Ethical Issues in Biological and Allied Sciences

Divya Singh
Department of Zoology, Meerut College, Meerut, Uttar Pradesh, INDIA

ABSTRACT
Ethical issues related to biology and other life sciences along with healthcare or medical sciences are studied in a separate discipline named bioethics. In post genomic era, bioethics provides a framework for discussion of ethical, legal and social issues, notably genetic information privacy, genetic discrimination, gene therapy and stem cell research. Medical Ethics or Biomedical Ethics deals with relationships between doctor and patient, including issues such as informed consent, truth-telling and end-of-life decisions. Bioethics, however, is wider because some of the ethical issues arising out of developments in the life sciences concern, not so much the practice of health care, but issues related to research and emerging technologies. The global dimension of many bioethical issues, such as differences in life expectancy, access to resources and the problems caused by pandemics, raise questions regarding the feasibility of a global bioethics.

Keywords--- Biobanks, bioethics, genetic privacy, gene therapy, stem cell research.

I. INTRODUCTION
Bioethics is a recognized discipline in the academy, an established practice within the clinic and a source of guidance for healthcare policy and the conduct of human research. The term ‘bioethics’, though first coined by Fritz Jahr (1927) [1] and then re-coined by Van Rensselaer Potter in 1970, took on its contemporary significance through the insights of Sargent Shriver and Andre Hellegers [2][3]. The Kennedy Institute at Georgetown University, Washington, DC created a cadre of scholars dedicated to exploring scholarly issues, as well as to creating a cadre of professional ethicists or bioethicists able to give guidance for clinical choices and public policy decisions. The term bioethics itself had been accepted as identifying a field that offered a wide range of services. Three of these services were those traditionally associated with philosophy and the humanities: (1) the analysis of moral claims and concepts, (2) the assessment of moral arguments and (3) the display of the geography of alternative approaches to moral issues. Bioethicists had also come to assume a role long coveted by philosophers: (4) the provision of moral advice. It is a multidisciplinary field of study including ethical, legal, philosophical and social aspects of developments in life sciences and medicine. In this review, we have focused on ethical issues involved in contemporary research topics of biological, medical and allied sciences [4].

II. BIOBANKING
The term biobanking itself describes a diverse range of research and clinical activity, ranging from research in the epidemiology of common complex diseases, pharmacogenetics, rare genetic diseases, oncology and stem cells, to therapeutic applications such as blood transfusion or organ transplantation. Biobanks are situated in a range of institutions such as hospitals, universities, pharmaceutical companies and charities and vary in provenance, size, composition, methodology, economy and governance. There is disagreement among academic commentators, scientists and policymakers about what defines a biobank and whether this is the best term to use, with some preferring expressions such as ‘genetic database’ instead [5][6]. Despite such ambiguities, there are strong expectations among scientists, policymakers and others that biobanks will play an important part in improving future human health and in bringing substantial economic benefits to those who use and invest in them. Two particular issues in the governance of biobanks – which have impinged directly on questions about their legitimacy – have attracted particular attention: the first concerns the process by which individuals consent to deposit tissue samples and personal information with biobanks; and the second relates to the rights of ownership, control and financial benefit that comes from the use of these samples and data by third parties that include commercial organizations.

