'SHIFTING PERIMETERS': SOCIAL AND ETHICAL IMPLICATIONS OF HUMAN GENOMICS RESEARCH

Report of the International Seminar held at
National Institute of Advanced Studies, Bangalore

November 15-16th, 2010

Organized by
Indian Institute of Advanced Study, Shimla, and
National Institute of Advanced Studies, Bangalore

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Introduction

Representing emergent global assemblages of science-techno-capital power, research on the human genome has made quick alliances with market networks, flexible capital, and global research. Despite the growth of human genomic research (HGR) and its presence in a wide array of possible uses, the ethical, legal, and social implications (ELSI) of human genomics have largely been reduced to a footnote. Research on the human genome and its allied science and technical engagements stand to be read at multiple levels: as new information which has implications for a range of disciplines; as sources for new medical knowledge that can be deployed against a range of diseases; as the prototype for new organizational structures for conducting science and technology research; as holding the mastercode to the possibilities of remaking the physiological constitution of humans; as commercialized knowledge in which humans can exercise their choice and options to redefine the physical and social body; and as a body of knowledge that has the potential to alter the perimeters between science and society and the very constitution of a range of disciplines.

In seeking articulations over these issues and concerns, this seminar was a preliminary conversation to bring together understandings and interpretations related to several questions:

1. What are the potentialities of the body of knowledge of human genomics? What significance does it have for the disciplines of medicine, neurobiology, psychiatry, sociology, anthropology, political science, public administration, jurisprudence, and history?

2. What regimes (legal, ethical, political) are required to manage the linkage of human genomics research and its use in a wide variety of fields? What significance does human genome research have for the increasingly market-based, commercial, and profit-oriented research enterprises ?

3. What are the potential advantages and disadvantages that countries, such as India, face in the conduct, dissemination and use of human genomic research?

4. What national and international regimes (legal and ethical) are required to ensure that knowledge and information from human genomic research is used as a public good and, therefore, what new transnational regulations are required to ensure this?

5. What are the implications of the use of human genomic research in the fields of a range of new medical knowledge (psychiatry, psychology, physiology etc) and practices (such as personalized medicine; profiling; predictive genetic testing etc)? What ethical and legal concerns need to be borne in mind even as these gain wide usage?

6. What are the larger universal concerns relating to the possibilities of using human genomic research to alter the physiologies of humans and hence what larger ethical and philosophical issues can be raised about the very constitution and understandings of the 'human'?

Bringing scholars from India, the United States of America, United Kingdom, South Africa, and the Netherlands, the international seminar held at NIAS, jointly organized by the Indian

Institute of Advanced Study, Shimla, and the National Institute of Advanced Studies, Bangalore addressed some of the concerns and issues and concluded with a call for further studies and policies related to the understanding and regulation of human genomics research. Part I of the report is a summary of the presentations and discussions. Part II is a summary of the concluding discussions and recommendations to take the discussions forward.

Part I

The Ethical, Social and Legal Implications (ELSI) of human genome research received a major push in the Human Genome Project. Although concerns about the abuse of genetics and apprehensions about possible misuse of science in the name of eugenics are not new, the rapid developments in genomics, information and communication technologies, and in emerging technologies such as nanotechnology have given rise to many new questions and new issues and challenges for academics, policy makers and perhaps for human kind itself. Issues like privacy, intellectual property rights over genetic materials, sharing of genetic resources/materials and developing regulatory regimes can no longer be considered as issues that are of relevance only to developed countries.

Given the rapid globalization of knowledge and its applications social scientists cannot afford to be complacent in their assessments about Ethical, Social and Legal Implications and this is all the more true of law and policy makers as laws and regulatory regimes struggle to cope with technological developments and need frameworks that are adequate enough to perform what has been called as ‘Real Time Technology Assessment’ and think in terms of anticipatory governance.

