4. Studies in India

4.1 Methodology of interviews in India

4.1.1 Interview strategy in India

India is usually referred to as a "developed developing country", so it faces problems of both developed and developing countries. India is a country of more than one billion people; every seventh person in the world is an Indian. India, with 16.7 per cent of the world's population, is the second most populous country in the world. The main reason for promoting biotechnology and medical research is not only to reduce the burden of disease in the nation but also to develop scientific research to a compatible level with that of richer countries.

The government of India has regarded biotechnology as a "vision". The vision statement says, "Attaining new heights in biotechnology research, shaping biotechnology into a premier precision tool of the future for creation of wealth and ensuring social justice - specially for the welfare of the poor." (DBT 1999). In order to provide some perspectives on how biotechnology policy is being debated in India and how far the goal of the vision statement is achieved, interviews were conducted with government officials over various biotechnology issues in different ministries and government institutions in order to compare the ethical issues raised by biotechnology in national governance with that of FAO.

4.1.2 Sample characteristics.

The interviews focused on the bioethical challenges that 24 policy makers faced in developing policies in biotechnology and genetics research in India. Only 4 of the subjects were female, and 15 of the 24 subjects agreed to being tape recorded. Interestingly most of those who did not wish to be recorded were in more junior positions, as they were more fearful of being quoted, although their anonymity was guaranteed. These 15 included all 4 of the women. Most of the high ranked officials were interviewed. Some of the interviewees were members or had observer status in different ethics committees or on review boards set up by the government or its institutions.

4.1.3 Institutions surveyed

The institutes that were surveyed included the All India Institute of Medical Sciences (AIIMS), which is the biggest government hospital in India; the Department of Biotechnology (DBT) under the Ministry of Science and Technology which serves as a nodal point for all biotechnology related research; Indian Council of Medical Research (ICMR), the apical body in India for the formulation, coordination and promotion of biomedical research; the Ministry of Health and Family Welfare; and National Institute of Science Technology Advanced Development, an Institute responsible for transfer of technology, linking people to technology and promoting federal efforts at local level. The details are shown in Table 4.

Table 4. Institution surveyed and number of respondents in India

Department	Number
All India Institute of Medical Sciences (AIIMS)	3
Department of Biotechnology (DBT)	5
United Nations Food and Agriculture Organisation (FAO, India)	2
Indian Council of Medical Research (ICMR)	3
Ministry of Food Processing Industries (MFI)	2
Ministry of Agriculture (MoA)	2
Ministry of Health and Family Welfare (MHW)	5
National Institute of Science Technology Advance Development (NISTADS)	7

4.1.4 Areas covered in biotechnology

Various ethical issues were raised during the interviews depending on the area of biotechnology that policy makers were involved with. It included broad areas of food and agriculture, health care, and medical research, which will be considered separately in the following sections.

4.2 Results of Indian survey regarding Food and Agriculture

In order to make direct comparisons to the results from FAO described in chapter 3, categorization was performed using the same 7 broad concepts of food, rural development, information, biotechnology, sponsorship and funding, environment, animal issues. The importance of areas covered during the interviews was also analyzed as in FAO. The importance of areas covered is shown below as percentages of those who did not mention any issue related to the broad concept category (figure 13). Although biotechnology is very popular issue, specific issues were raised less when compared to basic issues related to information management. Also the issues of sponsorship and funding were popularly raised (table 5).
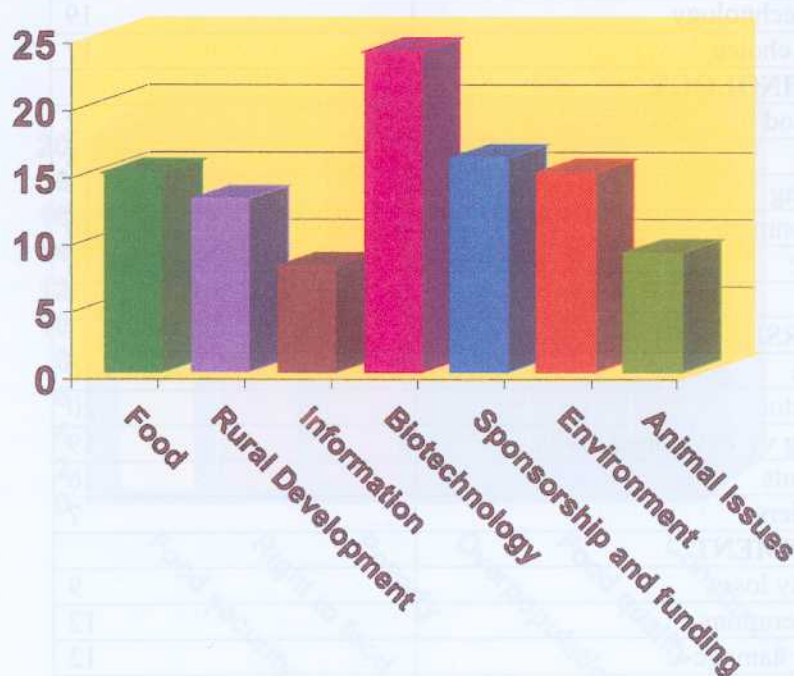

Figure 13 :   Percentage of those who did not mention any issue in each concept category in India

Table 5: Results of Indian Interviews regarding Food and Agriculture issues

CATEGORY	Number of people raising the issue
FOOD	
Food security	6
Right to food	7
Poverty	19
Overpopulation	18
Food Quality	11
Consumer's health	11
RURAL DEVELOPMENT	
Sustainable rural development	9
Dependency on experts	7
Gender issues	18
Urbanisation	10
Cultural Difference	14
INFORMATION	
Information access	16
Information dissemination	20
Safety of technology	19
Consumer choice	17
BIOTECHNOLOGY	
Organic food	2
GM food	8
GM labeling	12
GM environment	10
Terminator	6
Monsanto	5
SPONSORSHIP AND FUNDING	
Corruption	10
Private sector	20
Developing vs. developed divide	19
Governments	16
Trade barriers	7
ENVIRONMENT	
Biodiversity loss	9
Future generations	12
Ecosystem damage	12
Genetic resource ownership	11
Pesticides	5
ANIMAL ISSUES	
Animal husbandry	3
Religious views	3

4.2.1 Food

About 35% of the population in India lives below poverty line, and 86% of the population lives below US$2 per day. In the interviews, poverty was a concern raised by 19 people; poverty exists due to overpopulation, which was raised as a major concern by 18 people. Population is more concentrated in the rural parts of India given that 70% of the people in the country live in rural areas where poverty is most concentrated. The degrading quality of food in the country, where most people rely on street food, was raised as a concern by 11 people. This has ultimate effect on the health of the consumers, and 11 people raised consumer health as a big concern. 7 people also raised ethical concern of right to food in the context of access to food. All these factors lead to food insecurity, which was mentioned as a concern by 6 people (figure 14).

Example comments are shown below to explain the issues and the concepts related to the keywords.
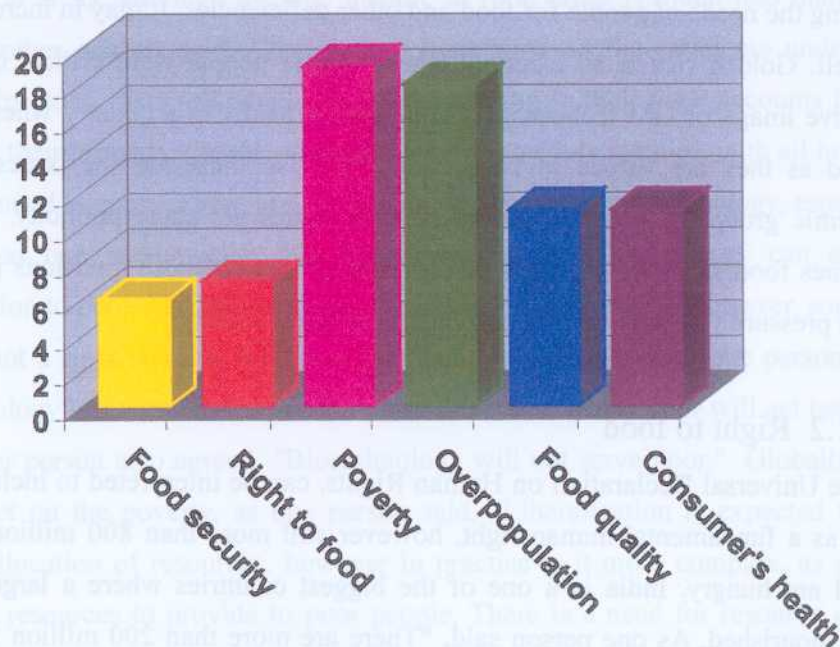

Figure 14: Issues raised under the concept category FOOD considered to be of major importance in India

4.2.1.1 Food security

Many factors add to the problem of food security in the country. As one person said, "There is no one reason for shortage of food, it includes many factors like, overpopulation, poverty, imbalances in the production systems, and also lack of commitment to improve the situation." India has improved agriculture production since independence and, especially the Green Revolution brought a massive increase in the production, as one person said, "Even now there is enough food for poor, it is the problem of distribution. The state of Punjab would be richer and richer with biotechnology even if there are some poor still there." There is a projected public protest against in Europe against biotech food, however, where people do not have sufficient to eat and hunger is part of every day's life, the situation may not be the same, as another person said, "I think people will accept it because people need food." If GM food can provide more nutrition, it might be welcomed more than other food, as another person said, "If it is better than conventional food, why not?" Some policy makers in India look GM food as a solution for many problems. As one person said, "GM food because in the longer term they may be helpful to India because of increasing population of the country. This may help in meeting the needs of people for food and other deficiencies. It may in increasing nutrition as well. Golden rice is an example taken." Some people were critical of publishing a negative image of GM technology as one person said, "In a country where lives are not valued as they are valued in Europe and U.S., so these are the issues of interest to academic groups or political groups so such issues get some publicity. Here the issue becomes food security." Another person added, "But on those questions it depends how much pressure you have on yourself regarding food security."

4.2.1.2 Right to food

The Universal Declaration on Human Rights, can be interpreted to include the right to food as a fundamental human right, however still more than 800 million people in the world are hungry. India is a one of the biggest countries where a large population is under-nourished. As one person said, "There are more than 200 million people in India who do not have basic rights, such as food and shelter." Another critique of biotechnology said, "The government is spending millions on biotechnology research and building high tech laboratories, but they can't fulfill basic right to food for the people." Poverty leads to significantly less options and people are ready to do anything for food, as another person

said, "It is ironical that when you step out of this (Department of Biotechnology) building, you can see many beggars lining up for money. They are the real picture of this country, where people do no have access to food and water, and inside we sit and talk about rights and high-tech modernization." However, an optimist stated, "Biotechnology provides options for fulfilling the needs of poor people, some basic human rights, such food and water." Fundamental human rights may be more thought of as a problem in places where they are not achievable, as another critic said, "The West is more conscious of the environment rather than right to food because people have enough to eat, but here if you are hungry, you will do anything to get food."

4.2.1.3 Poverty

Poverty is an issue for most of the countries in the world, and especially in the Indian context, which is one of the biggest countries in terms of population. As one person said, "There are so many people, poverty is very high and people don't have means to purchase food even at the lowest prices." Poverty exists in many phases, as an expert said, "It is difficult to measure poverty in India, for example, you will find more beggars in cities than in rural areas, although average income in rural areas is much less than in urban areas." Another analyst said, "You cannot generalize all the problems under poverty umbrella. In India, there are people who have nothing in their bank accounts but hold a big land as their property. On the other side you have people in cities, with all luxuries but living in rented houses." There are many expectations from biotechnology, especially for the poor, as one person said, "On the other side is biotechnology can give some compensation to poor, like labor at least, it can serve the purpose." However, some people fear it is not a right solution for basic problems in the country, as one person doubted, "Biotechnology is not that important for poor. I'm not sure how poor will get benefit from it." Another person also agreed, "Biotechnology will not serve poor." Globalization has some affect on the poverty, as one person said, "Liberalization is expected to lead to efficient allocation of resources, however in practice is it more complex, as we do not even have resources to provide to poor people. There is a need for resource generation and then we can talk about providing a better life to people." People are poor in many ways, as another person said, "Poverty also results in people being poor in their rights. They have no power even to demand." Politicization of the issues is not good, as another person said, "Poverty is not reduced or resolved because politicians do not want to resolve it. They need votes in the name of poverty."

4.2.1.4 Overpopulation

India has the second largest population in the world, so overpopulation was another issue raised by many interviewees. More people means more food, as one person said, "Europe and US are not bothered about food security. In fact they have surplus, moreover they have means to import anything they want. But to feed one billion people is not an easy thing." Allocation of resources need to be balanced in development, as another person worried, "It is better to fight for population first rather than bringing biotechnology." One of the consequences of overpopulation is poverty, as one person said, "I think the best way to deal with poverty is to focus on measures for reducing overpopulation." Overpopulation is more than just the number of people in the country, as another interviewee remarked, "Overpopulation occurs when population cannot be supported by carrying capacity of the country." Cultural beliefs also contribute to overpopulation as one person reasoned out, "In India people believe that having a child is a will of God, so they do not even take measures to avoid pregnancy, especially in the villages where there the image is the more children you have, more prosperity will come." On the issue of population control another interviewee said, "It is not that government is not conscious of population, we have started many population control programs, like educating women, distributing free condoms but the results have not been very successful." Another person said, "Condoms are only used by 7% of men in India. The fact that so few men use condoms is not because they are impossible to find, many men choose not to use them, and the responsibility is placed on the woman and many rural women are either too shy to use or do not even know how to use."

4.2.1.5 Food quality

Poverty, overpopulation and food security are integrated issues. Food security is not only access to food, but also access to safe food. As one person said, "For us it is a dual problem, first people do not have enough to eat, and what ever they eat is also not reliable. Hundreds of people die every year due to food borne diseases." Another interviewee also agreed, "Another most important area is of food safety in India, food adulteration is a daily problem here." One person gave examples, saying, "A couple of weeks ago so many people died by mango karnel poisoning, some people say it was because of hunger but I am not so sure. A similar problem occurred in 1998 when people died because of oil poisoning." Cheap food is sold in the streets on which many poor

people rely on this, as one person said, "India has lot of street food which is unhygienic; people who can't afford food usually eat street food or stale food from street vendors. Street vendors sell old food at cheaper rate and people by and get sick. So food safety is very important issue for India." There is a food law in India, as one person gave example, "In fact India also has PFA (Prevention of Food Adulteration Act) 1954. It is a big compilation of many laws of, probably it was written by the British. It is very strict act that is why all the industries want changes in it. But the Ministry of Health and Family welfare is still conscious on that." Laws are not always applicable where there is not enough food available. As one person said, "You cannot expect local street vendors or dhabas (local food stalls) to follow PFA. They earn their living by selling food, may be they don't even know about it. I am not even sure how many good restaurants even follow PFA rules."

4.2.1.6 Consumer's health

Bad food quality is a concern for people who buy it. Concerns were also raised over providing safe and nutritious food to people. One person said, "The health of consumers is a major problem, because people go for cheaper food which sometimes is not reliable." One person when commenting on the measures taken by governments said, "We are trying to promote packaging of food before it is sold in the market, but it is very difficult because of the general image that packaged food is not fresh, although it might be more safer to eat it." On the issue of GM food one said, "I believe biotechnology can help to improve food insecurity situation but in India more important issue is food safety." One promoter of GM food said, "People do not have enough to eat in this country, if GM food is safe for the consumers there is no reason why consumers should not be given a choice to healthier and safer food. At least US claims that people have been eating GM corn for quite a long time now, and it has not been adverse on the health of the consumers." Consumer organisations view was explained as, "Consumer organisations that not opposing direct entry of GM food, they are concerned over biosafety issues of GM food until it is cleared." On the issue of consumer choice one person said, "At least in India, we hope there will be no challenges against GM food, people want food, and if it is not harmful to health and cheaper to afford, there is no reason why people would go against it."