For ethicists, lawyers, social scientists and others, biobanking is a significant sociotechnical activity in the
field of biomedical research that raises a wide range of issues relating to the formal conditions and procedures by which individuals are recruited to these initiatives; how biobanks establish their social and political legitimacy through novel governance structures; how public and recent work on the political economy of the life sciences in the twenty-first century by sociologists of science and technology points to the broader economic context in which biobanks must be situated. Biobanks, whether for epidemiological, pharmacogenetic, cancer or stem-cell research, are positioned as having a pivotal role in the “bioknowledge economy” [7]. With their promise to utilize the genetic or biological characteristics of populations as resources for the production of intellectual property, biobanks are seen as key elements in the production of ‘biovalue’, by which life itself is seen as productive of surplus value [8]. In addition to their potential to be resources that will improve human health, biobanks could also provide the means for boosting national or regional biotechnology and the pharmaceutical sectors. With the exception of private cord blood banking, where individuals pay to have tissue stored for potential future use [9], most types of biobanks operate on the principle that individuals would voluntarily and freely provide biological samples and personal information. The transaction between the biobank and the volunteer or patient is, therefore, a noncommercial one and has sometimes been conceptualized as a ‘gift relationship’ – a deliberate echo of Richard Titmuss’ use of that expression in relation to blood donation [10][11] – to emphasize that people should be acting altruistically. Access to and use of biobanks, however, might very well be on commercial terms, with biotechnology and pharmaceutical companies as well as universities as likely future users of these resources. This has led to a debate about whether and on what terms such organizations should financially benefit from research conducted using samples freely provided by individuals. As many existing biobanks move from the banking to the research phase, opening their resources for researchers to access and use, it is clear that many of the issues will remain pertinent for the foreseeable future [12][13][14].

III. PRIVACY OF GENETIC INFORMATION

Previously untouched topics such as consanguineous marriages leading to abnormal births in particular communities, featured in media debates. In the past two decades, issues around genetic testing have been popularly debated within academic and medical communities; also in the media. Thalassemia, Down syndrome, neural tube defects are prevalent in the Indian subcontinent and large numbers of skin cancers are seen in the South East Asia [15]. Monogenic disorders are inherited, and may be contained within a family. The private interests are negotiated by biobanks in a context of great commercial interest in human tissue and personal clinical data and how biobanks reflect cultural and political discourses of national identity and might serve to address the health needs of different groups in society. Common knowledge about inherited diseases is gradually increasing; however, it has also raised considerable issues with regard to paternity testing, foeticide for abnormal embryos and issues related to predictive genetic testing. The decision to take genetic test may be challenging, particularly where no cures and therapies are available and people do not have means to pay [16]. Genetic counselling is generally provided by clinical geneticists and doctors rather than professional genetic counsellors in large part of developing world. The lack of trained counsellors to help ethical decision-making on such issues hampers the development of services; and the ramifications are both personal and social. The positive outcome of a test is regarded as a burden and even the counselling can be socially conditioned especially in the ways it is provided, making it difficult for the bearer. For example, emotional, religious and social pressures are brought into the process of decision-making, it questions. This makes both the authority and the choice of the final decision either to continue or discontinue with pregnancy.

The process of decision-making can be very complicated and sometimes difficult to rationalize. Particularly in the two big countries of Asia, India and China, prenatal testing is not offered routinely to pregnant women. Fetal ultrasounds for gender tests are illegal in most of the Asian countries, but sometimes indirectly asked by the families and also illegally provided in some private practices. Although the one child policy in China has helped to control the population a little, it has placed considerable pressure on women in a society where boys are traditionally preferred in patriarchal family system. This is also seen in other countries in Asia. The notions of ‘abnormality’ go beyond physical attributes, and become highly complex with the intertwining of socio-religious beliefs, such as ‘fate’, ‘will of God’. Positive results can be considered as a ‘shame’ for the family and ‘burden’ on society [17]. The social stigma attached to an inherited condition is huge and affects all other aspects of life, such as college admissions and prospects of marriage in India. Hence, the ordinary couples very rarely undergo carrier testing and counselling.

Genetic privacy is a difficult concept to define, and even experts such as bioethicists disagree about it. The word privacy itself has many meanings, and some cultures have no word for it in their language. Is this kind of information secret, or particularly confidential? Potential misuse of genetic information assumes a very harmful consequence to a person. The so-called ‘DNA databanks’ – catalogued files of persons’ genetic profiles – that are predicted are an example of this concern. Misuse is most often assumed of governments, law enforcement,
employers and insurance companies, but the list expands as the social consequences expand. Genetic testing and genetic screening have different meanings. Testing involves families, and occurs when past experience and medical history indicate a risk for a genetic condition. Screening involves populations, such as all children immediately after birth, or all applicants for a particular job [18][19].