In his opening remarks Prof. Peter de Souza (Director, Indian Institute of Advanced Study, Shimla) made it clear that this was not yet another seminar but a prelude to a conversation among scientists and social scientists. He underscored the implications of developments in science and technology for the conceptual frameworks in social sciences. He spoke about the beginnings and the broader mandate of IIAS and explained how this conference fitted well with the mandate and agenda of IIAS. He stressed the importance of an enduring conversation among scientists and social scientists and expressed the view that such a conversation should be sustained over a period of time. He spoke about the new issues in ethics, policy research, and regulation in the wake of research on the human genome and suggested that this terrain was not yet explored. According to him the conversations among the inhabitants of the two epistemic worlds should result in co-operation and better understanding of the risks, limitations and implications of the scientific knowledge gained from projects like Human Genome Mapping. Elaborating this further he specified four clusters that needed further research and exploration. The first cluster was that of promises and possibilities of the new science and our capacity to process the data and understand the promises, risks and possibilities arising out of this Mapping. The second cluster was that of ethical issues that spanned various levels ranging from individual, group to community and the range of issues included discrimination, privacy, genetic profiling, questions of choice and consent and ethical issues in interventions at different levels of human society and whether we should choose the techniques just because they are available. In the third cluster he placed questions like what were the implications of these developments in genetics, particularly from a social science perspective, understanding of concepts such as person, privacy, choice, intergenerational justice, regulation etc. Prof deSouza wondered whether our current concepts are sufficient enough to cope up with the implications and impacts of the advances in scientific knowledge and practice and he alerted us to the emergence of new concepts such as bio-colonialism and bio-piracy. The fourth cluster of issues was that of regulation, policy making and the capacity of institutional frameworks to deal with the advances in knowledge. He put forth some pertinent questions in this regard and illustrated them with the story by Arthur Clark (Rendezvous with Rama).

Welcoming the participants, on behalf of the National Institute of Advanced Studies, Bangalore, Prof. B. V. Srikantan (Visiting Professor, NIAS) spoke about the beginnings of NIAS and the vision of Mr. J.R.D.Tata, who envisaged NIAS as an institution for inter-disciplinary research where scientists and social scientists were equally at home. He talked about the programmess being offered at NIAS, the courses that were organized at NIAS. He briefly explored the significance of knowledge explosion and illustrated that with developments in an exciting and new field in physics- nuclear reactions at low temperatures and was of the view that developments in this field would be of much importance in biology.

Prof. Wiebe E. Bijker (Professor of Science & Technology of Society Studies, Maastricht University, The Netherlands), a doyen in STS, made a presentation titled ‘The Governance of Risk and Benefits of Genome and Engineering- Related Experiences in Europe’. His presentation addressed two important and contentious issues – scientific expertise and democracy and how democracies can deal with uncertain science. Based on the experiences in the Netherlands to study and understand the trends in biotechnology that may need policy intervention he offered two examples – the $1000 genome (i.e. genome sequencing of an individual at a cost $1000) and the application of biotechnology in health care (e.g. stem cells, personalized medicine, and gene therapy)- to indicate how the Biotechnology Trend Report by a committee consisting of scientists and social scientists walked a fine line between expertise and judgment and thereby brought expertise to policy making. He discussed in detail the new risks in handling Human Genome Research such as indications of potential hazard although hard scientific proof was not available and hence the adequacy of current regulations was not clear. He stressed on the need to understand these new risks and underlined the importance of ‘risk governance’. Elaborating this further by looking at nanotechnology as a case study he specified the different types of risks (simple, complex, uncertain and ambiguous) and the associated issues that focused. He observed that risk situations needed different approaches and accordingly the involved groups would be different in each case while the core question however remained the same i.e. who decides. These debates on risks and expertise, and involvement of different groups, were a challenge to democracy particularly to democratic governance. He gave the example of the Dutch Societal Dialogue on Nano technologies as an experiment in science and democracy that dealt with ‘serviceable truth’ without compromising on scientific quality. According to him HGR would remake boundaries between science and society, regulation and democracy, and experts and citizens. These tensions, hence, called for engagements between science and democracy, for building conversations across disciplines.

In the discussion on his presentation several interesting questions were raised; on, inter alia, whether such experiments are unique to Netherlands, and if democratization of science and innovation were possible by stakeholders such as patient groups. Prof. Bijker reiterated that he was all for democratization in policy making and involvement of different stakeholders in decision making on new risks and new opportunities from developments in technology.

