in funding for genomics research both at national and international level. International aid agencies and many UN bodies have been involved in funding primary health care programmes in the developing countries, and research on diseases like AIDS/HIV and malaria where the prominent research has been done in developed countries. With no direct funding for basic research in genomics from international agencies in developing countries; many developing countries trying to venture into genomics research and make large-scale databases at the behest of the private companies from the developed countries and it may be said that private sector does not work on unconditional generosity (Mark and Steinberg 2002). In such cases a danger of inequitable commercial exploitation is even more acute because of the lack of regulatory and ethical bodies.

One untried option that has been successful in agriculture biotechnology is technology transfer, which involved transferring technologies to the developing countries that suit their environment, budgets and are applicable at grass roots level. Research and management training for genetic databases could be offered to people so that they can create their own small-scale databases for research. Some developing countries such as India and China have been very active in promoting information technology expertise in the country. Additional training in bioinformatics could prove critical in harnessing genomics knowledge within the countries. Database software that suits research needs, is affordable and easily applicable, could be developed.

The question of the choice of databases for developing countries arises only for big developing countries, for smaller poor nations of the world the choice is not the same. It could be argued that for the small poor nations of the world suffering from disease and hunger, investments in modern genetic databases like DNA banks and population banks may not be the best option. Investments for provisions

of primary health care, drug availability and preferential access to public databases for applied research would have more immediate impact on population health and genomics research.

### **8. Information management and accreditation systems**

Information management is the ability to access information and at the same time being able to disseminate information. It is a three-step process; acquiring knowledge, absorbing knowledge and then communicating knowledge, which is information (WB 2001). Proper information management is central to development and crucial for genetic databases. Ethical concerns of precision, privacy and confidentiality are raised because of the flaws in proper information management systems. Most of the modern genetic databases follow similar information management procedures; from sample collections for large population biobanks to sequencing, deciphering, annotating and producing information. Information management has been one of the essential weaknesses of the developing countries historically, either the information does not exist or waiting for results. Establishing accurate, reliable and trustworthy databases is a major challenge for developing countries. However, technical implementation of genetic databases with the use of computational tools could be easier and useful in information management.

Reliability and accountability of research means it is acceptable only if it is accredited. There are no centralised accreditation systems in many developing countries pursuing genomics research, where information could be centralised and institutionalised in databases. Fragmentation in comparative genomics research within the countries and a lag in the flow of information between research institutes is a critical issue that needs to be addressed while framing scopes of genetic databases. We can also say that genetic databases can be created with proper management procedures where all the information is accredited, stored and maintained centrally. At present, many institutions doing genomics research within the countries might have access to international genetic databases, but limited access to the information and knowledge produced within the countries. It is made more difficult by practical searching and accessibility issues of redundancy, inaccuracy and lack of customization of information and structural databases that are being faced commonly by the researchers with genetic databases all over the world.

### **9. Genetic databases and health care in developing countries**

In recent years, the global nature of health care research has been diverted towards genomics and it has given new meanings to medicine and biomedical research. Many developed countries of Europe, US and Japan have integrated the use of genomics technologies in national health care management. It has also been emphasised in the recent White paper from the UK government on future use of

genomics research in national health care. Millions of dollars have been allocated for creation of population biobanks and genetic databases to study genetic disorders, other diseases and the interplay between genes and the environment, and there are efforts to make it technologically available at primary health care level to people. It is said that the purpose of such genetic databases is to expand options for treatments that could be affordable to many people (White paper DoH UK 2003).

Health care research in developing countries poses special challenges arising from the combined effects of distinctive histories, cultures, politics, judicial systems, and economic situations. The extreme poverty afflicts so many and the primary health care services are inadequate, and the majority of population is unable to gain access to the most basic and essential health care services, although some of the developing countries like India have made provisions for some genetic tests at minimal costs. In such situations, modern genetic databases focusing on genetic interactions and drug choice may not be the best choice for developing countries. However, genetic registers known to be existing in health care services in many developed countries for a long time provide an option to create “low budget” databases that are critical and fundamental to medical research. Databases of prevalent genetic disorders like thalassemia, Down’s syndrome, are needed for understanding causes of diseases and patterns of inheritance in future generations. In addition, such databases would also be beneficial to raise public awareness of genomics, where the majority of people do not know the concept of “genes”, and sickness associated with misfortunes. However, such services would also be extremely difficult to implement because of the huge population, which is a major concern in designing any development program in poor nations of the world. The issue of choice and selection between various kinds of human genetic databases in health care is delicate for developing countries.

Most international sponsorship of research in developing countries has focused on gene-based medicine perspective. The externally sponsored healthcare research in developing countries has not taken into account traditional medicine. This is an area where a lot of information is available, which is passed from one generation to the other, sometimes without being documented and stored. Conceptualisation of “blood” and “disease” is seen in many traditional medicine methods, such as Chinese medicine and Ayurveda. There are opportunities to create databases about traditional medicine that might be helpful in compatible studies with biomedical research in developed countries.