**IV. DISCRIMINATION BASED ON GENOME SEQUENCE**

Asian participation in the Human Genome Project was limited. However, countries like India recognized the potential of the information and prospects of research into new therapies early on. With the boom in the Information and Communication Technology sector, India is trying to exploit the knowledge through bioinformatics and high output infrastructures in parallel with basic research. Several other countries in Asia, in particular China, Japan and South Korea, have focused on fundamental research in genomics and other similar fields such as stem cell technologies. Most Asian countries also understand the biocapital value of genomics, and hence concerted efforts are taken to enhance research infrastructure within individual countries. One serious concern is that there is an increasing gap between the high-level medical research and its clinical applications for populations. A clash is seen between the investment policies; on the one hand there is recognition of the need for better local primary healthcare systems, on the other huge investments are done in advance medical research to compete globally. With globalization the views of the people are changing; however, increasing understanding and acceptance of diseases does not necessarily mean that it will translate into increasing availability of healthcare in public domain. The healthcare is also becoming rapidly private, especially in advanced medicine. With the increase in per capita income of people, many are ready to pay a premium for a better healthcare in private practices.

The noncommunicable diseases are as much on the rise in Asia as communicable diseases. There is a sharp increase in the common but complex disorders that occur due to lifestyle and environment, for example obesity, diabetes, asthma and cardio-vascular diseases. It is estimated that by 2025 the number of Asians with diabetes could hit 198 million. Six countries in particular – India, China, Indonesia, Japan, Pakistan and Bangladesh – are listed in the World Health Organisation’s 10 Asian countries with the greatest prevalence of obesity in the continent. With such potential economic and social disaster, research is needed into therapeutic and preventative measures. The developments of biobanks and population based genetic databases within Europe triggered big countries in Asia to develop similar national level research resources. Globally, the majority of biobanks intend to look into lifestyle-related conditions and the role of the gene–environment interactions, with the possibilities of developing population-based screening and preventative measures. Some of the larger countries in Asia, including China, India and Japan and some smaller ones, such as Singapore and Taiwan, are in the process of setting up biobanks for research and development purposes, either independently or as collaborators in the international projects. The well publicized Guangzhou biobank project in China, or the Japan biobank project, and a biobank focusing on Women’s health in India, Parsi gene database in India and Taiwan biobank project are examples of growing interest [19][20].

One of the major criticisms of such developments is the rapidity of such developments, without the establishment of the appropriate regulatory mechanisms. The lack of stringent, Institutional Review Boards (IRBs) have resulted in the lack of trust in biobanking projects. These projects involve collection of biological samples. Given the lack of public knowledge about the nature and the potential of these projects, questions are raised on the autonomy of the participants, informed consent procedures and quality of the data. At the same time, there are other ethical arguments made about promoting research on race and ancestry which had astounding implications for medicine and ethics of healthcare. Traits, conditions, syndromes or diseases with an identifiable genetic component may be amenable to preventive interventions at the genetic level. No longer would a person be at risk for a disability or disease. Each time a discovery is publicized, the public might believe that, suddenly, a cure can be effected. This is not true and, in fact, identification is often possible long before any intervention is.