In his paper, ‘Beyond ELSI’, Prof. Sasheej Hegde (Professor, Dept of Sociology, University of Hyderabad) discussed the emergent forms of life and the ‘morality’ of HGR, and issues that go beyond the typical ELSI approach to HGR. Drawing upon the works of Michael Fischer and Nikolas Rose, Hegde linked the ideas of both with that propounded by Michel Foucault on biopolitics. He underscored that there was more to molecularization than explanations as molecularization was reorganization of the gaze of life sciences and its regimes, and practices, and, included both possibility and uncertainty. According to him this would mean that HGR was both conservative and revolutionary and the HGR thus posed a challenge to science studies. In other words we would have to be aware of both the relentless pursuit of modern biosciences and the reifications particularly through fixed conceptual forms and megaprojects. He had put forth a complex set of arguments and brought in ideas used by scholars in diverse disciplines in their pursuit to understand biopolitics and projects such as HGR.

Prof Sharat Chandra (Emeritus Professor, Indian Institute of Science) as chairperson of the session on HGR and ethics, shared some of his recent observations and experiences related to genetic research. He elaborated on how research on Downs’ Syndrome during the last half century had advanced our understanding of the disease but the treatments available had given rise to new challenges and issues that were not anticipated before. Genetic testing of embryos had brought in the possibility of predicting the chances of the baby born with Downs Syndrome and this itself raised many ethical issues as it gave the option of abortion if the parents chose not to beget a child with this syndrome. On the other hand, thanks to diet regimes and other approaches to improve the autonomy of children with Down’s Syndrome, their lifespan had increased. As a result, at least, some of the children outlived their parents. This had implications for care and support for these grown up persons with the Syndrome. As the family norms and obligations were undergoing change new issues had arisen. He also pointed out the insensitivity of experts to human suffering as they were more keen to pursue research on disease models based on mice than on finding cures or therapies that would enable parents to increase the intellectual capacities of those born with the Syndrome. He highlighted how a leading scientist who had earlier worked on this was aghast with the developments that enabled abortion as an option and how his own work could not attract funding in the later years. Prof. Chandra’s talk underscored the need to pursue scientific research that is geared to finding solutions besides advancing knowledge and pointed out the ethical issues and dilemmas faced by parents in using techniques like genetic testing of embryos for possible genetic ‘defects’ and ‘undesirable’ syndromes.

Prof. Madhava Menon (Radhakrishnan Chair of Rajya Sabha), began his talk with the issue of the use of endosulfan and the controversy over its continued use in Kerala and the suggestions to ban it. He traced the roots of modern concern and fear about the dark sides of science with the development of the atomic bomb and its use in Hiroshima and Nagasaki. He posited that pursuit of knowledge and all human activity should be for human well-being and this objective would be the touchstone to check the legitimacy of any such activity. Drawing upon the Universal Declaration of Human Rights (UDHR) and the fundamental rights as enshrined in the Constitution of India he argued that these provided the core principles in regulating research and in regulating science and technology. According to him, in a democracy where the rule of law accepted irreducible human values some activities could be prohibited if the outcome would negate or diminish those values. But these are not fixed and as international norms and jurisprudence on human rights continued to evolve, issues like informed consent, right to privacy, etc acquired new meanings, and new approaches were necessary. But several unresolved issues like patenting of human genes and ensuring fair and equitable benefit sharing in commercial transactions remained. He highlighted the ethical and regulatory issues in clinical trials in India and wondered whether the current legal regime was adequate to protect public health in trails. He pointed out that while this looked fine and reasonable in theory, in practice the core issue was that of enforcement and authority to regulate as all stakeholders might not come under the jurisdiction of the same legal authority. Calling for a balance between regulation and research, he suggested that preventive strategies could play an important role in safeguarding the interests of vulnerable sections.

In the discussions that followed, a question about the conflict between fundamental rights and Directive Principles in the Constitution was posed and it was suggested that the legal regime might end up legitimizing some activities in the name of regulation and hence the logic and rationale behind the idea of regulation and the corresponding cost-benefit approach should be questioned. Prof. Menon was of the view that potential conflicts could be resolved and a balanced approach could be evolved. In response to this it was suggested that an anticipatory legal framework would be needed and the risk/benefit approach could be used instead of cost/benefit analyses.

In his opening comments on the session on bioethics, Prof Vinod Gaur (Visiting Professor, Indian Institute of Astrophysics, Bangalore) discussed the challenges posed by the explosion of knowledge and the internationalization of this acceleration. According to him this, in the context of genetic research, could result in genetic exclusion and hierarchy and a system of exclusion. He called for a harmonization of knowledge and values and observed that in our search for knowledge we should not ignore principles such as the sense of justice and respect for diversity.