4.2.2 Rural development

As discussed above more than 70% of population in India live in rural villages and small towns. The condition of women in villages is deprived due to various cultural stigmas, and the need for better environment for women was raised as an ethical concern by 18 people in interviews (figure 15). Sustainable rural development is necessary for the country as a large population lives in rural areas to provide better quality of life, which was raised as a major concern by 9 people. However, it cannot be achieved without having enough expertise, the need for experts for development was raised as an issue by 7 people. People migrate from rural areas to urban areas, and also rural areas evolve into urban areas through mechanized lifestyles. This issue was raised by 10 people. Rural people have their own culture and traditions, which need to be considered during development process. The issue of cultural differences was raised by 14 people.
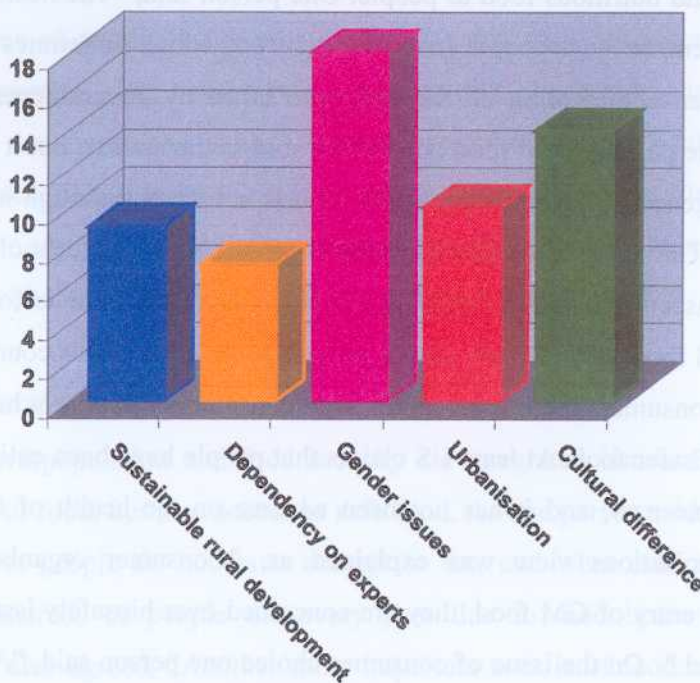

Figure 15: Issues raised under the concept category RURAL DEVELOPMENT considered to be of major importance in India

4.2.2.1 Sustainable Rural Development

Rural India encompasses three fourths of the country's population and there are many inadequacies in the rural parts of India, as one person visualized, "Rural people are characterized by low income levels, inadequate to ensure a quality of life compatible with physical well being." The government of India has a special Ministry of Rural Development, however still the efforts are not enough, as one person said, "Sustainability has entered into the discourse but not into action." Sustainable rural development can only be achieved by participation of local people and genuine efforts, as one interviewee suggested, "The poor should be given opportunities by income generation activities. Giving them opportunities for income generation is very necessary, then rich should pay." Environmental sustainability and rural development are linked, as one person said, "Rural development has to be integrated with environmental development. There are environmental problems, villagers cutting trees, deforestation problems and it is causing many other problems in villages such as land degradations, and irrigation problems. If we want to develop rural conditions we need to focus on environmental problems also that are caused by poverty and over exploitation of natural resources. It is interlinked." Some people also look forward to using biotechnology in for rural development, as one person said, "I hope that biotechnology does help in advancing sustainability."

4.2.2.2 Dependency on experts

Lack of expertise is a common concern for all the developing countries. Consultations are needed in carrying out developmental programs, as one person said, "We lack experts in almost every field, it is really an ethical concern while developing strategies, because first your have limited resources and then you also do have people who can guide you or make proposals where the resources could be reasonably used. Many times it happens that lot of money is wasted that could be used effectively, had there been good expert advice." Another person said, "We need experts who are just not academicians but also people who have social commitment, who understand cultural sensitivities of people, who are just not technocrats. People who are far sighted, they should be imaginative. They should just not be governmental bodies." Ordinary people also could be good experts, as another person said, "Common people can sometimes be really helpful in understanding the problems, since they face it everyday." In applying biotechnology, one interviewee suggested, " A two-tier system will be helpful because separate specialists and experts are needed for

both areas. They may give more justice to the subjects rather than a combined committee, a separate panel may be a better option."

4.2.2.3 Gender issues

Gender issues are taken in the context of discrimination of women in society, which is common in most Asian countries, and India as well. Rural women especially face a tough life, as one person said, " If you wish to improve rural conditions, it is extremely important to improve the situation of women in villages. They live in the world of just four walls of a house, their whole life." One person gave an example, "Women are marginalized in India from a nutrition point of view. Men have to get the best to eat and women don't get enough to eat." There are many other ways that women are discriminated, as another person said, "Women in rural areas are responsible for household activities, harvesting fields, taking care of large number of children, and also maintaining social relationships in which they forget their ownself." Social traditions also contribute to the gender problem, as another person quoted, "People do not want girls because of the soul reasons of dowry. They cannot afford to educate the girls and then also pay a dowry for their marriage. The more the better qualified the boy is the more demands need to be met. Then there are caste and religion problems, which add to it." Another person gave example, "Female foeticide is common in villages for the soul reason of dowry and vulnerability of women to social disputes. Especially in areas like Bihar and Rajasthan, it is so common to kill the infant girls just because family status goes down if you do not have a boy who could be heir of family legacy." Even in the cities women have problems, even if they better educated and informed about their rights, as one person said, "Although in big cities women have entered the mainstream, still majority of them comprises informal sector and causal labor force in the name of jobs." However, there are programs started for uplifting the standards of women in the society, as another person working in FAO in India said, "FAO recognizes sustainable development very much. We have lot of programs for women, special programs on food security are the main thing in FAO which also includes women's participation." Education is necessary to bring confidence among women, as another person said, "This is well recognized thing that if you educate a woman you educate a whole family and future generations."

4.2.2.4 Urbanization

Rural areas are converting into towns and cities rapidly as demand for infrastructure and communications are expanding, as one person said, "The typical image of villages in some parts of the country is rapidly changing, you can find telephones in villages and television are a common thing even in villages now." Some people were worried about cities encroaching rural areas. One person said, "Delhi is expanding very rapidly and even the near by villages are now covered in the territory, and we need to make provisions for all those areas also, already there are so many people in the city, it is causing lot of problems." Urbanization also brings differences in thinking among people. As one person said, "I've seen that people born, brought up, educated and earning in urban situations are more tuned to scientific things against those who have a rural background." People rush to cities because there is a lack of basic facilities in the cities. As one person said, "People who are living in rural areas, they have less access to modern health care services as you can find in urban areas, people do not have means for proper communication and transport, less educated people are there." On the issue of urban poverty one person said, "The number of slums is increasing because people are migrating to cities. Even if they do not find a job properly, they still dwell in cities because of the attraction of fast and rapid life here." Some people attributed urban problems to mismanagement. As one person said, "We cannot tell the rural people to remain as they are all of their life. They have the rights to access to all the things. Better planning in the cities is necessary to settle people and give them chance to improve their lives."

4.2.2.5 Cultural differences

It is considered that one of the bad aspects of modernization is Westernization of the cultural values. As one person said, "I am sometimes surprised the way televisions have changed the family values and traditions of our society. Children prefer to say hello or good morning rather than touching feet of their parents, is it part of modernization?" Differences are also found in the lifestyles in cities and in the villages, as one person said, "People in villages have their own rules and ways of life and you can not expect them to be changed in a month or two to adopt new things". Even in accepting or rejecting technologies, cultural values sometimes determine our choices. One person said, "So you either become very pragmatic in accepting modern technologies a, have lesser concerns about the ethical aspects. When you have more of cultural influence, that in spite of being

257

the scientist, your cultural influence still prevails on your scientific knowledge." Another person agreed, "The way you have been brought up a, value systems you imbibed during your bringing up, has its effect on the perception as well as expression of issues."

We need to balance the cultural ideals while addressing rural problems, as one person said, "Rural people are socially and culturally deprived people. When you implement technology, to ensure that it really works in the rural environment, besides looking at economics and environment, there is also a cultural aspect that is very sensitive. You cannot expect people to merge with your ideologies but rather we need to merge technologies with people's ideals." However one skeptic said, "You need to make a choice sometimes, whether you feed the people or you stick with your values and let people die of hunger."

4.2.3 Information

Information is central to development for any process. Access to information for applying proper technologies was raised as an issue by 16 people (figure 16). It also a duty of information holders to provide correct and unbiased information. Proper information dissemination was raised as an issue by 20 out 24 people interviewed. Especially in the case of biotechnologies, it is necessary to have the right information, given that there are many doubts about its safety. Safety of technology was raised as an issue by 19 people. Information about GM food to make a rational choice was raised as an issue by 17 people. The details are shown in figure 16, and example comments are shown below for the range of issues that interviewees raised.
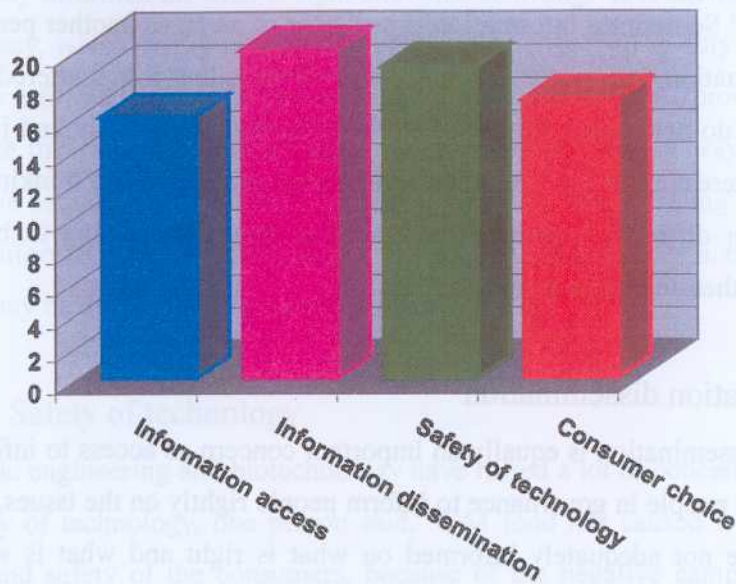
Figure 16: Issues raised under the concept category INFORMATION considered to be of major importance in India

4.2.3.1 Information access

Access to information is easier if there is a better infrastructure, as one person said, "We are trying to computerize all the information, since it is rapid and storage is convenient. It is contradictory, as on one side we talk about information provision to all but a large number of people do not even have money to buy television sets. How could you expect them to be going to the internet to check things." Also whatever information is available whether it is reliable or not is a question, as one interviewee worried, "The ordinary public does not know what is going on at the government level. It is a two way problem, on one side people are not interested because of the mistrust, the other side is that whatever information is given, is also not proper". Another ethical concern was raised, given that the vast majority of the people are not educated enough to understand the issues, as one person said, "But recipients should also need to be educated enough before receiving such a rich flow of information. "

Also people should be open to provide information. One person said, "I would like to act in a manner that knowledge is shared and transformed. People are not even willing to share nowadays." Sometimes information is available in parts, as another person said, "It is not that information does not exists, but the problem is that it is scattered in different departments, we do not have a culture of storing information properly and just focus on what is most interesting to us." Another person also said, "We are thinking to collect information from different institutions and analyze them; and trying to bring all the information together under one proper system."

4.2.3.2 Information dissemination

Information dissemination is equally an important concern as access to information. It is the duty of the people in governance to inform people rightly on the issues. One person said, "People are not adequately informed on what is right and what is wrong. It is another issue of legislative inadequacy which is expressed as an ethical challenge." Whatever the information is available needs to be contextualized, as another person said, "But as a professional I feel that they should take time and discuss the ideas and information so that things are done at common people level. Otherwise problems will never be solved." Information dissemination is also a responsibility of people who produce information, as one person said, "Dissemination of knowledge is a big ethical question; difficulty in assigning and designing the work while working as a scientist. In general of research, research agenda determination is a big question." Transfer of information is not easy in a multiethnic country, as another person said, "We are a multi linguistic country, if you have information, and you want to convey, the first issue that always comes up is the need for translation into local languages, which is a major hurdle because even if information exists, if you are not able to deliver it to ordinary public, it becomes a serious ethical concern." Especially to farmers, any information regarding agriculture is crucial, as one person said, "On the other hand at diffusion level, I would like to work for a strategy which could be applied in transition and over the period, hopefully world will be using biotech and other knowledge for sustainability." On the question of which type of information is required for the farmers, one person said, "At the farm level whatever information has to come will be from farmers and to produce quality seeds a lot of feedback is required from farmers. How seeds are performing? Whether they are available or not? If the seed is required to be changed? Cooperatives also need to change, they are also not easy to change. In becomes more difficult in WTO type of setup,

260

the way it is being structured." Some people challenged the legal system that does not make it compulsory to disseminate information. One person said, "People are not adequately informed on what is right and what is wrong. It is another issue of legislative inadequacy, which is expressed as an ethical challenge." It is duty of both ends to give and take information, as one person said, "Both consumers and providers should do it to minimize the gap." Information can be disseminated in many ways, as another person said, "We cannot blame lack of logistical support for not providing information, you can spread information in many ways, like campaigns, advertisements, even mouth to mouth, which may be the most easiest way in Indian society."

4.2.3.3 Safety of technology

Genetic engineering and biotechnology have raised a lot of concerns on the whole issue of safety of technology, one person said, "GM food has caused a lot of fear regarding health and safety of the consumers, because of the negative campaign. A lot has been misquoted and misunderstood even by educated people." The general image is that scientists wish to pursue their own goals without giving due consideration to the safety aspects, however it may not be the same for all. One scientist said, " To me health and safety are not unimportant; and on the whole as a researcher and I want them to be studied." Safety can be measured in different ways and the concept has more than one dimension, as another person said, "But finally how much of weightage they are going to give to environmental risks or safety risks is not merely a question of what ethics they hold themselves, these decision makers. My understanding of the problem or other will be different. So there will be variable degrees or spectrum of opinions." Safety aspects are necessary to be taken into consideration, however it should be based on sound science, as one interviewee said, "People have the habit of anticipating consequences sometimes without enough rationality." Especially in developing countries, it is a major issue given that they lack sufficient expertise and infrastructure to measure the safety concerns, as another person remarked, "I don't think anybody can conclusively say that they are safe or unsafe; our country is still adolescent. It knows a few things and does not know many things, but it believes that it knows many things and that is the saddest part of it." Since the whole research and following debates began in the rich countries, the decisions for the developing nations are more difficult, where it was not a goal as one interviewee quoted, "At research level even to understand something, it requires purpose to be known. This

whole research was not started in poor countries, so obviously you will have dilemmas on making decision on something that is not your recipe."

4.2.3.4 Consumer choice

In poor countries where people do not have food to eat, the question of choice does not exist, as one person said, "Consumer choice is only a question where people see plenty in the supermarkets, it is not for people who do not even have three meals a day. If genetic engineering can feed the hungry people, they will accept it. It is an issue of need and demand, not of choice for people." Some people doubted even if genetic engineering brings more productivity, or whether it is available to all. One person said, "I think in such countries where there is an upper crust which is ambitious and aware but there is lot below so even if it comes whether it would be affordable to everyone or people who really need them is a question?" Consumers should be aware of the new products to make a rational choice, as another person said, "And we are also we are also involved in creating the consumer awareness and awareness in the industries, you need to inform consumers so that they can make a choice." In policy development, especially with respect to food, consumer organisations can play a significant role, as one person said, "If you wish that consumers should understand better about GM, you need to involve NGOs that represent them. They represent people and you need to make them understand first so that there is no negative opposition against it. People would accept it if they are properly informed." On the issue of labeling for consumer choice, another person said, "Labeling would work where food is packaged and then sold in the markets, but in India people buy fresh vegetables each day from street sellers and people would consume without awareness, if it is good, its good, if not people would reject it anyway."