The tendency to label ‘gene identification’ as somehow exact and predictive is problematic. Many conditions are results of multigenic and multifactorial influences. Ages of onset, clinical manifestations and progression can vary greatly from individual to individual. Perhaps asymptomatic carriers might be labelled as somehow diseased, as might persons whose genetic profile can identify only a predisposition. What purposes might there be for making a diagnosis when no treatment is possible? The identified genetic component could be used to discriminate. An insurance carrier might refuse coverage, claiming that a genetic test revealed a ‘pre-existing condition’. A military organization might refuse promotion or assignment, claiming the person could not tolerate high-altitude training conditions. Prospective teachers might be refused employment if progressive disorientation and mental instability characterize conditions for which they carry a gene or genes. Coercive policies could be adopted by governments and insurance carriers; these policies could mandate prenatal and premarital testing. What will be the rights of persons who, during a pregnancy, learn that a fetus will be born with a debilitating condition, and who choose to continue the
V. GENE THERAPY

Gene therapy can be defined as the deliberate transfer of genetic material for a therapeutic purpose. It is an experimental process and as with all experiments that involve human beings, many specific protections for research subjects are in place, within laws, research protocols and codes of ethics of the scientific and medical professions. The world’s first human gene therapy experiment began on 14 September 1990, when a 4-year-old girl with adenosine deaminase (ADA) deficiency was injected with some of her own, genetically modified, bone marrow stem cells. People with this disease have a malfunctioning ADA gene, which leads to the destruction of T cells due to the build-up of toxic levels of deoxyadenosine. The cells had been removed from her body, cultured in the laboratory, and treated with a vector (a retrovirus) in an attempt to transfer an ADA gene into her malfunctioning cells. French Anderson, who led a group of clinician/researchers who conducted this pioneering experiment, had defended gene therapy research in public for several years before the US government gave the team permission to begin clinical trials. He argued that ADA deficiency is an ideal candidate disease for gene therapy because it results from a known genetic cause, is progressive and fatal, and has no known cure. Previous animal studies on transferring genes into T cells had also achieved promising results. The experimental protocol also required that the patients with ADA deficiency would receive polyethylene glycol (PEG)-ADA in conjunction with gene therapy. PEG-ADA is a version of the ADA enzyme that is somewhat effective in reducing toxic levels of deoxyadenosine in T cells [21].

Gene therapies are more likely to be successful if a single mutation is implicated in causing a disease or disability. There are, however, many difficulties with both the process of insertion and control of the inserted gene. The process is expensive, and available only within select hospitals and research centres that have the available technology. Somatic gene therapy (SGT) is similar to other forms of medical treatment in that the goal is to treat or prevent diseases in individuals. SGT raises questions concerning safety and efficacy of treatments and protection for human research subjects. Since these initial experiments, somatic gene therapy (SGT) has grown steadily. Thus far, tens of thousands of patients have been enrolled in SGT experiments worldwide. The diseases that researchers have attempted to treat with SGT now include severe combined immune deficiency (SCID), cystic fibrosis (CF), familial hypercholesterolaemia, Canavan disease, coronary artery disease, arterial restenosis, rheumatoid arthritis, Gaucher disease, alpha-1-antitrypsin deficiency, Fanconi anaemia, various forms of cancer, heart disease and HIV/AIDS. Proposed future SGT targets include Lesch–Nyhan syndrome, phenylketonuria (PKU), haemophilia A or B, Duchenne muscular dystrophy and Huntington disease, among many others. Additionally, public and private funding for SGT has risen from several million dollars per year to hundreds of millions of dollars per year since 1990. If one includes genetic research that has applications for SGT, then one can multiply financial support for this research enterprise tenfold.

Germline gene therapy is different from traditional medicine because it involves manipulation of the human genome to prevent the birth of children with genetic diseases. Germline gene therapy has been much more controversial than SGT, because it creates risks not only to patients but also to future generations, and because it may lead to genetic enhancement. Genetic enhancement raises a number of difficult issues, including the ethics of changing human traits, parental control over children’s lives, exacerbation of discrimination and social inequalities and eugenics. Although therapy is the word used, the procedure is still a medical experiment. Even if the experiment appears to be initially successful, long-term effects are not known. Germline gene therapy has not yet been attempted with human beings but has been successful in mice. People in favour cite efficiency in the use of healthcare and monetary resources. Suffering associated with a disease need no longer be a family’s special burden, shared through generations. Persons opposed cite the possibility of unpredictable and unforeseen consequences for which the original patients and all their descendants are at risk. Several commentators have identified the human gene pool as the shared property of all people, suggesting that to tamper deliberately with it for a narrow personal goal is unethical. Enhancement gene therapy may be somatic or germline. No single genes seem identifiable for
traits that a person would want to have enhanced or created. Discussion currently centres on height (stature) and intelligence. Issues of personality, temperament and behaviour are also being examined. The great complexity underlying these traits is not understood, although speculation abounds. Even if a biological underpinning is observed, the external environment will affect the outcome. Whether such a genetic component is a determinant, or one of several factors, continues to be examined and debated [22].