Dr. Ratna Puri's (Gangarams' Hospital, New Delhi) presentation underscored the importance of HGP for diagnostics and therapeutics. She discussed the issues in genetic counseling and the factors that influence patients in genetic counseling. Eschewing an approach that divides choices as absolute rights or absolute wrongs she focused on the interface between law, ethics and culture in genetic counseling and laid emphasis on the basic ethical principles to be followed by doctors and counselors. Dr. Puri highlighted the fact that the burden of genetic diseases at birth in India was high and yet there were only 47 genetic counseling and testing centres in India. In addition, the absence of affordable treatments and lack of insurance coverage force parents to consider prevention as a priority and with increasing acceptance of abortion as a choice prenatal diagnosis was in great demand. She gave examples from her experience and discussed how patients wanted directive advice from doctors as they were considered to be experts and preferred doctors to tell them what they should do rather than take decisions based on counseling alone. Citing from her experience, Dr. Puri argued that while there was an increase in the number of couples who preferred testing and counseling, the decision making was not a question of simple choice as families had a role to play. According to her, the previous incidences of genetic disorders in extended families and increased awareness had resulted in more couples, particularly the educated ones, opting for these tests sometimes even before marriage lest they should beget a child with a genetic disorder or symptom. But the knowledge outcome of the tests was like a double edged sword in predictive testing and the response could range from guilty feeling to depression or helplessness. Her experience suggested that there was a preference to know than not to know or do the predictive testing and for several reasons test results were not shared with family members. She argued that prenatal testing could help in reducing the burden of genetic diseases and prenatal testing was often sought for genetic defects such as deafness and albinism. Drawing upon a controversial case on whether to permit or not an abortion of a 26 week foetus, as the fetus had cardiac abnormalities, she suggested that many women acted as autonomous and responsible decision-makers despite family and social constraints and considered genetic testing as their duty to the family and to the unborn child. In the latter part of her presentation she dwelt upon the challenges of ethical practices in genetics, in light of the increasing use of ART and direct to consumer genetic testing. She discussed the question of genetic discrimination and wondered whether knowledge of human genetic variation would increase or reduce prejudice. Her talk illustrated the ground reality in genetic testing where knowledge need not always be comforting and the dilemmas posed before persons who opt for genetic testing. Such an analysis of the range of issues from lack of insurance to lack of adequate number of trained doctors/ counselors drove home the point that genetic testing and the outcomes could not be viewed in isolation of social contexts, values and preferences.

Dr. Linda MacDonald Glenn (Albany Medical Center, New York) made a presentation on ‘Human Genome Research + Converging Technologies = The Singularity?’. She argued that law had classified persons and objects either as person or as property but that was changing and there was a continuum and animals were considered as property and not as full persons. She pointed out that the idea of quasi-property and associated property rights had to be constructed in case of embryos as their ownership and commodification created problems for traditional concepts of property or person. She highlighted the technological convergence that involved genetics, nanotechnology, and robotics and the concerns related to the convergence for privacy, access and the societal impacts of such convergence. Turning her attention to the ethics of patenting of genes and gene sequences she spoke about the controversy over patenting BRCA1 and BRCA2 genes and the judgment that declared such patents as invalid. She also mentioned and welcomed the position taken by the United States Department of Justice in this, which supported the idea that genes as occurring in nature should not be patented. Her talk focused on the legal aspects of ELSI in genomics research and issues in extending Intellecutal Property rights over genetic knowledge. A participant raised the question of the relationship between law and ethics and pointed out that the law often laid the parameters of what constituted ethics.

In his talk Prof. Venkat Rao (English and Foreign Languages University, Hyderabad) gave a scathing critique of European modernity and the violence that was unleashed by it over humanity. He was skeptical about the grand claims of progress, science and modernity and stressed the need to think in terms of new conceptual frameworks that were informed by post-modernist thinking and are sensitive to the realities of post-colonial societies. He drew attention to metaphors like ‘Book of Life’ and pointed out that the new possibilities opened up by Information and Communication Technologies that enable archivisation and embodiment outside the body and the resulting new ways of inscriptions that facilitated encoding flesh as data and vice versa. In his talk he drew upon ideas like ‘biocapital’, ‘surplus health’ and recent theories by Nicholas Rose and pointed out that technological possibilities could mean striving for sovereignty over everything and more desire for control. Thus, according to him, what was at stake was life itself, in somatic, body/molecular levels. To counter this he suggested we would need to draw upon different heritages of Europe and recent works in STS, biopolitics, and anthropology of techno-science so that non-European cultures could handle these developments and provide different forms of cultural understanding and response than to buy the universal claims of technoscience and its totalizing visions that enable new technologies of control. His presentation highlighted how critical humanities could be useful for us in both understanding and responding to these developments in life sciences.