4.2.4 Biotechnology

The government of India is keen on using biotechnology applications for several purposes, however, the issues related to GM food did not dominate much, which is similar to FAO, as only 50% of the interviewee mentioned GM labeling as an issue and 8 people raised GM food as an issue (figure 17). Nevertheless environmental concerns of GM were mentioned by 10 people. The use of terminator technology for insect resistance crops was mentioned exclusively by 6 people and 5 people also extended the topic to its inventor company Monsanto. Organic food was mentioned in comparison with GM food by 2

people. Figure 17 below shows the range of issues mentioned and example comments are also shown to explain the types of issue raised.
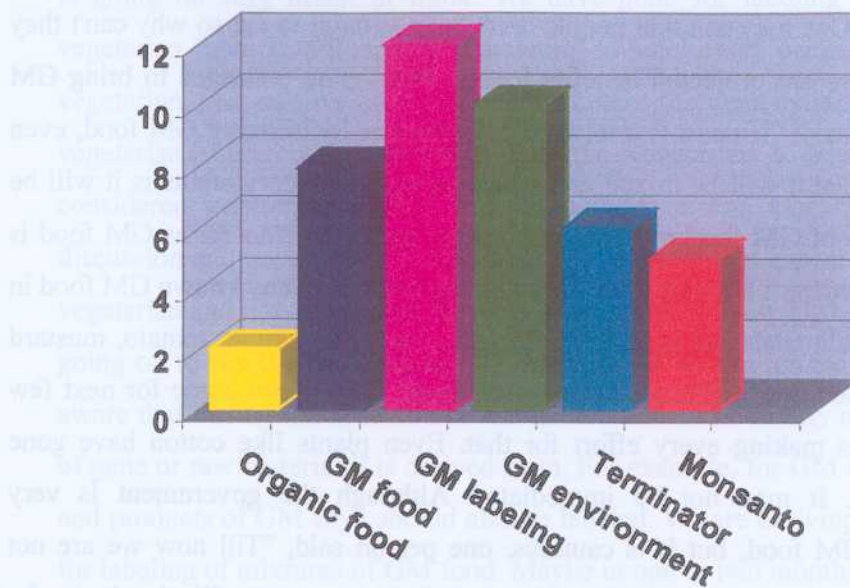

Figure 17: Issues raised under the concept category BIOTECHNOLOGY considered to be of major importance in India

4.2.4.1 Organic food

Organic food is a recent trend, however, some people felt that it had existed for a long time in India. As one person said, "People in the West have been talking about organic food recently, however, I believe it is not a new thing for Indian farmers, for a long time and even today, in the remote parts of the country you can see farmers depended on organic manure from cattle dung and ashes for pest resistance, and weeding is manual. It is both by chance and by choice being done by the poor farmers because they do not have money to buy even subsidized seeds and pesticides, so they have to depend on what is known as a common way of agriculture. And now it is being sold as new thing in the name of organic." Between the choice of GM food and organic food, another person said, "Even if organic food is brought to the markets in India, its use would be restricted to very few people, may be those who are rich and who have certain health concerns. Ordinary people cannot afford it. So may be Indian consumers might prefer GM food, if it is cheaper and affordable."

4.2.4.2 GM food

There were mixed responses with regard to adoption of GM food in the country. As one person questioned, "One may ask that people don't have enough to eat so why can't they use GM food?" There are projected benefits for the developing countries to bring GM food, as one person said, "If there is a lot of cost advantage by bringing GM food, even without our knowledge it will be mixed and whatever our regulatory status is it will be there." On the status of GM food in India, one person informed, "As far as GM food is concerned, at the moment it is not allowed in India. We don't have any known GM food in the market. But certain trials are going on with GM plants like cotton, tomato, mustard brassica in very closed conditions." Another person said, "It will not come for next few years, government is making every effort for that. Even plants like cotton have gone through that phase. It may not be immediate." Although the government is very enthusiastic about GM food, but it is cautious, one person said, "Till now we are not completely prepared for accepting GM food." Safety concerns still dominate for resistance to accepting GM food as another person said, "There is a lack in the analysis side of GM food." Another person said, "Regarding GM also there are several nutritional concerns and there are some misconceptions as well. Some sentiments will be affected on the issue of vegetarian and non vegetarian as well." Even if there is a public distribution system that exists for subsidized food, it is not effective and does not reach all people even in the cities, people fear the same for GM food, as one person said, "Even if there is a regulatory mechanism, and I'm sure it will not reach all the parts of country. It might be in pockets." It is no doubt that GM food debate has been catalytic in raising bioethical issues as one person said, "I'm not directly concerned with the exact definition of bioethics but I know that GM is part of bioethics."

4.2.4.3 GM labeling

Although there is a positive attitude from the government as it has accepted genetically modified food, more important criteria for GM food was labeling since there are religious sentiments and ethical constraints among public as one interviewee said, "There are several bioenzymes or bioadditives derived from biotech processes from non vegetarian sources and being used for preparation of vegetarian foods. So these things need to be considered when labeling for vegetarian or non-vegetarian is undertaken. In India it is a big issue and people are very concerned. So we have to be careful on such things." The

large population in India is vegetarian, one practical reason is that it is cheaper and people feel safer. One person said, "One example is vegetarian or non vegetarian for food which is going on very much in India. We have gone for labeling of vegetarian and non-vegetarian food. It will now be mandatory to label every package as vegetarian or non-vegetarian. But still we have to decide whether the gene extracted or derived from non vegetarian source and introduced into the vegetarian source, whether it would be considered vegetarian or non vegetarian, GM or non GM. This is also a point of discussion and government has to take a decision on that aspect." Mandatory labeling of vegetarian and non-vegetarian was implemented from June 2002 in India. Efforts are also going on to resolve the labeling of GM food, as one person said, "Consumer should be aware that this is GM food and on the label it should be clearly mentioned that what type of gene or raw material it is derived from. For example, for GM soya it should be labeled and products of GM soya should also be labeled. We are deriving a method on how to go for labeling of mixtures of GM food. Maybe in one or two months we will come up with a solution, at least minimum labeling. It will be mandatory under PFA 1954. Presently no GM is allowed in the country." At the international level, one person informed, "We have taken the stand in the codex committee on food labeling for comprehensive labeling of GM food." How to satisfy consumer organisations is also an issue in India, as one person said, "Consumer organisations are mainly concerned with labeling things. Our country's consumer organisations want to label every GM food."

4.2.4.4 Environmental concerns over GM

There are many concerns over the affects of genetic modification in organisms when they are left in the environment, as one suspicious person said, "Nobody knows what will happen if you plant GMOs." Genes are feared because of mutations that can never be predicted perfectly even with all precautions as another person feared, "When you intervene at the gene level, it is not easy to anticipate. We do not know yet whether particular gene that we withdraw or make it inactive; what impact it would make on rest of the organism. How does that interact with environment? I don't think answers are there." Some people feared the harmonious balance of nature, as one person said, "Biotechnology should not much change the nature of products. It should not bring any cause to harmony of nature. If it brings something that was never seen in nature, it is harmful." Another person said, "It should not cause any environmental hazard, problems to plants and animals or indigenous people living there." However, there were some

enthusiastic people who saw lot of potential for applying genetic engineering for environmental purposes, as one person said, "We want to use biotechnology for bioremediation and waste recycling in specific locations, as is done in the many industrialized countries, it might be more cost effective. Also there are proposals for developing biofuels and bioenergy using different techniques. We should be seeing at the positive potentials of biotechnology as well."

4.2.4.5 Terminator genes

Terminator technology has been controversial all over the world. Even in India there were mixed views expressed on applications of terminator genes. One opponent said, "If India decides to absorb Bt cotton, at least with Terminator I will not agree." Another person said, "I don't think that this kind of technological application is very ethical." Another person gave example, "There is no wonder why farmers burnt the Bt crops in Karnataka, because it is not favorable to them. Government is selling people's right in the hands of few people." Some people felt that there was a negative media approach towards terminator, as one person said, "Media has sensitized terminator issue. Also NGOs have also not taken a rational stand and made farmers go against the technology without any justifiable reasons." Despite NGOs resistance there are trials being allowed in the country, as another person said, "We have allowed certain trials to go on for pesticide resistant genes, Bt cotton, Bt grassica." Another optimist said, "NGOs have been focusing on one side of the issue, but they do want to try and see the returns. If Bt can provide better returns to farmers who lose their crops due to pests and suicide, I am sure all this noise would stop after one harvest. We need to be patient to decide."

4.2.4.6 Monsanto

Monsanto was mentioned in the context of terminator technology. One person said, "Monsanto's cotton is also going on in uncontrolled field conditions. There is so much hue and cry over this and farmers are agitated Monsanto has said that they are not using GM plantation but we are not sure." Monsanto's strategies have raised a lot of ethical concerns, as another person said, "It is Monsanto's ethics, which showed Monsanto in a very bad light, buying local companies and establishing itself in poor countries." People raised doubts about Monsanto also trying to influence government, as one person said, "It

is not that GEAC is completely unaware of ethical considerations, saying let's go ahead of the short-term trials. People will come to know Monsanto's connections very soon."

4.2.5 Sponsorship and funding

For developing countries the main issue is economics. Multinational companies try to influence policies through donations and sponsorships. Private sector involvement was raised as an issue by 20 people. The governmental role and their legislative policies in allocating funds was raised as an issue by 16 people. Internationally how poor countries get marginalized in debates due to rich countries domination, and the existing divide between rich and poor countries was raised as an issue by 19 people. International trade and barriers for the products of the country was raised as an by 7 people. The issue of internal corruption that hinders development was raised as an issue by 10 people (figure 18). Example comments are shown below to explain the type of issues that interviewees mentioned, and a summary is in Figure 18.
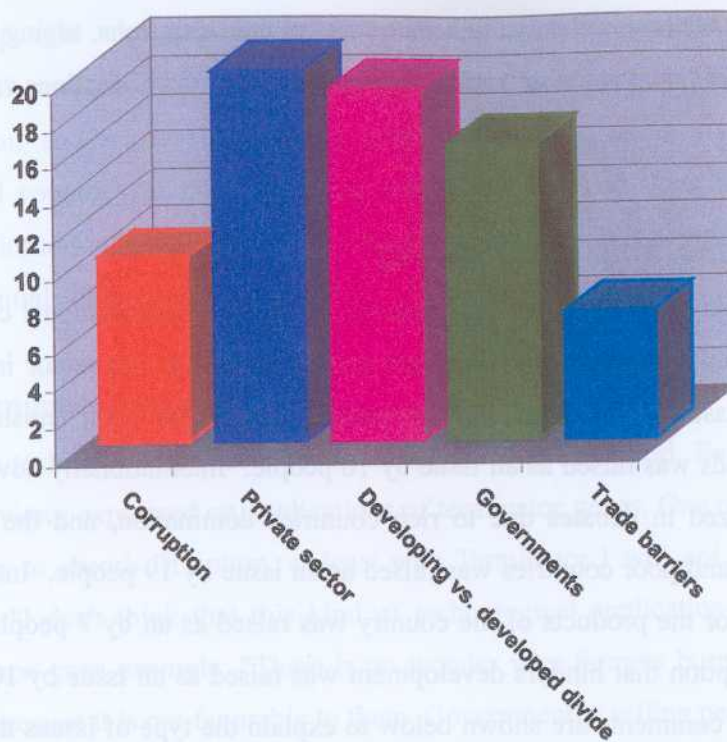
FIGURE 18: Issues raised under the concept category SPONSORSHIP and FUNDING considered to be of major importance in India

4.2.5.1 Corruption

Whenever there is involvement of money, corruption exists as one person said, "Whenever there is a funding from somewhere, one of the first things we look into is the avenues for corruption in projects." It is more prevalent in poor countries, given that they lack resources. One interviewee said, "Corruption is a problem not only in India, but also it is a universal disease in all the countries, and especially poor countries are more vulnerable to it given that all the interested parties wish to extract the maximum out of minimum funding, and they do whatever it takes to get funding." Mismanagement of funding and also many scandals involving large amounts of money has tarnished the image of governments in nations, as one person said, "Whenever we have a project, although very promising, first fear is how much amount is going to go to the politicians, and how much actually be available in the end to carry out the tasks." Some people worried about the impact of corruption on people. One person said, "The ultimate affect is on the poor who suffer discrepancies because of bureaucratic corruptions, why there is no change in their lives even though government records show big figures of investment in

rural areas?" Corruption is a continuous process, as another person said, "Whether you look from top to bottom or bottom to up, at each level there is a corruption, as you go higher level, it looks less vivid but it is more intense and has far reaching implications." On the issue of lack of resources for research, one interviewee said, "Government has been cautious to invest money in GM because not only because of the resistance from NGOs and international image, but also because government funds are empty due to corruption."

4.2.5.2 Private sector

The general image of the private sector is corporations that are purely profit oriented and do not have any humanitarian approach, as one person said, "The private sector is worst in that respect. They don't have any regards for ethics. They are completely profit oriented." Small private companies in poor countries are sometimes taken over by big multinational companies, as one person said, "Indian private sector seed industry is nothing but to get some material from MNCs and multiply." The image of the private sector deteriorated down due to some of scandals around the use of biotechnology involving big multinational corporations, especially in agro-biotechnology. The fears of patents have raised concerns about poor people, as one person said, "If MNCs bring biotechnology, obviously poor will be marginalized. This would be applied by rich who have money and poor will be marginalized." Poor farmers in remote villages have been severely affected directly or indirectly due to multinational corporations taking over the seed business, and its ultimate affect on common people as one person said, "It is really silly that on one side farmer is using a lot of money and government says you burn the crop. So what can ethically be done? If you compensate them it is fair enough. But compensation means resources from somewhere to be diverted which is taxpayers' money and from where taxpayers' money will have come? That is also to be considered. It is part of bioethics that we need to resolve, but also who should pay for it?" Private companies wish to make money quickly as another person said, "That private sector is also unethical that they're not even willing to wait for short-term trials." Approval of trials should be given to those who comply with the conditions, as another person said on the issue of approval of the trials and markets, "I'm a nationalist but not nationalist enough to give undue benefits to Indian private sectors." On the issue of international seed business that is occurring, one person said, "I can't say on every aspect but I have been following how it would affect industry, helped sector and agriculture. This is about seeds, which might be

becoming available through MNCs and farmers would struggle again and again every year for seeds. This thing for developing countries farmers is going to be very tough. We will be more marginalized. They will become dependent and costs are set by MNCs and sometimes MNCs are insensitive. This will make poor poorer and rich richer even if it is supposed to be beneficial." However, some people were in favor of privatization of agriculture, as one person said, "Even though private sector is profit oriented, at least some goes to the people who work in the companies in some form, but here even if we show higher productivity every year, still the number of poor and deprived people is not reduced, rather increasing."

4.2.5.3. Developing / developed divide

At international level, poor countries face a stiff competition in globalization process, as one person said, "Market liberalization has put up a lot of pressure on developing countries to look for markets." Another person agreed, "For us the main issue how to develop equivalent standards as demanded at the international trade level." The issue is not limited to trade with rich countries alone, it has many other dimensions, as one interviewee said, "Developing countries like India who have rapidly growing economy, but they may not be able to enter the rich market, whose access actually will determine the changes in economic terms in the country." Some people also criticized WTO policies, one person said, "WTO policies are guided by politically powerful lobbies which see their own benefits." Another person said, "WTO needs to develop training and technical assistance for its poorer members, and combat poverty." The divide between rich and poor countries is growing, because of the international trade regulations as another person said, "The Least-developed WTO members make up 20 percent of the world's population. But they only account for 0.3 percent of the world's trade, and WTO should encourage fair play, the rules of the game have to be fair, and all the members have to be equipped with the same tools." The ultimate outcome of trade is also affected on the poor people. As one person noticed, "Drugs are already not accessible and with government pushing for taxes and to balance the international pressure, life of common people is really at stake. Rather than competing with the world, government needs to make policies at home for its own people."