VI. STEM CELL RESEARCH & CONCLUSION

From the point of view of consumers, activists and patients, stem cell research may seem to have materialized from nowhere, a miraculous discovery with great potential. Unlike contemporary genomics, which has become very much goal-directed and focused in character, stem cell researchers have not one or two therapeutic goals but in fact hundreds of possible research and clinical trajectories for their laboratories. Moreover, embryonic cells have long figured prominently in basic research in human and veterinary cell biology, in clinical trials of possible therapeutic techniques and even in a number of successful therapies. Basic research involving stem cells is most often focused on fundamental problems of developmental biology. The roots of stem cell research are to be found in understanding the chain of events and set of structures involved in processes of embryonic and fetal development. At the heart of these studies is the question of how a human embryo transforms into a complex human being. There are at least two kinds of highly flexible embryonic stem cells, the core from which an embryo begins its developmental journey post-blastomere: hES cells are best classified as ‘totipotent’ cells and ‘pluripotent’ cells. The totipotent hES cells are found in the dividing fertilized egg. These cells have the unique ability to develop into any cell or tissue types found in the human body, for example, liver, cardiac, nerve or blood cells. In addition, they have the capacity to form a complete organism. Pluripotent hES cells are found in the inner cell mass of the blastocyst, the stage of development in which the dividing cell mass forms the shape of an almost hollow ball. Although pluripotent human hES cells can develop into many, if not all, cell and tissue types, it is currently not believed that they would have the ability, if implanted in the human uterus, to divide and mature into an organism. Pluripotent stem cells are the cells most often used in embryonic stem cell research.

In order to obtain embryonic stem cells, the inner cell mass of a blastocyst must be isolated from its outer shell, removing the embryo from what would have developed into the placenta. Moreover, the inner cell mass is disassembled by taking out individual embryonic stem cells for research purposes. The embryos used for hES cell research usually come from embryos created through (IVF) but not utilized for that purpose. The euphemism ‘spare’ or ‘leftover’ embryo has been coined by clinicians and used by politicians to describe this source of cells for hES research and therapy.

Irrespective of the form of embryonic cells to be utilized in research, the involvement of assisted reproductive technologies (ART) embryologists, technicians and clinicians is omnipresent. The processes whereby embryos are created (whether from donor eggs and/or sperm intended for research purposes, or as a byproduct of reproductive healthcare), analysed, stored, removed from nitrogen freezing or destroyed, are all procedures that require, as a matter of course, the technologies, clinical expertise, patient population and institutions of ART. It is thus no surprise that the largest research programmes to date in the field have employed obstetricians, andrologists, reproductive endocrinologists and even ART psychologists and social workers. Ethical issues related to these individuals’ participation in stem cell research include three key problems. First is the question of whether and under what circumstances patients or research subjects should be allowed to participate in the donation of reproductive materials for stem cell research, particularly where that research involves the creation of embryos for research purposes. Second is the question of whether reproductive clinicians and technologists should be involved in the non-reproductive use of cloning technologies for the creation of nuclear transfer derived stem cells. Third is whether clinicians involved in the derivation of embryonic stem cells should be held responsible for the failure of those cells in clinical trials or therapies using those cells. On none of these issues is there professional consensus at this point, although all three issues will receive the attention of the ethics boards of professional societies in near future [23][24].

REFERENCES