Drawing upon his expertise in philosophy of biology Dr. M.G. Narasimhan (NIAS, Bangalore), in his presentation, drew upon debates on the idea of the gene and the use and abuses of genetic information and argued that in the name of ethics options in research and search for knowledge should not be pre-empted. He began with a description of DNA and the Central Dogma of Molecular Biology which described the coming together of the theory of evolution and the new Genetics. He pointed out that with the growing anxiety about genetic determinism. He explored the idea of genetic information as a biological entity and the implications of this idea and the definitions associated with this idea. He explained that the three main uses of genetic information (i) as a tool of identification at the level of the individual, (ii) as a diagnostic tool and (iii) in the context of predictive screening. He illustrated the abuses of genetic information in different contexts ranging from eugenics to discrimination by insurance firms. Describing the shortcomings of a genes-centered approach in biomedicine he drew attention to the alternative approach suggested by Kegley and favoured a dialogic approach in decision making in the context of genetic analysis and its implications. He pointed out the dilemmas in possessing genetic information and handling it, and put forth the case for a global watch body over abuse of genetic information on a massive scale. His talk brought together concepts in biomedicine, theoretical debates, and the use and abuse of genetic information and cautioned against genetic determinism even as he pointed out that ethics should play a role in these but that should not be based on *apriori* assumptions about beneficial and malevolent aspects of research.

Dr. Norma Tsotsi (Steve Biko Centre for Bio-ethics, University of Witswatersrand,South Africa) started with a description of the death of Steve Biko, a leader in the anti-apartheid movement in South Africa and explained how doctors were complicit in that and also pointed out that ultimately it was some other doctors who brought out the truth. She then spoke about the activities of the centre and described how South African society was still struggling with the after effects of the Apartheid regime. She described the ethnic diversity in South Africa and the significance of this diversity in a country where 80 percent of the population was Black/African. She spoke about the gaps in regulating biomedicine in South Africa and pointed that out that the law was silent on the use of genetic information. Peter deSouza pointed out that Dr. Tsotsi presented a developing country perspective and the importance of understanding the use and abuse of research on human genome in diverse contexts and conditions.

The next presentation by Dr.K.Thangaraj (Centre for Molecular Biology, Hyderabad) was keenly watched by participants as he presented the findings of a series of studies based on the analysis of genetic samples collected from various groups in India including that of indigenous groups in Andaman. He drew attention to the fact that certain groups were more vulnerable to some diseases due to their genetic make up and this had implications for prevention and diagnosis. He then presented the findings that showed the ‘genetic distance’ among groups and the uniformity and diversity in groups in India and explained the classifications used in the studies. He pointed out that due to endogamous marriage and closely knit kinship patterns in India the gene pools within groups showed remarkable uniformity although due to various factors there had been intermingling of genes from different groups at different times and in different regions. According to him different Indian groups had inherited different proportions of ancestry and he concluded by highlighting the possible factors that resulted in high genetic drift in India.

Questions were raised about the classification and assumptions behind these studies and how the scientists used concepts like caste, ethnic groups in these studies.

Dr.Thangaraj underscored the fact that the expertise of anthropologists was used and the work by Anthropological Survey of India (People of India project) was also used. Many questions were raised on the implications of these findings for social sciences and their understanding of Indian society but given the wide range of questions and the need to understand the findings of these studies a separate workshop/conference involving more scientists and social scientists would be desirable as due to lack of time and other factors discussions on these issues in this conference had to be limited. Nevertheless the presentation could be seen as a curtain raiser and the response it drew pointed to the need for more social scientists to engage in such research and for further understanding of the findings. The need for the ‘two cultures’ to talk to each other rather than talk past each other was highlighted in this session .