4.2.5.4 Governments

Internal politics of governance has a strong influence on the choice of policies and reforms in the country, as one person said, "If the government is not stable, it is very difficult to implement things. No one looks at the plight of people and politicians just keep trying to put their own agendas on us." Government is the most responsible body to ensure quality of life for its people. As one bureaucrat said, "People attack us for corruption and not fulfilling our duties, but we follow the instructions from the government, if they keep changing their stands, we can't help it anyway." On the influence of private sector on government one person said, "It is the ethics of governance, but they're bound to play a role. You can't sort out bioethics ignoring how ethics plays out in other areas. Finally public opinion and understanding will make the change. If public puts pressure on government that Monsanto is the real culprit because it has not a waited and it has corrupted and contaminated the situation. So it is a challenge to government that people are not even ready to wait with the protocols." Governments are not always projecting the true picture, as another person said, " Government thinks we have enough foreign exchange to buy food but I don't think so." However, it is always not the case, as another person said, " There are some programs where some genuine work is going on, like AIDS control or malaria control programs, due to the international pressure." Another person also said, "It takes time to see the results, but people want to change things overnight, its not that efforts are not being taken, the process is slow but not stopped." The results need to be effective to the people, as another person said, "In many cases though we know it is very positive but we are not able to get positive results at the users end".

4.2.5.5 Trade barriers

The main issue for developing countries is the WTO provisions through TRIPS. Developing countries need to participate in international trade to get foreign exchange and markets for their products, as one person said, "Once we are signatory to TRIPS and we are part of WTO we can't ignore whether it is good or bad but keeping in view of our long-term interests and keeping in view of for political implications and the wisdom of all the politicians who decided to be part of a WTO." International trade barriers have a severe effect on the lives of poor farmers, as another person said, "They will become dependent and costs are set by MNCs and sometimes MNCs are insensitive." Another

person said, "We are subordinated to a strategy at the hands of a few people. So the first thing that we should do is to try to make TRIPS more people friendly." However, there could be farsighted benefits for the resource rich countries, as one person said, "TRIPS indirectly effects in the sense that if they give patents to plants, animals and transgenics, I think it will make a lot of difference and explanation will increase of our genetic resources." Trade barriers result in lot of internal pressure also on the countries, as another person said, "Developed countries assist their farmers through agriculture subsidies and here poor farmers sometimes even pay tax to buy seeds and other things, and subsidies render farming elsewhere uncompetitive and force poor countries, many of which depend on agriculture, to import cheap surplus foods from the West. This creates lot of internal pressure on the government to subsidize farming in the nation as well."

4.2.6 Environment

The affects of genetic engineering on the environment have been a controversial topic, 12 people raised damage to ecosystem as an ethical concern. We need to conserve nature for the coming generations, issue of future generations was raised by 12 people. 9 people also raised the loss of biodiversity because of the environmental pollution and other activities as an ethical concern. Ownership of genetic varieties and farmer rights was raised as an ethical concern in the context of growing use of genetic modification. Issues of pesticides causing environmental damage were also raised as an ethical concern by 5 people (figure 19).

Example comments are shown below to explain the type of concerns people raised, with a summary of the issues in Figure 19.
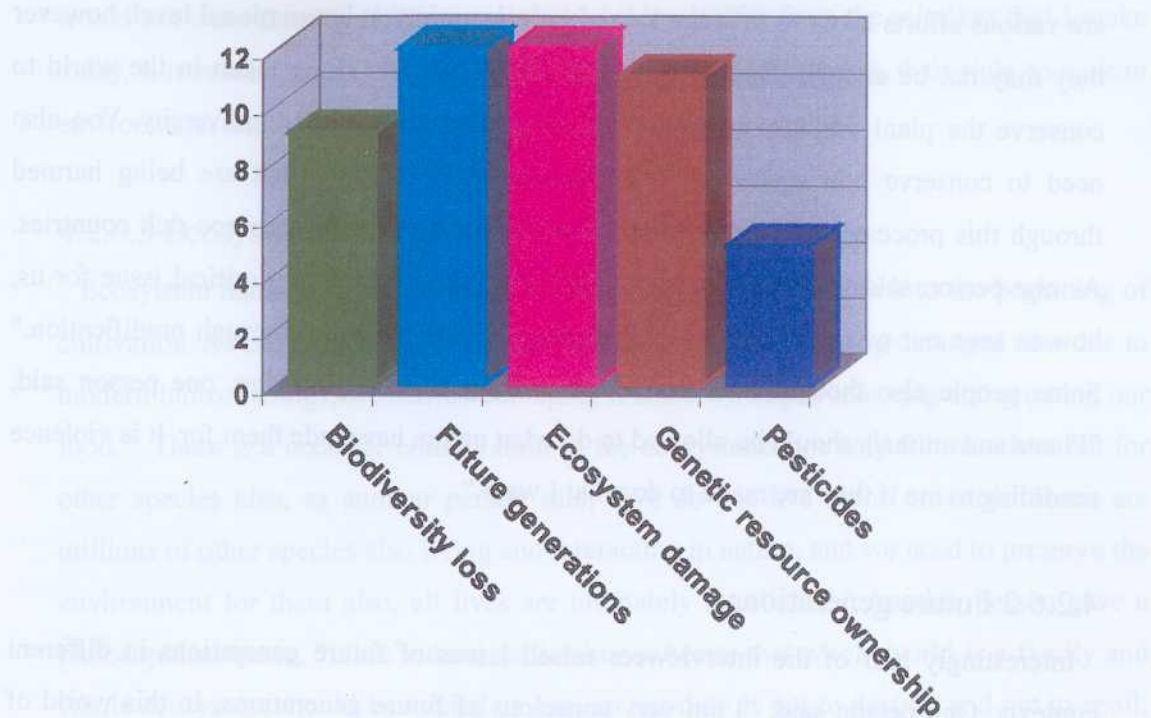
Figure 19: Issues raised under the concept category ENVIRONMENT considered to be of major importance in India

4.2.6.1 Biodiversity loss

Loss of biodiversity and existing varieties has become a major issue since the beginning of reports on the affect of genetic modification on environment and other species. One person said, "Genetic modification and patenting of new varieties have made us more conscious on the loss of varieties, not because we have become environmentally friendly, but trade." Some people were critical of the new varieties. One person said, "If you critically see, genetic engineering has nothing produced worthwhile. In developing new products, scientists take plant samples from the field to the laboratory, where the simple act of moving a single gene from one spot to another within a cell whether or not it causes an actual variation in the next generation, creates a "plant variety" deemed sufficiently "new" to qualify as a patentable invention. And then neither we have the land races that was a common use for the farmers nor the so called new varieties are accessible." There

273

are various efforts taken to save the loss of genetic variety at international level, however they may not be enough. One person said, "All the efforts being taken in the world to conserve the plant varieties is basically to conserve agricultural biodiversity. You also need to conserve non agriculture varieties and wild relatives that are being harmed through this process." It is an important concern for genetically resource rich countries. As one person said, "We are a resource rich country and it is very critical issue for us, how to save our own varieties from those being newly produced through modification." Some people also thought it as unethical to use genetic engineering, one person said, "Plants and animals should be allowed to do what nature has made them for. It is violence according to me if they are made to do what I want."

4.2.6.2 Future generations

Interestingly half of the interviewees raised issues of future generations in different contexts. One person said, "I am very conscious of future generations. In this world of market driven forces, future generations are being forgotten, even current generations are been forgotten." There is a need to conserve nature for its own sake, as another person said, "Plants and animals also may protest, we don't know when and how it will happen in future. At present we feel powerful and all things are at our disposal." It is a duty of human beings to reserve the things for coming generations. As one person said, "Being one of the most intelligent species on this planet, we need to be intelligent enough to understand that, to continue to exist in the years to come, we should be keeping something for future survival also, for the coming generations." One person also attributed the conservation movement to evolution, as he said, "We are conserving nature now because we feel threat to our survival, it is also a genetic drive, each species in the nature competes to perpetuate. Human beings also wish to perpetuate like other species, so we are now trying our best to keep our genes exist in the environment." Rapid change in the world is threatening many people, as another person said, " When the world was slower it was far more comfortable. So if I have to keep myself as an informed gatekeeper for this country, I have lot of responsibilities for current as well as future generations. How to keep people's memories alive, their knowledge systems alive? The challenges are enormous and policy makers are not yet up to the task at present. We have to define these things for the future." Another person said, "The sustainability of ecosystems is required not only for the present generations but also for future generations." We also need to consider the rights of future generations, as a women interviewee said, "As a mother, I

would not want that my children and their children suffer from the mistakes that I make today, it is same for all. I would like to have their rights protected, their right to a clean environment, and beautiful nature that I enjoy today as my rights."

4.2.6.3 Ecosystem damage

Ecosystem damage is a concern for a long time. We can attribute it to the beginning of cultivation. As one person said, "It is not that we ecosystem is being damaged now due to modern biotechnology, we started damaging it since we began selecting and growing our food." There is a need for conservation of the ecosystems not only for ourselves but for other species also, as another person said, "We do not live alone on earth. There are millions of other species also living and interacting in nature, and we need to preserve the environment for them also, all lives are ultimately interlinked." Another person gave a philosophical quote, "If we indeed realize in our hearts that whole world is a family and whole ecosystem should be treated as one, so our duty is not to destroy and not to spoil; but not necessarily to prevent change". Special concerns are raised for the affect of genetic engineering on the ecosystems, as one person said, "The main threat of modern biotechnology is to agriculture ecosystems. There are other species also living with the crops. When we talk about ecosystems getting deteriorated, we should first be focusing on our fields, trying to see a balance is maintained in the fields and slowly diversifying it into larger ecosystems." Another person said, "We should be careful that no harm is done to the environment and forests. Genetic engineering is good if it is not harmful for the nature, we should not try to change the course of nature, it is worth threatening our own existence." Some people were more worried about the health concerns, as another person said, "Environmental risks are at least taken into consideration by the fact that people are trying to see the way trials are conducted but as far as health risk is concerned, people say pesticide residues have been in the food chain for long time." The media has also been active in raising concerns, as one interviewee said, "Sometimes there are debates in newspapers, writing about ecological harms of technology and scientists of different galleries also debate on it."

4.2.6.4 Genetic resource ownership

For developing country's farmers there have been some big battles against big multinational corporations for ownership of varieties of their crops. One person said,

"Already farmers are suffering enough due to so many problems, like land, water, environment etc. Now one more is added to their kit. Poor farmers will not be able to save their seeds for next generations, and also pay royalty and tax to government for using their seeds. No wonder farmers suicide, when they become hopeless from nature and government whose policies are making their lives worse." *Genetic material should not be made private property,* as another person said, "If you call bioethics as ethics of life, knowledge about life or misuse of information, even the genetic material that is been taken and made into a private property, for me it is an ethical question." India has been fighting a long battle with US on patenting of basmati rice, as one person quoted, "We have been fighting hard to protect ownership of basmati rice that US granted patents on. By granting the Basmati patent to RiceTec, the US Patent Office had essentially deprived Pakistan, India or anyone else of their prior use-rights to all the genetic trait and genes that give rise to the essential characteristics of Basmati and other similar aromatic fine grain rice, and so denied them the right to sell such grain, in North, Central or South America, or Caribbean Islands." Another person said, "Basmati episode has taught a very big lesson to all the developing countries that it has highlighted the danger of the traditional users' age-old rights to use valuable germplasm from the public genepool being appropriated by monopolistic ownership under the guise of IPR." *Providing rights over the traditional varieties may have other consequences also in international efforts for collecting genetic varieties,* as one person said, "Countries are now becoming increasingly reluctant to contribute to the maintenance of public international genebanks and breeding programs. Those who contribute germplasm fear they will lose not only access and control, but also their age-old use-rights."

4.2.6.5 Pesticides

Environmental consequences of pesticides have been commonly known for a long time now. The biggest threat is of biomagnification once they enter food chain, as one person said, "We have problems of agriculture pesticide residues which is also significant in the whole food chain." Since the harmful affects of obsolete pesticides became commonly known, their use has been restricted, as another person said, "Several hundred thousand tons of dangerous, useless pesticides currently plague several countries around the globe, and they pose a great threat to human lives." Another person said, "Cleaning up pesticides is a big problem, no one would like to invest money in it but we need to consider that that as long as the toxic legacy of obsolete pesticides remains, sustainable development is

effectively impossible because water, soil and air continue to be poisoned." However, there are efforts being taken to produce people's friendly pesticides. One interviewee said, "Efforts are being taken to produce environmentally friendly biopesticides, not only for malaria and dengue but also for crops."

4.2.7 Animal issues

Animal issues were not a major concern for interviewees, although there is general image of it being a cultural sensitive issue. Only 3 persons raised religious concerns about animals. The issue of animal husbandry was raised only by 3 persons. Some comments are shown below to explain the type of issues people raised, and a summary is in Figure 20.

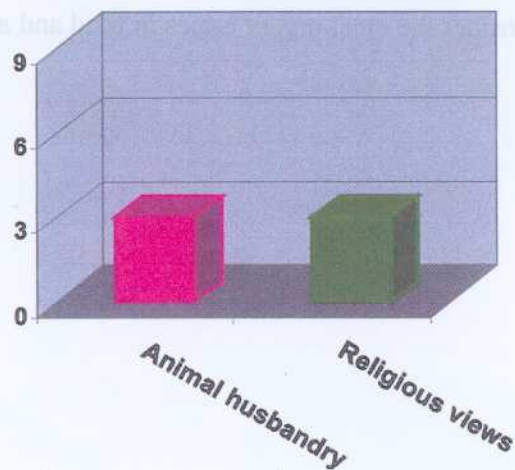**Figure 20: Issues raised under the concept category ANIMAL ISSUES considered to be of major importance in India**

4.2.7.1 Animal husbandry

Animals need to be cared for and preserved, as human beings are dependent on them. One person said, "We have been killing and eating animals for our survival although we have many other options, and that is our moral status. So how can we say we are better

277

then them". Some people consider transgenic animals as a product resulting from selfish human motives, as another person said, "All this much of modifications or corrections for this small race of human beings in comparison to many are the thousands of other nonhuman living organisms is very bad and violent. I do feel some benefits have come, but still there should be a limit and then one should monitor it."

4.2.7.2 Religious views

Religion plays an important role in determining the choices people have, as another person said, "We may have a perfect technology or a product but because of customs, religion and other social issues people will not like to accept that." However, some people consider the debate against GM as religious fanaticism, as one person said, "All the apologies for mistreating nature and living beings come from the restricted and narrow religion based thinking".

4.2.8 Most urgent issues in food and agriculture in India

Based on the interviews, we can consider the most urgent issues in food and agriculture in India as:

- ➢ Poverty
- ➢ Gender issues
- ➢ Safety of technology
- ➢ Information dissemination
- ➢ GM labeling
- ➢ Private sector
- ➢ Ecosystem damage
- ➢ Future generations

4.3. Results of the Indian interviews on health care issues

Policy makers dealing with health care in India raised several ethical concerns related to provision of health in the country. Table 6 shows the details of the key issues raised and number of people who raised each as an ethical concern. Figure 21 also shows the range of issues raised by the policy makers in India. Example comments are shown for each key issue to explain the type of concerns that people raised.