## **10. Regulatory procedures and ethical guidelines**

Developments in genomics have led to the formulation of a series of ethical guidelines and policy frameworks at national and international level, addressing several aspects of ethical concerns arising from the potential for their use that have implications on individual human beings and society. The speed of the genomics research, its multidisciplinary nature and ramifications have constantly challenged

the existing ethical frameworks used in medicine for a long time and the need to redress regulatory and policy frameworks. Many international guidelines have been made at national and international levels that address some of the ethical concerns, and development of more international ethical frameworks are sought with progress in basic genomics research and the new issues to be confronted. Although these accepted norms of international regulations restrict the imposition of values and priorities across national borders, and address some universal human values, not all these guidelines are favourable to the research environment for the developing countries for the reason that progress in genomics is largely centred in rich nations of the world. Arguably, some of the guidelines do mention special considerations for developing countries.

Many developing countries do not have regulatory procedures and ethical guidelines to conduct the genomics research and rely on international regulations for research. The recent Doha declaration is criticized as a failure to address the impact on health care in developing countries (Korea Times 2002). The lack of regulatory procedures or flaws in guidelines provides an escape route that allure the extensive private sector towards developing countries as testing grounds. There is also a common criticism for the private sector that a number of mega databases found in private sector have been generated from studies done in the developing countries, where access is not free.

Some internationally competing developing countries like India and China have produced guidelines and national statements for human genome research. For example, The Indian Council of Medical Research (ICMR) guidelines produced *Ethical Guidelines on Biomedical Research on Human Subjects* in the year 2000 that address some of the fundamental ethical principles that need to be followed before and during the research on human subjects. The issues of confidentiality, privacy and informed consent for individual research subjects, benefit sharing in clinical trials are mentioned as a requirement and a concern in the use of human DNA for research and therapy but there is scarce mention on the use of DNA banking, genetic databases. There are not many guidelines focusing specifically on genetic databases in the developing countries at present, because there are no efforts for large-scale databases existing for biomedical research. The HUGO ethics committee published its statement on Human Genomic Databases, which gives a very broad ethical guidance on the use and applications of genetic databases. It briefly mentions that “cooperation and coordination between industrialised and developing countries should be facilitated”. But there is a need for analysing how these could be facilitated especially in terms of using novel genes from the homogenous populations of much smaller countries. For example the controversy around the biobank proposals for Tonga, private sector involvement and cultural barriers have drawn much attention worldwide.

The developing countries need to establish ethical guidelines parallel to the implementation of technologies, policy frameworks constructed within socio-economic and cultural contexts; plus the existing frameworks need to be amended with the progress of genomics at global level.

Ethical frameworks for human genetic databases pose special challenges for developing countries and also under developed countries both in terms of logistics and cultural environments. Developing countries have heterogeneous people differing in culture, ethnicity, history and other socio-economic factors, and it is inappropriate to regard them as single entity. There are also differences in social values within geographical boundaries. Such factors would greatly affect the prospects of genomics research and genetic databases in particular. For instance, Malawi people believe that a person's blood contains his or her spirit. Whoever takes the blood would also control the spirit of the person whose blood was taken (Reeler 2000). It would be difficult to get consent from healthy individuals to donate for creating Malawi population biobanks or for large-scale population studies. At the same time it might be easier to create genetic databases to study genetic disorders commonly found in society with sick persons or donations done in the health care facilities. The level of freedom of expression, moral obligations to follow elders or heads in community and other social issues like male dominance in family need special considerations for consent and participation in research (Nuffield Council on Bioethics 2002). Such social and cultural considerations cannot be avoided for genomics research in developing countries and need to be taken consideration while framing research protocols and ethical frameworks in developing countries.

## **11. Conclusions**

The issues discussed in this paper may not be all encompassing but an attempt is made to address issues that have a blanket affect in applying genomics and genetic databases in particular to developing countries. The word "developing countries" is generalised although it is accepted that there are subtle differences in countries in the developing world. The factual differences between developing countries and developed countries give unique dimensions to ethics in genomics research at global level and call to redefine ethical principles and global policy frameworks. Universally accepted ethical principles of privacy, confidentiality and consent need special considerations in developing countries because their definition is also embedded in cultural context along research ethics. There is also a need to distinguish different types of databases when examining the ethical issues; especially in the context of creation and management of databases.

At the level of individual participation, well-defined principles of autonomy, beneficence and do no harm should be upheld and confidentiality and privacy of information is compelling for respect of the participants and dignity of human life. These principles have no geographical boundaries and have 'common value' to all human beings in every part of the world. These substantive principles help to establish standards to be adopted in collecting samples, their treatment in research, use of the acquired genetic data. Nevertheless, substantive principles alone are not enough to determine policy frameworks, especially when there are conflicts

between the principles (Rumball S. and Smith A. M. 2001). For instance the size and scope of databases may raise serious confidentiality issues, but in some cases a breach of confidentiality may be seen as serving a goal beneficial to society and for global social justice.

With large-scale genetic databases, there is a need to recognise the wider implications of these principles because the acquisition and use of genetic databases is still evolving. A very wide range of studies can be performed, and not all of them can currently be envisioned (Weizmann 2001). Hence, the precision and accuracy of information is also an important ethical concern since most of the databases are interlinked and generate other new databases for further research and development. Determining the moral necessity of genetic databases within ethical frameworks could be helpful for the future of humankind to alleviate disease and illness for the sake of a good life to all peoples of the world.

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