The last two presentations by Prof. Peter Glasner (Sociologist, University of Cardiff, United Kingdom) and Prof. Shiv Visvanathan (DAIIT, Ahmedabad) were interesting and provocative. Peter Glasner needed no introduction as he had been addressing issues on genetics and society for more than two decades. Glasner’s presentation titled as ‘Topologies of Genome: Mapping the New Genomic Era’ covered a whole gamut of issues from the visions of gene to the emerging bioeconomies in India. Starting with the genealogy of HGP and the gene as a cultural icon he pointed out the differences in the representations of the gene as articulated by different stakeholders. Describing the maps, topologies and metaphors of the genome he pointed out that proprietary products had been created by different types of samples, making genes as a mobile commodity. He suggested that the terms bio-economy, bio-materials, bio-value and bio-knowledge could be the new currencies. He described the topologies of global flows ranging from trust to personnel, from materials to standards and the multiple topologies and expectations of different stakeholders. He elaborated the promises of genomics and how the anticipated promises were guiding research and development, providing legitimacy and attracting funding. He presented some hard facts that challenged the myth that genetic medicine was about to fulfill its promise. He discussed the emergence of bioeconomies and using, stem cells as a case study he mapped the various sites and nodes in the bioeconomy of stem cells that transcended national boundaries and showed that a developing country such as India was inscribed into this and there was a value chain in India that covered different aspects from materials to treatment and research. Drawing upon the book ‘Local Cells, Global Science: The Rise of Embryonic Stem Cell Research in India’ he argued that legally non-binding regulations provided flexible spaces and facilitated rapid development in India in this field. Thus he argued that the global and local are fluid, with occasionally converging and conventional polarities being blurred. Calling for social scientists to deal with the topologies of the genome without succumbing to the hyperboles, Prof. Glasner’s presentation showed how social scientists could map the flows across space in genetic materials and rethink their understanding of national and global regimes in biotechnology in the light of bioeconomies that were both local and global, with clients and stakeholders dispersed in different regions of the globe.

In his provocative presentation, Prof Shiv Visvanathan (DAIIT, Ahmedabad) spoke about the need to create a framework for genomic discourse and suggested that while the formal constitution dealt with law, policy, economics etc., a tacit constitution to discuss the categories and emergent challenges is needed. He argued that although Foucault’s idea of biopower was useful it had little to say on bio-power as a notion of informatics. He drew attention to the work of Paul Rabinow and the SynBERC project. He then contrasted Mode I and Mode II and put forth the view that Mode III moves from uncertainty to emergence[2]. According to him on Mode II and Mode III Indian experience in terms of science studies and social movements could be relevant. Then he looked at the issue of diversity and race in the context of the Human Genome Project and UNESCO’s earlier work on race as a category and elucidated the views of RAFI (now ETC Group), Troy Duster and Cavalli-Sforza to argue that reflexive organizations that can cut across the opposition between experts and lay persons are needed. He cited the work of Michael Callon on French Muscular Dystrophy Patients’ Groups to suggest that a similar one in India could work on the issue of sickle cell anemia among tribals in Gujarat. In the rest of the presentation he called for a new commons of biology and made a plea for re-writing philosophy and an invitation to an ethical world which one can consider as an ‘open work’.

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[2] Mode I and Mode II refers to forms of knowledge production as hypothesized by Gibbon, M. et. al. first in 1994 and revisited in 2001. Mode I refers to typical academic, discipline bound knowledge whereas Mode II refers to problem focused and interdisciplinary knowledge and production of this is not confined to academic institutions. It should be noted that this hypothesis has been criticized and challenged. Mode III is put forth by Shiv Visvanathan as a new/another mode of producing knowledge. But Mode III science is a hypothesis put forth by Friedrich Hinterberger. Since Shiv Visvanathan did not refer to this it is not clear as to whether he is referring to the hypothesis of Friedrich Hinterberger or whether he is putting forth his hypothesis as Mode III. In the literature Mode I often means Mode I science, Mode II means Mode II science and sometimes post-normal science and Mode II science are used as synonyms. Gibbons, Michael; Camille Limoges, Helga Nowotny, Simon Schwartzman, Peter Scott, & Martin Trow (1994). The new production of knowledge: the dynamics of science and research in contemporary societies. London: Sage. Nowotny, Helga; Peter Scott & Michael Gibbons (2001). Rethinking science: knowledge in an age of uncertainty. Cambridge: Polity.