278

Table 6: Results of Indian Interviews regarding Health Care issues

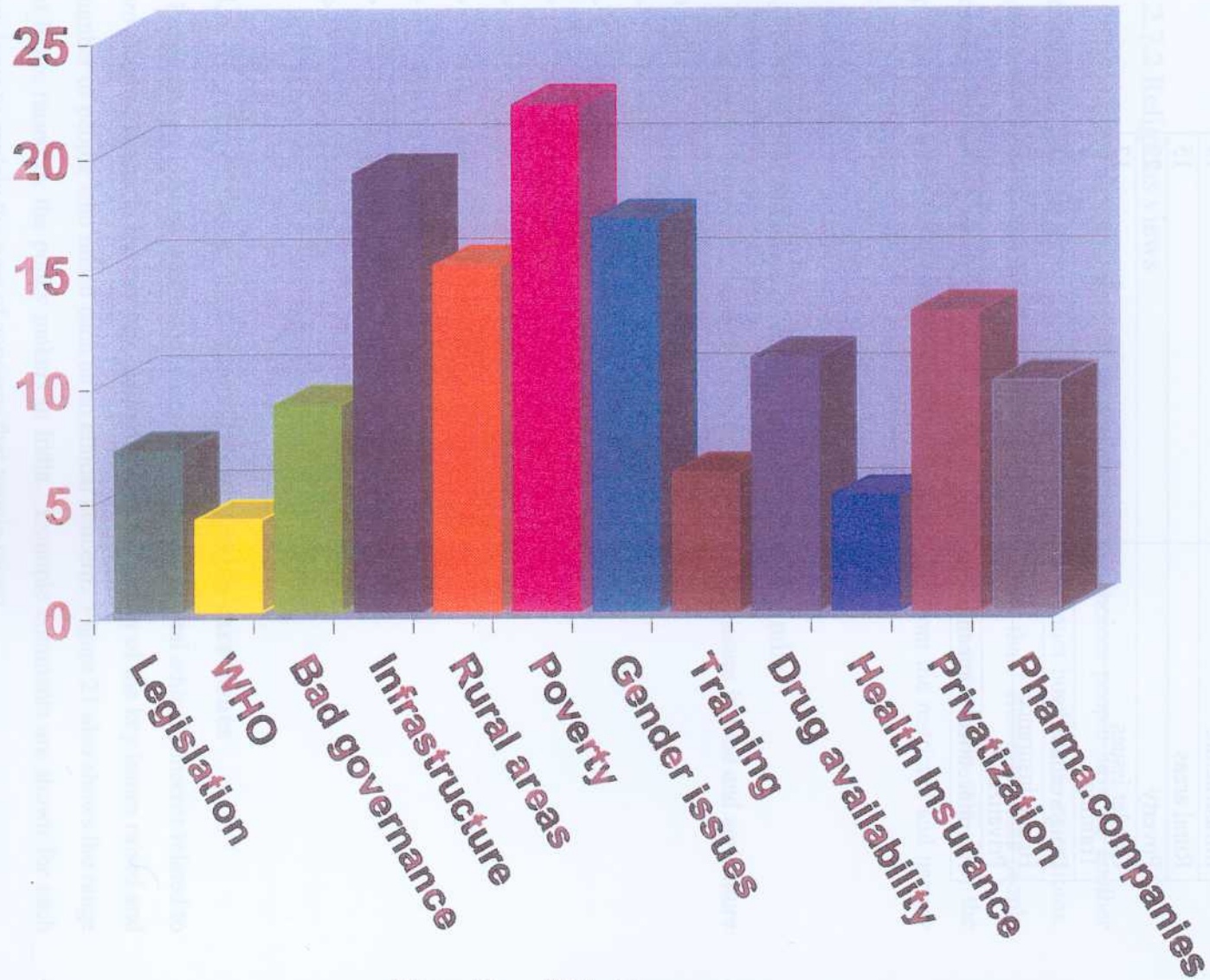| Issue raised	Number of people raising the issue
Legislation	7
WHO	4
Bad governance	9
Infrastructure	19
Rural areas	15
Poverty	22
Gender issues	17
Training	6
Drug availability	11
Health insurance	5
Privatization	13
Pharmaceutical companies	10

Figure 21 :   Ethical issues related to HEALTH CARE in India

4.3.1 Legislation

Laws are sometimes necessary for society to behave more ethically, as one person said, "With the law, people would be little conscious when breaking the law so as penalty action could be taken." Another person also agreed, "Otherwise alone with guidelines it is a very difficult to control." Inadequacies in the health care policies may occur due to several reasons, as one person said, "We are a country of big population with diverse cultures so our problems are also diverse. Big population increases the problems sometimes to the extent that it becomes impossible to resolve them." The situation of the healthcare policy in India was explained as, "Particularly the contemporary health care policies contained a lot of legislative hurdles and legislative continent has not been getting the dual emphasis and importance." Another person said, "Ethical issues arise because of lack of proper legislation and health care strategies." Health care provision is written in Indian constitution but there are lacunae make it difficult to implement solid policies for the nation, one person said, "They are very important in Indian context because we are a federal system of governance and the founding fathers of the Constitution kept health care as a state subject. So each state is autonomous and they can formulate their own health care policies." People also tend to not follow the laws because of the socio-cultural restraints, on the issue of sex selection, which is prohibited to do testing, another person said, "You can keep legislating but the reality is ground reality, it is people who have to face so many problems in society."

4.3.2 WHO

International health care and disease eradication is under the jurisdiction of WHO. Like FAO, WHO also focuses particularly on poor countries. One person said, "WHO has been very active in promoting various projects in India, related to AIDS, polio vaccination, leprosy etc." However, one person did not agree with what health is, "I don't agree with WHO's definition of health because nobody can have all four satisfactions at a onetime." International efforts are more recognized than national efforts, as one person said, "Whenever a program is implemented, if it is from WHO, it is taken more seriously and people take more efforts because of the international image, but if it is ministry's own program, nobody bothers, because first the funding is limited and then there is a general image we do not make plans properly. People trust WHO more than their own ministry"

4.3.3 Bad governance

Proper governance of health care is a critical issue since it is directly related to ordinary public. Even though there are government-run institutions, the services are not good, as one person said, "Government always say that they don't have money but I think apart from that there is disorganisation. Management is not good, so availability of services in the health sector is a major problem." Even if the programs exist, bureaucratic measures may be too lengthy to put programs in action as one person said, "The hassles of getting chemicals, research material and then government put duty on it." People rush to government hospitals since they are cheaper and certain things are also subsidized, as another person said, "In government sector partly because of the rush of patients it gets choked. The system is too inefficient because the number of patients coming to government hospitals is so large and the incentive given to doctors working in government hospitals is very less." Even there is a subsidized healthcare, management is not properly done, as another person said, "Even then government sector 90% of the money the patient still have to spend on medicines or buying this or that for the patients. Theoretically it may be free but still you are asked to buy bandages etc." Bad governance also results in denying rights to poor, as another person said, "The gap between rich and poor is growing every day. Government has to make the policy." Governance also becomes difficult when there is not a proper system, "In India we have so many hospitals and so many research institutions, medical schools so it is very difficult to keep a track on what is going on in which institution." On the effect of governmental policies on the common people, one person said, "Politicians do not even seek proper advice from experts before they chose to decide on things, sometimes its just a matter of political rivalry and of course you will not have good results in the end." Better coordination is needed as another person said, "Management is not good, availability of services in the health sector is a major problem."

4.3.4 Infrastructure

Lack of facilities in the hospitals is a big problem in India, as one person said, "Hospitals hardly have any heart-lung machines or artificial respirators. How can an earlier patient be taken off when a new patient comes?" It is especially a concern in public hospitals, as another person said, "Government hospitals are cheaper but less equipped with good facilities." There are various efforts taken to improve the situation, however the

situation is not improved. One person said, "In practice still lack resources in terms of logistics, training and manpower." There are very less laboratories to test various genetic diseases, as one person said, "The type of infrastructure required, the type of trained manpower required cannot be proliferated in each and every laboratory. It would be in a very few labs whether in government set up or private setup. Being small in number it is much easier to monitor them." Another person compared it with West, "They are already a generation ahead from us." Infrastructure also requires storage facilities, as another person said, "Inefficiencies in the storage, prescribing, and use of drugs are so extensive each year millions of rupee worth drugs are wasted which could have been used for saving lives, just because we do not have proper storage facilities." There also exist problem of networking, as another person said, "The transportation system is poor, roads are impassable, which delays the delivery of medical supplies." The problem lies both in cities and villages. One person quoted, "In villages the situation is worse because hospitals do even exist sometimes, people have to travel far to reach hospitals. In cities we have a different problem, there are often electricity cuts, Without electricity, hospitals cannot function effectively and vaccines lack proper refrigeration, rendering them unusable; you will find generators only in ICUs or operation theaters, even then it is not guaranteed."

Infrastructure also involves provision of clean water and healthy food to the patients. One person said, "Even inside the hospitals you cannot trust water and food. Lack of clean water and food and sanitation facilities lead to rapid spread of diseases. It also complicates oral administration of medicines." However the trends have been changing, and skilled professionals wish to work for the country as another person said, "But now the infrastructure is getting much better than some people are returning back. If you give them facilities they're willing to come back and give a try. Even abroad also not many are in very good jobs. They end up as technicians. But it is difficult to induce them because of money." Another interviewee said, "We are working for promotion, also for research and development, creating infrastructure facilities."

4.3.5 Rural areas

Provision of health care in rural areas is essential since approximately 70% of the population live in the rural villages. One person said, "Even after 50 years of independence we failed to provide a hospital in each village, it is a serious ethical issue."

The distance between cities and villages is large which is an obstacle for rendering services, as an interviewee said, "If the accident happens a little far away from Delhi, the victims can at most get the primary health care, very fortunate if secondly health care. For advanced tertiary health care he have to depend on big cities. Even if you get a timely transportation he will not have enough economic resources, so this is a lot to do in the health sector in our country both at the strategic level as well as the conceptual level." Another person said, "They don't have access to proper hospitals or timely services for patients." Most people in the rural areas do not know about the advanced health care, as another person said, "People who are living in rural areas, they have less access to modern health care services as you can find in urban areas, less educated people are there." Personal choices of practitioners are also an ethical issue, as one person said, "Doctors do not wish to work in the villages because there are no chances of improving their practice, it is a big competition in the medical field. They do not earn much in villages and then they lack resources to carry out even primary health care in the villages." Another person said, "Any medical student looks for a bright future by going abroad for studies. Not only they learn more but also they earn more once they are back. People have a tendency to trust returnees." On government measures for rural people one person said, "From time to time we have launched special campaigns exclusively in the villages, like vaccination programs for infants, rural eye camp surgeries, childcare training programs for women. But I agree it is not enough, we need a permanent resolution." However, these programs are difficult to implement, as one person gave as an example, "Rural India face problems of resource management. With inadequate technology, the doctors in the camps give second best treatment." Another person said, "The lack of post operative care is another factor leading to failure of rural surgeries."

4.3.6 Poverty

Healthcare will not be accessible even if it exists because it is unaffordable even at most cheapest rates, as one person said, "We try to reduce the cost, we have hospitals like mine which is a trust hospital where you can reduce the cost. But there also we can reduce the cost to a certain limit, from 100% we can reduce to 50% but we can't go below 50%. Some people can't even pay 50 % then I can't help them." It is more of a problem in rural areas, as another person said, "Firstly we do not have hospitals in villages, and even if there is some healthcare center at a distant location, people cannot even afford transportation to go, and by the time patient is somehow brought to the hospital it is too

284

late, so that is the image of poverty in the country." Another person also said, "The poor do not have access to proper hospitals and timely services." Many social problems arise due to poverty. One person gave example, "We have high child mortality rate, and female foeticide, it is due to poverty, children die due to lack of health care against infectious diseases, and girl child is killed because of other social reasons." It is also a dilemma for the doctors as one person gave example, "I had a family where two children very much looked like that they had fragile X chromosome. Father was earning less than 3000 rupees, so 1500 rupees was too much money for him for a test and secondly wife was pregnant. I can't take the risk, already the two boys were affected and they had 50 % chance that third would also be effected."

Governmental policies sometimes are also not favorable to poor. One person said, "Government provide subsidies in the health sector only for major operations and extremely serious cases like accidents etc. But they do not have provisions for the primary health care which is needed the most." Even if publicly funded hospitals look cheaper, it always may not be true for poor, as one person gave example, "Patients don't want to stay in hospitals. They want the treatment done and go back same day. In AIIMS if patients have to stay a week for the same treatment done but it may be cheaper rate. But the amount of money he spends in one week, makes all the balance, but people rush to the government hospitals considering it as cheaper." Another person said, "Poor people go to government hospitals because some private clinics exploit poor people a lot." Poor people need to keep a minimum healthy condition, as one person said, "Poor people value good health a lot, because they are depended on physical labor; a fit, strong body is an asset that allows poor adults to work." Also costs of healthcare are not affordable as another person said, "In particular, poor families are concerned about the health of their breadwinner. When he or she dies, or needs a expensive medical treatment, the costs may be devastating, which may include their whole life savings, so in vain, they prefer to avoid medical treatment and endure suffering, otherwise they family will be thrown into extreme poverty from which they cannot escape."

4.3.7 Gender issues

Gender issues are a common problem in all the nations, but serious in poor nations, as one person said, "Then there is female foeticide taken very seriously in India. It happens because doctors do it." Doctors are sometimes helpless, as one doctor put the dilemma,

"We will do it for muscular dystrophy, male has a higher risk of being affected but female does not have that much risk. But if a female is effected they would say no that they don't want to bear pregnancy as she is carrier of muscular dystrophy; saying her children will have problems that and it would be difficult for them to get her married. So that is one thing that bothers us." Another interviewee said, "There justification to know the sex is that they need a man who can continue their business etc." A sick girl child is a burden sometimes, as one person said, "Boy who has some retardation or some problem has more easy life than of female who has some problem." Doctors have the primary duty to avoid gender discrimination, one person said, "People do ultrasound to know the sex of the fetus, but after all abortion is done by doctors. There are considerations other than professional considerations, because people to it."

Although there is a legislation against gender based mortality, but it still exists, as one person said, "Although the government has banned prenatal diagnosis for sex determination but still there is a tendency that they want male child, it is not so difficult to do it and sometimes the pregnancy is advanced so they can't do anything anyway, so when the girl child is born there are cases of female infanticide, they are done secretly in cities, but in villages it is common thing." Some persons also put the discrimination on cultural values. One person said, "Even now in villages, girls are not given opportunity to learn and educate, people think that women should remain in the house and it is the same thing taught to girls all their lives, which makes them hesitate to go ahead and explore things." Another person said, "In villages, a women is not considered decent and good, if she interferes in what can be termed as men's job." However the trends are changing and government is making efforts to increase the awareness, one bureaucrat quoted, "We have several programs for empowering women, there are schools opened for training of women in basic heath care, also community dairy programs which is run by women, rural banking where women can take loans and do savings."

4.3.8 Training

Training can help to increase health care among people. It is necessary also necessary to better avoid infectious and communicable diseases. One person said, "Giving free drugs or routine health checks are not enough to keep a check on the health of the rural people. They need to be trained how to avoid diseases by adopting simple changes in their ways of life. We need to teach them to boil water, or avoid smoke, wear slippers and many

286

other ways of keeping clean and hygienic, training is worth saving money." Training is essential for rural women, as another person said, " We especially want to focus on training rural women for care during labor and followed by childcare and communicable diseases, especially women with HIV." On the professional level, there is a wide knowledge gap between professionals. As one person said, "There is need for medical professionals to go through a legal training as well because medicine is no longer be practiced alone with moral responsibility. Also many legal experts are not able to understand health care perspectives. Doctors fear treating patients sometimes because of legal complications that can follow if something goes wrong." In hospitals it is a big problem, as one person said, "Trained manpower and finance is biggest constraint in healthcare." Whether morality can be taught, one person said, "Being an ethicist is a commitment and it is not training. You can't train ethicists."