One of the participants asked whether he had abandoned the critique that he and Nandy put forth in the late 1980s and whether this presentation was an acknowledgment of taking a new position. Shiv Visvanathan clarified that while that critique was relevant then, in today's context one had to think beyond that and engage with science rather than withdraw or refuse to participate.

At the final session some suggestions for follow up were made. These included building up collaborative groups among scholars in India and other parts of the world. Another suggestion was to hold more such conferences and explore new issues bringing together scientists and social scientists. Both Beijker and Glasner were supportive of the first suggestion. Prof. Peter deSouza suggested that an edited volume could be published in 2011 based on the papers/presentations made at the Conference. The conference concluded with most members consenting to the need for India to develop better regulatory frameworks to regulate research and application of genome research and for an all-India body to consider the work of international groups, such as those in The Netherlands, to enhance the democratization of human genome research and to bring in both transparency and accountability in scientific and medical endeavours. All the participants also concurred on the need for more intense conversations among disciplines so as to engage with the social, ethical, and legal implications of the future human genomics research.

Part II: A summative overview and recommendations for further activities

The conference should be seen as a beginning of a new initiative in interdisciplinary research and advocacy. One of the outcomes of the conference, an edited volume should be published between 2011-2012. The four sets of issues as enunciated by Prof. Peter deSouza can be used a framework for further research and dialogue. The four sets are overlapping and hence the interfaces have to be identified and on that basis groups can be constituted to work on themes and specific issues. The Conference also revealed that the conversation among scientists and social scientist can be mutually beneficial. In the future more scientists should be invited and social scientists should be made aware of the directions of genomics research in India, the funding patterns, research themes, their social relevance and impacts. A key suggestion from one of the senior participants, Prof Sharat Chandra, was for the need for social science engagements and comments to be accessible to the science establishment and the larger community. Given the currency and spread of genetic testing and allied applied medical applications, there is a need for a mapping of the current and proposed research in India in genomics and the related ELSI aspects to be identified as a priority. For instance stem cell research in India is being pursued at different institutions but the ELSI aspects have not been studied in detail.

1. Further Studies and Research:

What is needed is a series of studies on various aspects including ethical, regulatory, legal issues and the adequacy of the current regulatory regime to cope up with the developments in science and technology. Prof. Madhava Menon pointed to the possibility of the human rights framework being the guiding principle in ensuring that genomics research and application of technology does not violate the rights of the people of this country. But, given that genome research has the possibility of being commercialized and hence commodified, it can blur the borders between what is human, and non-human, and lead to the creation of chimeras that can challenge our cherished assumptions about humans, animals and nature. This aspect has been studied by sociologist, anthropologists and we can draw upon this research to understand developments in India.

2. Review of and implementation of regulatory regimes:

Another challenge is that in a globalized world, while the practice of science and technology are getting universalized, the regulatory regimes are not. As a result what is unethical in one country can be considered as perfectly acceptable in another country. With governments taking the lead in promoting biosciences and encouraging commercialization of technology, the regulatory regime in one country may not be sufficient to regulate genomic research elsewhere. Researchers can migrate and samples can be procured and therapies and treatments can be offered elsewhere although direct exports may not be possible. Some studies indicate that there is a global market for stem cell therapy, tissues/ samples and ART (Assisted Reproductive Technologies) has resulted in more commodification of human reproduction. Given such trends, the legal framework in India may be inadequate to address these issues and provide a just and ethical regulatory mechanism.

3. Frameworks and Guidelines for ELSI in India

The challenge before us is to do research that is relevant in the Indian context while drawing upon the works done elsewhere and we should identify issues that are specific in Indian context and give importance to them. For example, by now there is enough literature on genetic screening and testing in Europe and USA and the response of the societies and communities to that. This has been supplemented with studies on regulation of these screening practices and their place in overall health policy and regulation. But in India, as Dr. Ratna Puri's presentation pointed out, there is a need to understand the genetic disease burden in India and develop capacity to ensure that genetic testing is available to those who need it most. Of course the ethical issues remain and cannot be wished away. But how families, couples and individuals respond to the testing and what values and norms guide them and how they face this knowledge and cope with is important. Informed policy making can be made on understanding these needs and orientations. While we can draw upon studies developed elsewhere (e.g. Rayna Rapp's work on amniocentesis and Latino communities in USA, extensive studies across Europe on response of various communities to genetic testing), there is need to pay attention to the specificities of India's social and family structures and cultural priorities.