4.3.9 Drug availability

Medicines need to be affordable even if they are available. As one person said, "Drugs have gone very costly in India. To many they are not accessible because of unaffordability." Especially, in villages the issue is more complex. One person said, "Even if you have a community hospital in villages, medicines are available in limited quantity. You have limited staff and sometimes there are not even doctors available." Bad governance and lack of infrastructure also count for the lack of drugs, as another person said, "People do not have access to timely drugs, for several reasons. Drugs go bad because of mishandling, and sometimes there are reported thefts of drugs from the medical stores, which also contribute to lack of drugs in the markets." Another person said, "Health is a basic right of people, and it is government's responsibility to make drugs accessible to all people." International competition and patenting has also made it difficult for people to get access to drugs, one interviewee said, "Patenting of the drugs has become a critical issue, and it has biggest affect on the lives of millions of poor people in developing countries. You have HIV/ AIDS and many other diseases; people do not even have access to basic antibiotics and vaccination, and you are making it more difficult for people to at least be alive by putting royalties." Another person said, "It would be very difficult for people to afford drugs when TRIPS comes into force, after 2005. We have been exporting generic drugs to many African nations where large populations are still dependent on cheap imports, of drugs which will vanish, threatening lives more." Lack of trained experts also a problem, as another person said, "For the

287

majority of the world's poor and most vulnerable citizens, there is no practitioner in their community trained in the prescription of essential drugs. There are indigenous practitioners who are experienced clinicians but not formally trained in the allopathic system of medicine. They need to be trained in the use of essential drugs if these medications are to be truly accessible to the world's poor."

4.3.10 Health insurance

Health insurance is essential if we want to ensure all people have access to medical care, but not necessarily applicable in all the circumstances in all the countries. As one person said, "It has a role for those who can afford it." India does not have a national health insurance policy, when asked will it work in Indian situation, a higher official said, "I'm totally against it. I'm totally against managed health care system whether it is in the form of insurance cover or any other form. Because if you see a country like U. S. spend 16% of the GDP on it and 40 million Americans have lost health insurance, so it has been a dismal failure. A country like America which definitely has a good governance than India a, and there also this insurance coverage is a failure. Another thing is that we already have insurance covered in many other sectors but not in health. Insurance sector is not people friendly." However, another person differed, saying, "It will come, as the privatization is spreading." The affect of genetic testing on health insurance is many, one person gave example of AIDS, "The other question about AIDS, which gives an impression that a person might become sick it is practically a predisposition identification, and I have a very serious problems about it, especially in the country like ours. As such there is lot of unemployment, these could be used against people as discrimination. Ultimately it may happen that even after 20 years the person does not get sick, but he loses 20 years of his active life, which could have been productive. Third is their effect on access to medical health or health insurance."

4.3.11 Privatization

In India privatization of the health care is increasing, because those who can afford it prefer private hospitals, as one person said, "Moreover the number of patients visiting government hospitals is so large that doctors can't give enough time to patients. Private clinics or private hospitals provide good services to patients. I think now the number of private hospitals is at least equal to government hospitals." There may be several

advantages of privatization, as another person said, "Privatization is good and bad. Privatization is good because without that advanced health care cannot be achieved." Heavy competition in private healthcare also has some advantages. One interviewee said, "They have a personal stake and a personal interest. At least managerial efficiency is higher if not professional." Another person also agreed, "There has to be private participation and private participants are definitely better managers." Even though private sector is expensive, but helps in setting up international standards of health care, as one person said, "Privatization of health care is good in the sense that it brings advanced health care to the country and it keeps wheel running." Many times the government does not introduce something because of the fear of opposition from public, which may not be the case for private sector. One person said, "They are in a position to take a risk because it is part of their game they did they have a better international equations." However, some people criticized privatization of health care for its commercial approach, as one person said, "It is their interest to ensure that it does not stop but it is bad also as it leads to commercialization of some things which has an intrinsic value." Private sector is sometimes expensive because of the extra costs of provisions of fancy treatment, as one person said, "Private investor is basically a merchant. They spend a lot on advertisements and publicity, which are unnecessary things to induce and allure people, and ultimately the whole thing is passed on to the customer i.e. the patients." Another critique said, "At the end of the day commerce becomes the determining factor, that is the worst side of private sector and we can't avoid it." Some people felt there is a need for better regulations, as one person said, "We must ensure that if we have private health care we have an adequate regulatory mechanism so that people are not deprived of the health care simply because they're not ready to pay the charges or tariffs as determined by the private-sector."

4.3.12 Pharmaceutical companies

Pharmaceutical companies play an important role in determining the health status of people. As one person said, "The agenda of pharmaceutical companies is very important to be clear and properly understood, as their ultimate goal is profit and not to serve the people. However, they are one of the most critical part of the healthcare system who would determine the availability of the drugs, and we cannot ignore them." Pharmaceutical companies use different means for promoting their products, and try to

influence in different ways, as one interviewee said, "Other problem for practicing doctors is that they are very much influenced by pharmaceuticals. Doctors sometimes prescribe medicines from particular company." Another person commented, "The nexus between doctors and pharmaceuticals is seen in fact all over the world because companies give them incentives." Companies try to attract doctors in several ways, one interviewee gave an example, "They give them gifts, provide them funding for abroad travel for a conference presentation; which is not possible by many government institutions to afford. So it is naturally doctors will be obliged to that company." However, there are strict rules for the government employees, as one doctor said, "The government of India has banned that nobody can accept any money to attend conferences abroad. But many private hospitals accept it." Pharmaceutical companies in developing countries are very small and it is difficult to compete with big multinational companies. On the situation of Indian pharmaceutical industry, one policymaker said, "At the moment pharmaceutical company people are thinking that for core drugs about 80% is out of treatment, and this will continue for at least a couple of years and then better drugs through recombinant technology will come through and it would be costlier if produced outside and being imported. So they are gearing to some sort of a joint venture with MNCs. Certain major players are trying to develop R&D also."

4.3.13 The urgent health care issues in India

In summary the urgent health care issues in the India revealed through the interviews were as follows:

- ➤ Bad governance and lack of legislation
- ➤ Economic issues
- ➤ Primary health care in rural areas
- ➤ Infrastructure
- ➤ Privatization

4.4 Results of Indian interviews on medical research

Many developing countries, including India are rapidly adopting new technologies for medical research, as there are many avenues for research in India. Medical research is fast developing in the country, and policy makers raised several ethical concerns related to medical research in India. Table 7 and figure 22 show the details of the key ethical

290

concerns raised and the number of people who raised the issue. Example comments are shown below to show the type of concerns that people raised during their interviews.

Table 7: Results of Indian Interviews regarding Medical Research issues

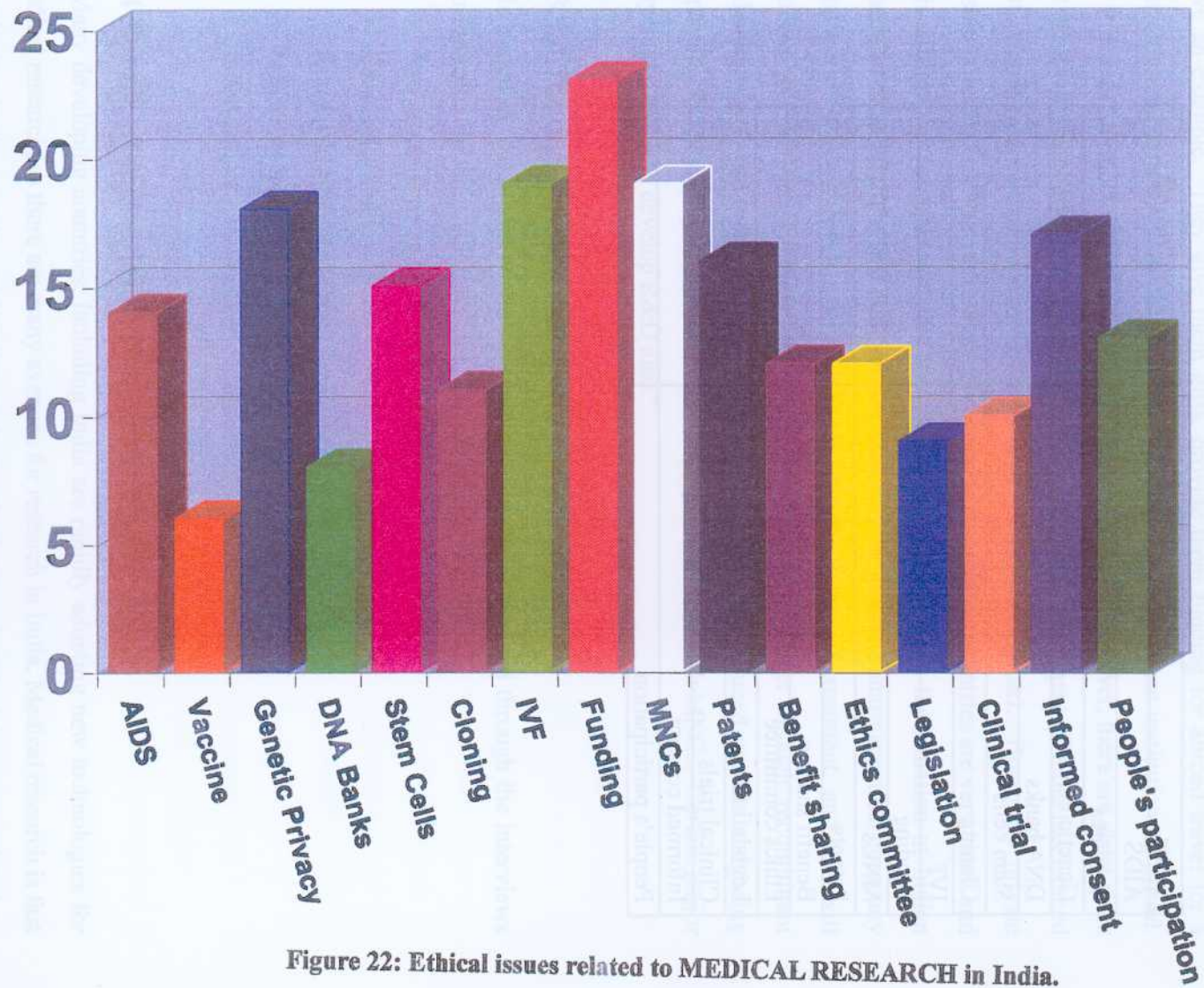| Issue	Number of people
AIDS	14
Vaccines	6
Genetic Privacy	18
DNA banks	8
Stem cells	15
Cloning	11
IVF	19
Funding	23
MNCs	19
Patents	16
Benefit sharing	12
Ethics committee	12
Legislation	9
Clinical trials	10
Informed consent	17
People's participation	13

Figure 22: Ethical issues related to MEDICAL RESEARCH in India.

4.4.1 AIDS

According to the National AIDS Control Organisation (NACO), 3.5 million people are living with the HIV/AIDS in India. It is a serious issue for policy makers in health sector. One person said, "AIDS is one obvious and most vital areas where government is focusing on because of the rapid spread of disease for which we have no cure." There are several programs underway with national and international collaborations in the country. One person said, "There are several training and awareness programs started with the help of CSOs, UNDP, UNAIDS and we have set up some objectives, like to reduce blood-borne transmission of HIV, introduce Hepatitis C as the fifth mandatory test for blood screening, to conduct annual Family Health Awareness Campaigns among the general population." Despite several efforts, it is difficult to reach all people, especially in remote areas. One person said, "There are practical and logistical problems that makes you difficult to reach out to people in remote parts of the country, it is not that people do not know about it, they suffer but it is difficult to provide them minimum care." There are several ways a person gets HIV infected, however in India one person said, "In India the main source of HIV is prostitution, and hetero sexual partners, that account for 75% of the total infection in the country." One person gave reasons for the rapidly growing incidence of AIDS in India, "AIDS is growing in India although a lot of efforts are taken, one of the most important reason is the male behavior, men although infected, go to brothels in towns and villages where people are not so much aware of the consequences and intensity of the disease, this migration from urban to rural is one of the key issues to be focused on." India also initiated medical research in AIDS, one interviewee informed, "Recently India started studies on vertical transmission on and HIV/AIDS from mother to child and there are short-term trials which is even shorter than Thailand protocol been done in the last two years and from this year we have introduced neverpin to prevent mother to child transmission. So these protocols have come to us and we have examined them."

4.4.2 Vaccines

Vaccination to prevent diseases is a common practice in health care in India. With biotechnology at the forefront, efforts are being taken to produce genetically engineered . vaccines. With regard to AIDS vaccines, one person said, "There is a retrovirus vaccine trial going on in India which is the extension of the trials going on in U. S. In U. S. the trial was stopped because of the reported intersusception." However, there are other social

stigmas attached to vaccine trials in AIDS, as one person said, "My concern is on another issue, tomorrow we have an HIV vaccine available and we want to do a clinical trial, that itself is a very controversial issue. As soon as we inject the vaccine the person will become zero positive, then a social stigma will immediately be attached." Another person informed, "Recombinant hepatitis B vaccine is being produced by Bharat Biotech in Hyderabad." Some persons were confident that biotechnology can provide solutions for vaccines. One person said, "If I look into DNA vaccines, DNA vaccines would be going to be much cheaper than already available vaccines." Another person on vaccine trials informed, "Or we develop such a vaccine which does not elicit the antibiotic response but gives them other type of response so that one would come to know that this person received the vaccine and such a response came because of the vaccine, that type of vaccine we are trying to work on." Animal concerns for vaccine trials were also raised by one person, "Ethics can be applied in many ways. For example in Madras there was trial going for producing 4 different vaccines for venom. Blood was taken out from horses 5 to 7 times a day. So in that case how we can apply ethics? Is it good to take out blood so many times? Should we no do research and produce a vaccine."

4.4.3 Genetic privacy

Genetic privacy concerns were raised in the context of clinical trials and genetic screening. However, it is difficult to keep the privacy of the person, as one person said, "Now the issue comes up, when we say all these DNA based diagnostic tests, based on genome analysis which is being kept as confidential as possible, it becomes a dichotomy. Here you are asking a person to go out there and get the tests done. You know the results, doctors know the results and then also you are giving drugs. So this sort of dilemma is there." Prenatal genetic screening is commonly done in India, however the doctors put the dilemma like, "We should not do prenatal diagnosis for genetic diseases for which there is no cure or treatment, however sometimes parents want us to tell the results of the genetic tests because it gives them options to continue with pregnancy or to abort." However a strong legislative support is needed, as one person said, "We do not have enough legislative strategies for privacy of diagnostic tests. If I disclose any status, it does not amount to any criminal offense. It just amounts to violation of my medical ethics." Another person also added, "We need to have strong protections against the misuse of personal medical information including data derived from genetic diagnostic tests." Misuse of genetic tests by insurance companies was also feared by some interviewees.

One person said, "Genetic testing has the potential to identify hidden inherited tendencies toward diseases and spur early treatment. But that information could also be used, for example, by insurance companies and others to discriminate against and stigmatize people." Keeping genetic privacy is also difficult culturally. One person said, "It is very difficult to keep something as private in Indian society, the fundamental principle of genetic privacy is that the person should have a control over information. When you talk about informed consent in India, first family has to decide, the decision itself is not personally done. We regard family as a unit, no wonder for something sensitive as genetic testing, it cannot be a person's decision, so ultimately somehow the information is opened. If as a doctor I do not tell to the family, I could be forced into legal battle because there is no protection for the doctors in this regard." However, some people were optimistic, as one person said, "We need to protect the privacy of people, although it is difficult. A trend is seen that people are going to genetic counseling and seeking advice before the tests are done. At least in the big cities it is becoming common, people want to do genetic testing to plan family and future of their children. We try not only to protect the information on results but also the identity of the person. It is better handled by private consultations."

4.4.4 DNA banks

Enthusiasm for the prospects of biotechnology has been visible with the establishment of DNA banks in the country, as one official said, "The cell banking facilities have been established. Cell banks have ethical review committees and they will look into the issue of material transfer, agreements or memorandum of understanding between the person who wants to donate the cell line and will also give permission to pass it on to other persons that is the scientists." Higher efficiency is need in order to avoid the misuse, as one person said, "There are potential benefits that justify the establishment of DNA banks, but the most important part is responsibility of the proper management and protection of the subject's interests." However one skeptic said, "It is a good effort, but the issue just does not end with establishment of the banks, but you need to look into security mechanisms, infrastructure supply should be continuous, computerized tracking, encryption etc, I am not sure if we have skilled labor for it." Another critic said, "The amount of money spend on establishing one tissue bank, to which ordinary public has no use, could have been spend in establishing a small hospitals in 2 or 3 villages, you are also not sure where all this fuss around biotechnology would lead to in the end."