It is here that there are exciting opportunities for sociologists of health and society, medical anthropologists, psychologists to work with doctors and counselors to understand how families in India respond to the screening and what role the changes in family structures, kinship norms and modernization can play in the response to the tests. For example, it will be worthwhile to understand how the nuclear family structure and desire for single child / two children may influence couples' preference for children with no genetic disorders. Are couples who resort to ART also keen to undergo genetic testing? On the other hand, we need studies on the issues faced by families that need support in terms of insurance, access to care for children born with different genetic disabilities, and how best their needs over a life span can be met. Another issue is whether genetic testing should be made mandatory in some cases or in some circumstances and whether communities can be provided with screening options when the genetic disorder burden is high and widespread. Obviously there are ethical issues that cannot be ignored but we cannot wish away the reality and cite relative ethics as an excuse for inaction. In such circumstances scientists, doctors and social scientists will be able to draw upon their collective wisdom and conversations to help policy makers.

The ELSI aspects of genomics are overlapping, and this is inevitable. In terms of further work, and building upon this conference, it is essential to identify themes/issues for more focused work. Workshops can be organized on this basis (e.g. a workshop on genetic testing in India and ELSI issues, a workshop on human genetics research in various groups and the social scientists' understanding of Indian society and insights from population sampling, a workshop on the state of genomics research in India and related ELSI issues). These workshops can be two-day events and the participation can be limited to 25 to 30 persons. Some themes can be identified on a priority basis where work has been done on this and where there is a wealth of literature and data to draw upon while some themes can be identified for further work. Thus a series of workshops planned over the next two years will enable us to move forward with a clear focus and deliver outputs that help both policy makers, the academic community, and the larger community.

For instance a workshop on regulation of research, therapy and commercialization of genomics can cover ELSI issues in clinical trials, stem cell research, biobanking etc and identify the gaps in current frameworks, take into account prospective issues that would need attention in future and can come up with suggestions for government. These structured workshops will need studies as core inputs and the workshop itself will be a forum to deliberate on the studies rather than to present them. For this a core group of 4 or 5 persons can be formed and the group in turn will identify the issues for preparing the studies and commission them. The study reports can, in turn, be used both as back ground papers and for deliberations as the reports will have both parts; analysis/survey of issues, research questions, and proposed solutions/suggestions based on the analysis. Each study in turn will be supplemented by brief papers/scoping notes and case studies. Such an approach will draw upon experts in different fields and enable them to work together in studying an issue with insights from their respective disciplines.

4. Collaborative Studies and Research Networks:

In the USA, ELSI research in Human Genome Project was first funded by the Department of Energy and NSF. There was active interest in these issues from civil society groups and academics. The President’s Council on Bioethics published reports on various issues. The most interesting aspect was that in many projects ELSI research provided ample scope for inter-disciplinary and collaborative research and this was reflected in the outcomes ranging from edited volumes to articles/papers. In the UK, ESRC played an important role in this research by funding centers/units in different Universities. These centers are still active and have produced a significant body of scholarship. Many countries in Europe provided funding for ELSI through various ministries, councils and centers in universities. Institutions working on Science, Technology and Society (STS) issues took active interest and as a result there was a cross-fertilization of ideas. Nordic countries were no exception to this and some of the interesting work in Europe has come out of countries like Norway and Denmark. In India funding for such research can be provided by different agencies such as ICMR, DBT, UGC, and DST. A suggestion in this regard is that to begin with, the DST, DBT, UGC, ICSSR and Ministry of HRD can form a consortium with other agencies/departments to call for, evaluate and fund such studies. The ESRC’s model of funding centers can also be considered. It is important to involve institutions like CSIR, Anthropological Survey of India in these initiatives. DBT and ICMR can be requested to set aside 2-3% of the funds allocated for genomics research to fund ELSI centers and support them for five years to begin with. These centers can focus on specific issues/ themes and can provide inputs to policy making besides helping DBT and ICMR in formulating regulatory policies and in addressing ethical concerns in research and commercialization.

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