4.4.5 Stem cells

Stem cell research is also an proceeding as public and venture capital research in India. One person said, "For stem cell research we have already decided that we would go ahead with stem cell research with proper regulations." The government is enthusiastic about the therapeutic use of stem cells. One policy maker said, "I have very clear views on stem cell research. I have no reservations that stem cell research is quite ethical for therapeutic purposes. We should encourage it." Another person also agreed, "I have some reservation on the productive part of stem cell research but in deeper analysis I feel if we start comparing a six cell mass to a human being, it is not correct. Those 6 cells are closer to a fertilized egg than a human being. So those six cells are not worthy to same kind of human dignity to which a grown-up individual is." Scientists who are policy makers also favor the use of stem cells. One scientist said, "I don't understand why and how if we grow embryos by cloning and utilize them for therapeutic purposes I don't find anything wrong in it. we are not slaughtering human beings or fetus. In fact we are not even slaughtering embryos. It is rather a pre-embryo of six cells. I am not sure what is the ethical justification for denying people the fruits of science, if it can improve their health and quality of life." Another person said, "I don't find any moral miscarriage in utilizing stem cells for therapeutic purposes." Stem cells could be used for producing organs, which is a big issue the country faces, as one interviewee said, "There are people dying of organ failures or heart failures or from incurable diseases. Having realized full potential of stem cells, if we do not pursue it for therapeutic purposes for those moral considerations, then it is contrary to human dignity." How to draw moral limits and what is a public benefit. One person said, "If it is going to be creating organs for replacements, as long as the benefits overweighs the public cause, they should be evaluation of this before any decision is taken. Research at that level as a research agenda, I don't have anything against it." India is inherently a society affected by traditional cultural values, as one person said, "Had there been no moral opposition, we would have been five or six years ahead of the present time. People are dying of illness, people need kidneys, is it not immoral?" Another person asked, "What makes you feel when there are five or six cells? Are they as big as or as good as a human being?" Some people were not sure if stem cell research was appropriate given the amount of skill and infrastructure required. One person said, "Research as such can be there by utilizing the knowledge but how much appropriation is there? Whether private benefit overweighs public benefited or vice versa, a decision should be taken considering that."

4.4.6 Cloning

The issue of human cloning was raised in similar context to discussion of stem cell research and limits to genetic research. On the legislative status of human cloning one person said, "Human cloning is totally prohibited." Another person also said, "Nothing could be done related to human cloning. Whether it is nuclear transfer technology used for cloning embryos and then use them for stem cell research or other biotechnologies." Different reasons not to clone humans were given, one person said, "If the technology itself is not perfected, we will not like to venture in it." It may also not be acceptable in the society as another person said, "Human cloning in India for instance will an not be accepted by anyone because of a religious and social customs." One person gave a unique reason for cloning of humans will not be possible, even if allowed. He said, "Even if we allow to clone human beings, nobody will do it. Somebody may clone out of curiosity or craze because to manufacture human beings by traditional way is much easier and cheaper than to clone human beings. If I want to have some business in human beings, I can produce by conventional methods, there is no problem. It is technologically easier, economically cheaper, simpler and less risky. So if somebody's out to exploit human beings for some immoral purpose, he can do even today. In India people produce children like cats and dogs. By the time they're 10 to 12 years old, family has additional hands to work. Is it not contrary to human dignity? So human cloning is an art, which will not be primarily used for producing human beings even if we allow it, because there is another methodology, which is cheaper available. So I'm not able to understand all the fuss about human cloning. In that process a lot of therapeutic promises have been killed." Human cloning for therapeutic purposes is also not allowed, as one person informed, "It is a related question. If you talk to scientists they would say it should be allowed for therapeutic purposes. But by and large we feel no. We will not allow for that. Human cloning for therapeutic purposes will not be allowed and we have it in our ethical policy on research on human genetics." One person challenged the moral identity of clones. He asked, "Human beings are manufactured in billions through out the world. What is the dignity they are enjoying that we need to produce more?"

4.4.7 In Vitro Fertilization (IVF)

In vitro fertilization (IVF) has been commonly used for more than a decade in India. IVF clinics are commercially successful for different reasons. One person said, "IVF

technology has been becoming seemingly affordable for people, also IVF clinics are very well commercialized for other purposes like abortion, they have high rates of patients because such things are not possible in government hospitals." Stem cell research is very positively and actively taken in the country because of IVF clinics. One person said, "So the fear is that since we have the chances of having a lot of embryos because of IVF clinics, there is going to be great clamor of exporting embryos to get money. So we are putting a ban on exporting embryos and at the same time we will not allow research without any appropriate mechanism." A proper regulatory mechanism is essential, as some persons agreed, "Because of IVF clinics we have lot of spare embryos and we also know even if you have a regulation to stop it, it is not going to stop and it will definitely continue. So it has been decided by the government that it will allow stem cell research to continue, but with certain conditions." Another person said, "We have spare embryos available from IVF clinics. If someone wants to do and unethical practice and wants to earn something out of it, can commercialize it. How are you going to regulate this? It is a big issue and we have been asking Ministry of Health and family welfare to be more vigilant on it and see what can be done. It is very difficult to dig upon this issue."

There are guidelines for IVF clinics, as one person said, "In assisted reproductive technologies also we gave guidelines but they are more applicable to practitioners doing IVF; but it is the smallest chapter in the book. Now we have made separate guidelines for accreditation of IVF clinics, which has more of service components." On the monitoring · of stem cell research and linkages with IVF clinics, another person said, "There will be a national apex body which will monitor these studies. All centers that are doing such kind of IVF studies should be accredited." However, there are always fears of misuse of aborted fetuses, one interviewee said, "Common people will suffer the most, emotionally because they will lose their children and their fetus could be traded." There is also lack of skilled professionals, as one person worried, " I agree we have IVF clinics so we have lot of foetal tissue available for research. But there are only a few people available for doing research in foetal tissue transplantation."

4.4.8 Funding

For poor countries the main obstacle to carrying out research is a lack of finance. As one person said, "That is the issue faced by developing countries that you can't do what you want to do because of limitations of financial availability." Medical research requires

a lot of facilities, which are expensive but all are essential, which need to be balanced with other requirements of people, as one interviewee said, "We have crude infrastructure and a less technical support but the point is how much resources we put on their disposal." Limited funding is a hindrance to carry out good research. One policy maker said, "The main issue is availability of funds to do research. The environment you work in, should be cordial enough to do research. We lack in quality research because of limited funding. That's why many proficient people leave the country to work abroad. There is brain drain problem." Another person said, "We have lot of economic compulsions making us behind in research."

Research institutions have to find other resources to cover the expenses. One person said, " The government also supports with some small money, we try to get support from overseas or international organisations." The government has allocated funds especially in genomics, as one person said, "DBT has put a lot of money for this. Lot of money is available and some good work is going on there is no question about it. Jawaharlal Nehru University, Saha Institute in Calcutta, CCMB in Hyderabad and in Delhi also many institutes are involved. But it is much less than when compared to the west. But the delivery of results is not that much, it is a very slow, the outcome is a very less." Proper allocation of funds with good project design is necessary to produce good results, one person agreed "Personally I feel that finance is not the constraint. DBT has put up a lot of money. Although they say that there are lot of bureaucratic hassles in getting money. First is approval and then it takes months together to release the funds." Another person agreed, "We cannot always argue that we do not get funding, funding is available and there are big donations for the projects that are rational, technically applicable and properly deigned; we should look at our limitations of lack of skills to design internationally acceptable projects. But we fail to satisfy donors. We must accept this limitation." Even at a higher level, there are limited funds, as one person said, "A lot of post doctoral studies that are going on and other departmental research is done with very less money, and they don't take ethics committee's clearance because of small funding." Another person said, "We do a lot of research at small level because of small sponsorships and funding, which is sometimes worrying because it becomes a raw information for many of the multinationals and other big research institutes, and they gain a lot by saving time and money on collecting raw data."

4.4.9 Multi National Corporations (MNCs)

Multinational companies wish to extend their roots in developing countries to develop their business in a variety of areas. Especially for life sciences companies, developing countries are attractive. One person said, "It is not surprising that MNCs are very much interested in India, because we have a perfect environment for testing their products." Some people worried about the number of companies, as one person said, "It is a very big debate that is going on within country. How to control them and we accept that we are more receptive to this. Especially in some of the areas which I call high sciences or science intensive area." There needs to be proper controlling mechanism in the country for participation from MNCs, as one person said, "If an MNC offers a drug for testing in hospital, we don't have any law." Patenting of drugs by multinational corporations is also a concern for domestic companies who produce cheap drugs. One person said, "If you see MNCs part, they are not marketing the drugs by generic names, they are marketing by brand names. Quite often they come out with combinations. All kinds of irrational combinations are done. In the name of those combinations they say how can we market with the generic name because there are many ingredients. So if the ban them saying you can't manufacture or market them, we'll lose those drugs. Whatever we are getting we will not get even that. So we would have to import everything and in that process the drugs will become more expensive. So we can't say you pack up and go. That is our of irony."

Brand name for drugs from MNCs are expensive and unaffordable for poor people in the country, and generic drugs are sold by local companies who provide them inside the country. However while most Indian drug companies export drugs to other developing countries, they do not have big markets in rich countries, as one person said, "MNCs charge too much for a drug, they make a lot of profits out of it. Same drug in India we can make at much cheaper rate. Marketing drugs in the West has become very expensive. Regulatory agencies, controlled trials, toxicity studies are very expensive. Some justification is there also but even then it if they recover all the money, still they don't reduce the prices." MNCs also try to influence research through big funding. One person said, "We always have a dilemma while sanctioning a project. Which to chose, you have a big name of international company and a local domestic company. It is difficult to decide as we need good funding and good projects but at the same time we need to make sure to give an opportunity for our own domestic companies."

4.4.10 Patents

Patents are commonly feared by poor countries because of are held by rich countries. One interviewee gave the reason as, "This will make poor poorer and rich richer even if it is supposed to be beneficial." Especially for countries producing cheap generic drugs the issue is important because of WTO decisions, as another interviewee said, "I know from January 2005 it is going to be every product under a patent and we have made everything aware to industry but the industry is moving very slow and they have found another ways as well." Developing countries fear the loss of markets for their drugs after 2005, as one person said, "We can't manufacture them either because even generic items are patented for 10 years. How to control? That is why I say compulsory licensing and parallel importing it may be answerable in few drugs that are being manufactured by in Indian companies and technically no harmful. But it cannot be a universal solution to the drug crisis. For that purpose I say that should have certain provisions by certain amendments." Local pharmaceutical companies face a tough challenge from MNCs. One person said, "There are few pharmaceutical companies trying to work very hard so that we have our own patents; we can develop our own drugs. For instance, to tie up with MNCs and have a production unit set up with in the country. Maybe then the drug available within the country would be cheaper compared with advanced countries." Another interviewee said, "India is also signatory to GATT. A lot of noise is there. People have objected to India being signatory to GATT because it is going to affect the local pharmaceutical industry."

Developing countries export generic drugs to many poor countries, including ones in breach of U.S / European/ Japanese patent laws. Export of drug in violation of patent laws will be difficult once TRIPS is into force, as another person said, "India is one of the leading countries for generic drugs. And the moment am not sure if we have taken any final stand of not. Patent issues are taken very seriously in India. India is next to China and Brazil, which has great capability of producing generic drugs. We produce quality drugs and supply it to economically weaker countries." People fear that drugs within the country might be unaffordable. As one person said, "We are worried if patents come into force, we have to buy our own things at much higher costs from outside." However, one person differed, "I don't think it will affect very much. People are afraid that costs may go up but as far as marketing area goes, recently WTO has agreed that the manufacturing drugs in your own country would be allowed at cheaper rates. Patent laws may not be that strictly enforced. But they will not allow these people to export them. Although I don't

301

have much knowledge about it, but I think the companies for opposing because it allows them to make it here only for your own country. I think they are justified but they want to export it to other developing countries. Basically I think it will not have that much effect. Now the period of patent has also come down."

4.4.11 Benefit sharing

India is a big country with lot of rich resources that could be harvested and shared, as one person said, "We have a vast potential of genomics research in India. We are very rich in diversity, we have a kind of racial affluence which is not available in many other countries. We are multi ethnic and multiracial society so there is an enormous scope for research in human genomics. That is our intrinsic ability." People are also enthusiastic about human genomics, but benefits need to be shared, as one higher official said, "One thing that we have dealt with is; supposing in population studies something is that come up which has IPR or patent issue comes up or patents leading to commercialization come up, at least 1 to 3% must go back to community for their welfare.80% is a waived for development."

On the issue of research using human subjects, one person said, "We are trying to look into privacy, confidentiality, benefits or other burdens that come up on the person. Also sharing of any benefits that arise after research. That also that also has been built up in our documents." Some people argued it being unethical. One person said, "There are cases of misuse of samples that are collected and used for genome analysis. I think it is very unethical on the part of researchers to make money out of those things and people do not even know for what purpose their blood was taken." The issue is not easy to resolve, as another person said, "Sharing of benefits that derive out of research is a complex issue. We have to look into various things like, community consent or individual consent, is it for a particular disease or for general information, then there are bureaucratic procedures, involved. So it takes time to design and implement things." Some people feared the roles of MNC in research, "Benefit sharing is more easier when it is public project, it becomes more complex, when you are collaborating with private sector, because usually their terms are difficult and not easily acceptable."

4.4.12 Ethics committees

The role of ethics committee has become more critical since the beginning of genome research, and developing countries are also learning to set up various ethics committees at national level. In India one person said, "We have a central ethics committee at ICMR, which is a national ethics committee, a kind of referral ethics committee. Any ethics committee that has any problems can refer their proposal to us and government of India's departments refer their proposals for ethical clearances to our committee." However, there is a lack of ethics committees at institutional level, as one person said, "But we can't say with 100 % guarantee that all the institutions have ethics committees. There are institutions that don't have ethics committees." There needs to be coordination between national and local committees. One person said, "We need a central accreditation mechanism so that all the centers that are doing such research should be accredited by the committee and should get approval for doing it." Some institutions do not make ethics committees because of limited funding for the projects. One person said, "Since many research institutes do very small projects, they do not think ethics committee approval is needed. The general trend is that only for big projects it is thought about, and big projects are a rare case." Also only if it is collaborated with private sector, as another person said, " They think that only if they have projects submitted via a funding agency, because the funding agency within the country or outside demands that you submit the ethics committee's approval, clearance only then you should have ethics committee's approval." All the information needs to be centralized under one system. One person said, "We are thinking to collect information on all the ethics committees of different institutions and analyze them; and trying to bring all the ethics committees together under one proper system." Mandatory guidelines are made for establishing ethics committees in India. One person informed, "It is going to be mandatory for all research institutions to have ethics committees and follow the guidelines." Another person also added, "But now when any drug is brought to FDA in U. S. or in India to DCGI, trials have to show whether it has been approved by ethics committee or not. They must have ethics committee's certificate." However, people need to be made aware of ethics committees. One person said, "People do not even know that we have medical ethics committees to which they can approach if some things come up. There is a very limited knowledge about it. We need to inform people about such things."

303

4.4.13 Legislations

Legislative policies are needed to carry out the research properly. One person said, "We lack medical legislations for most of the things, and it becomes a big problem when you have foreign collaborations." Another person gave an example, "Recently we had a problem in Kerala where anti-cancer drug was tested. We're not able to book them." On the research with human subjects, one person said, "ICMR has made guidelines for the research on human subjects, which is first guidelines made related to medical research in India. It is good effort, but still it is not sufficient in the case of any offence, we need laws more." Another person said, "There are many areas we don't have laws, like stem cell utilization, research on human subjects, assisted reproductive technologies, surrogacy." However, the Deputy Director General of ICMR informed, "We are going to legislate the whole of ethical guidelines and ICMR will be legislator." Another doctor said, "At present our actions are guided by ethics and responsibility rather than law. But ethics and responsibility quite often are not able to address the issues. I may be ethical but the others may not. So we need a law." One person gave the example of euthanasia, "Euthanasia depends how it is interpreted. If a terminally ill patient wants to die or his relatives asked to take out artificial ventilator, it is not an offense although I'm party to it. Offense comes when it is active euthanasia, I'm guilty of murder. Another situation is when a terminally ill patient tries to end his life but still he is not dead, he is charged with committing suicide. So active euthanasia conducted either by patient or by doctor is an offense. But to stop treatment or not to start treatment is not to an offense."

4.4.14 Clinical trials

Trials related to HIV have been controversial in many nations. About HIV trials in India one person informed, "Again going to vaccines, any vaccine you develop and gives one of very important immune responses known as CTI response. It is also correlated with HIV trials. Whatever the trials or studies that are being carried on till now have been based on subtype B or C, we are not so sure. That's why we are not permitting any trials to be done in India. Wherever subtype B has been done for example in Kenya or other countries like South Africa the C cell response has maximum been 38% or roughly 40%. So the 60% of people getting vaccines will never be protected. That itself is a big issue. Should we accept? What will happen to those 60%? Who will take care of those 60%? This is an issue that no one has been able to solve." Clinical trials involve the testing of drugs on

some patients, if it is effective, however some put the dilemma like, "Are we really going to provide drugs through out his life or we are going to provide drugs for limited period of time? It is an issue for which we have not yet taken any decision, it is very much alive issue." On the issue of placebo-controlled trials, one person said, "Wherever threatening diseases are concerned, it should not be. Supposing it is a drug trial been done for a disease where for a placebo it is not going to make much difference, probably there it can be done. There are substitutes for drug trials that can be done, but placebo as such cannot be done where you know that if you don't give a treatment it is going to harm the host or the patient." Another person on the use of clinical trials said, "Clinical trials are very much necessary for carrying out the research, it is not the problem with the procedure of the trials and testing; most of the time unethical work lies with administrative and bureaucratic procedures."

4.4.15 Informed consent

Consent from the participants needs to be taken for the trials as well as in the regular medical treatment. It sometimes become more critical in the clinical trials that involve collection and storage of the samples, as one person said, "Consent form is only for the primary purpose when one is using that sample or secondary purpose when one has to go back and get the permission. If they visualize that they would like to use it for secondary purpose, let it be built up at the time of collection of sample itself. After a couple of years if they want to use that sample again and, it becomes an unlinked sample. There is no record. Supposing they kept normal DNA samples and used it for secondary purpose and it is still there and if a new technology comes up in five years time and they would like to go back and use it; again they would have to go back to the original consent form and use an on-lend consent form. Then only it could be used." It is not only necessary for the large-scale studies but also for small-scale studies. The issue is both personal and communitarian, as another person said, "We expect in population studies that before consent form is taken individually, the investigator talks to the whole community as much as possible, explain to them about the study."

The subject of consent may be the family and not just the individual. One person said, " For example, stem cell research issues are very hot right at the moment. We have made it sure that consent form must be filled by couple and not by one partner. The question is

that it has to be in the language that person who is giving consent must understand the language barrier to there could be people who don't even know how to write or read. We are permitting that let their consent be recorded. We record statements on video or audio tapes. It should be good enough for an evidence of consent. There is total autonomy and no abuse or financial help etc. It is a total voluntary approach. Anyone who wants to be part of the team is welcome. We advice that sample which has been given by volunteers, if volunteers want the samples to be destroyed it should be destroyed, and if they want the data should be destroyed it should be destroyed. It is sort of check that we have kept on it." Another person said, "Informed consent is to be made into regular procedure, because of the legal complications that can follow if something happens to the patient, it is sort of a shield that can cover practitioners, when it is for complicated things."

4.4.16 People's participation

People participation is important to understand the attitudes of people and placing policies accordingly. However, it is critical issue for developing countries, given that people do not know about technology and government policies much. So they are hesitant to participate in the government matters. Even the professionals are not responsive and do not deliberate to participate, one person gave example, "In fact we had prepared the draft for ethical guidelines in 1988 January, it was sent to more than one thousand people for comments a, hardly 120 people replied. Of course it was from medical professionals. Following that we had a regional public debates in four regions of the country. We gave advertisements in the newspapers so that public can come and attend but unfortunately public participation is a very limited to except the journalists, who write on health and medical issues came. But real public participation was very less." Public participation is very less, as another person said, "Public thinks that these are all the issues of professionals which is something above their head." People do not know about things, especially research and trials; and that is one reason that they hesitate to participate. One person said, "Majority is not interested in it. They are just interested in their routine health care services. For them it is of not much interest. We need to create general awareness." One medical ethics, one person said, " Now because of so-called unethical trials or unethical studies which journalists report, people are coming to know that there is something called medical ethics. They can approach human rights organisations to ask for redressal." People do not about ethics committees. One person said, "Being such a big country, public awareness regarding such committees is a very limited." It is also a

question of governance, as one person said, "It is the ethics of governance, but they're bound to play a role. You can't sort out bioethics ignoring how ethics plays out in other areas. Finally public opinion and understanding will make the change." Education is necessary, as another person said, " We need to create awareness among people and the best way to create awareness is by education. Education will help them to know what is happening in the world."

4 .4.17 Most urgent ethical issues in medical research in India

The most important in medical research in India can be summarized as;

> Economic issues
> Reproductive technology
> Governance of medical research
> Patient autonomy

4.5 Governance of biotechnology in India

4.5.1 Issues in policy making in India

The overall results highlight some specific issues facing policy makers in India in the governance of biotechnology, both in food and agriculture, health care and medical care. They can be summarized as below.

4.5.1.1 Lack of knowledge (ignorance) and enthusiasm by the public.

The results show that there is very limited public participation in policy making in India. Ordinary public is not aware of what goes on at federal level. It is an important issue for a nation that is world's largest democracy. Participation from public should not be limited alone to electing future governments, but also in deciding the programs and policies that have implications for ordinary people.

4.5.1.2 Random information management.

Information is central to development. It is also an issue related to participation from ordinary people. If people are kept informed of the federal efforts, it would be a motivation for the people to learn and be responsive. Management of information, access and state of global information are crucial for carrying out the bureaucratic tasks and

scientific research. Science is progressing fast, and becoming a key component in deciding the directions for diplomatic relations between the countries. It is also important for economic and social development within the country. Information needs to be collected, analysed and stored under a proper system so that people and institutions can have access to it whenever needed.

4.5.1.3 Fragmentation in comparative research

Fragmentation in the research within the country can be overcome if the information is centralised and also institutionalised. Many institutions do similar type of research, but there is a lag in the flow of information between the institutes and also from institutes to government, which leads to fragmentation in comparative research. Central depositories to compile specific information for specific purposes save labour and costs.

4.5.1.4 Distrust of the government by NGOs and Consumer organisations.

There are several consumer organisations and a wide variety of civil society organisations (CSOs) in India, which work as a bridge between people and government. They also have an ethical responsibility to be informing people about the government's efforts, and their confidence in government is necessary to get the trust of ordinary people. Consumer organisations play most critical roles in making ordinary people accept and reject products introduced in the market. There concerns need to be taken into account while deciding market strategies and product availability for the consumers.

4.5.1.5 Lack of Institutional Ethics Committees

Lack of institutional ethics committees for granting permission for the trials was raised as an important concern in the interviews. Many hospitals and research institutions involved in clinical trials do not ethically review procedures. As medical research is progressing in the country, both in public and private sectors, institutional ethics committees are becoming a prerequisite in to carry out research, as they are allotted independent jurisdictions for approval of the projects. It is also required at the international level, and is essential when international collaborative research is undertaken.

4.5.1.6 Lack of a central accreditation system

Accountability of the research means it is acceptable only if it is accredited. There is no centralised accreditation system at federal level, although some national bodies like ICMR and DBT hold some authority to officially approve the standards for the institutions. However, for international standards, the government is still dependent on UN agencies like WHO, or the FDA of United States. It is an advantage for the private sector. There is a need for a central accreditation body that has procedures for certifying standards both for national and international standards.

4.5.1.7 Lack of legislative framework on sensitive issues

Lack of legislations is one of the most critical issues facing policy makers. If there is a legislative provision, government policies cannot shift, change or dilute easily and quickly. Sometimes laws are helpful to keep the system working smoothly. Fear of the judiciary also helps to avoid many unethical incidents, although all the dimensions need to be taken into account while legislating. In medicine, it is more serious issue where both the lives of healthy as well as unhealthy people are involved. Proper legislation is also important for international relations.

4.5.1.8 The gap between Rich and Poor

The gap between the Rich and Poor is not only an international concern, but also within the country it is very much exists. As discussed earlier, more than 35% of the Indian population lives under US$2 per day. However, there are people who are having access to all the luxuries, the upper crust is thin and below is the huge population under poverty. The middle class forms the largest group in the country; however rich and poor both need to be taken into account when drafting policies. Balancing rich and poor on the same level is an extremely difficult task given that rich form the main economic resource and poor people are the largest proportion in the country.

4.5.1.9 Cultural diversity

India is a secular country with many religions, 17 official languages and 25 different states with their own cultures and ethnicity. Balancing traditional sentiments, religious concerns and cultural values and community principles is challenging while framing policies at national level. Communitarian concerns need to be taken care of in a democratic system.

4.5.2 Governance of genetic engineering trials in India

Despite several hurdles, the government of India established a review procedure for GMOs trials in the country. India has 2 national level committees, namely the Review Committee on Genetic Modification (RCGM) and Genetic Engineering Approval Committee (GEAC) (See figure 23). The RCGM's main function is to examine experimental trials; i.e. initial GMO field trials under controlled conditions. The GEAC is responsible for large-scale commercial release of GM products. But specific ethical issues are not their mandate to look into. At the institutional level biosafety committees give the initial clearances for trials.
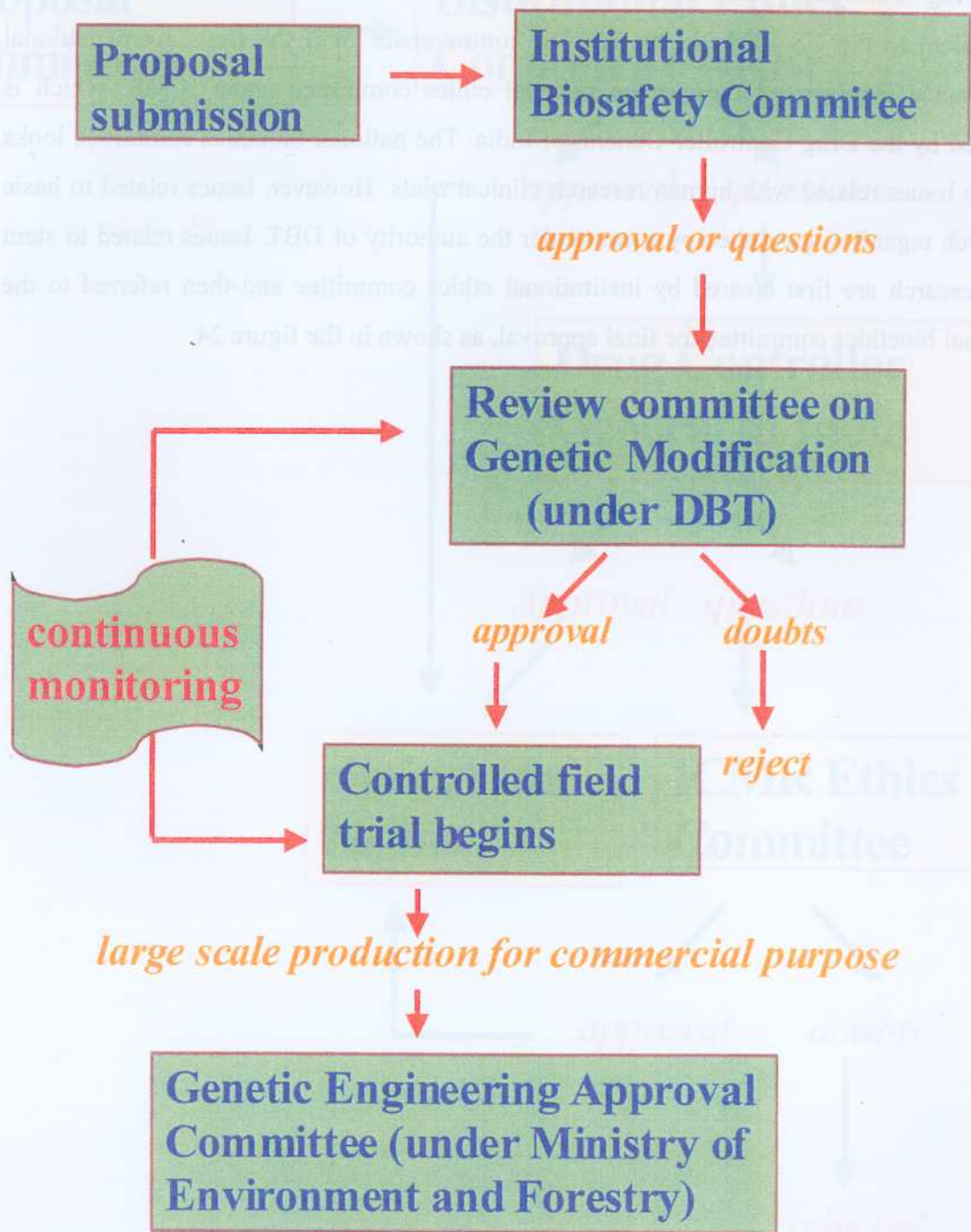
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┌─────────────────┐              ┌─────────────────────┐
│   Proposal      │   ─────►     │   Institutional     │
│   submission    │              │ Biosafety Commitee  │
└─────────────────┘              └─────────────────────┘
                                           │
                                           ▼
                                  *approval or questions*

                              ┌──────────────────────────┐
              ┌──────────────►│   Review committee on    │
              │               │   Genetic Modification   │
              │               │      (under DBT)         │
              │               └──────────────────────────┘
              │                    │              │
              │               *approval*       *doubts*
    ┌──────────────┐              │                │
    │  continuous  │              ▼                ▼
    │  monitoring  │         ┌──────────────┐   *reject*
    └──────────────┘         │ Controlled   │
              │              │ field        │
              └─────────────►│ trial begins │
                             └──────────────┘
                                    │
                                    ▼
              *large scale production for commercial purpose*
                                    │
                                    ▼
                   ┌──────────────────────────────────┐
                   │ Genetic Engineering Approval      │
                   │ Committee (under Ministry of      │
                   │ Environment and Forestry)         │
                   └──────────────────────────────────┘
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Figure 23: Schematic representation of the approval of the genetic engineering in India

4.5.3 Governance of clinical trials in India.

Approval for clinical trials in India is necessary for any kind of trial involving human beings. In India, an IEC (Institutional Ethics Committee), which is equivalent to what is called an Institutional Review Board (IRB) in many countries, approves all the projects involving human subjects. If the IEC has some questions, the proposal is forwarded to the Drug Controller General of India (DCGI) for clearance. DCGI is considered equivalent to the US FDA. In the case of controversies or if the trials are of national importance they are referred to the national ethics committee under ICMR, which is decided by the Drug Controller General of India. The national bioethics committee looks all the issues related with human research clinical trials. However, issues related to basic research regarding gene therapy come under the authority of DBT. Issues related to stem cell research are first cleared by institutional ethics committee and then referred to the national bioethics committee for final approval, as shown in the figure 24.

Proposal submission

Institutional Ethics Commitee (=IRB)

approval   *questions*

Drug Controller General of India

Approval   *questions*

clinical trial begins

ICMR Ethics Committee
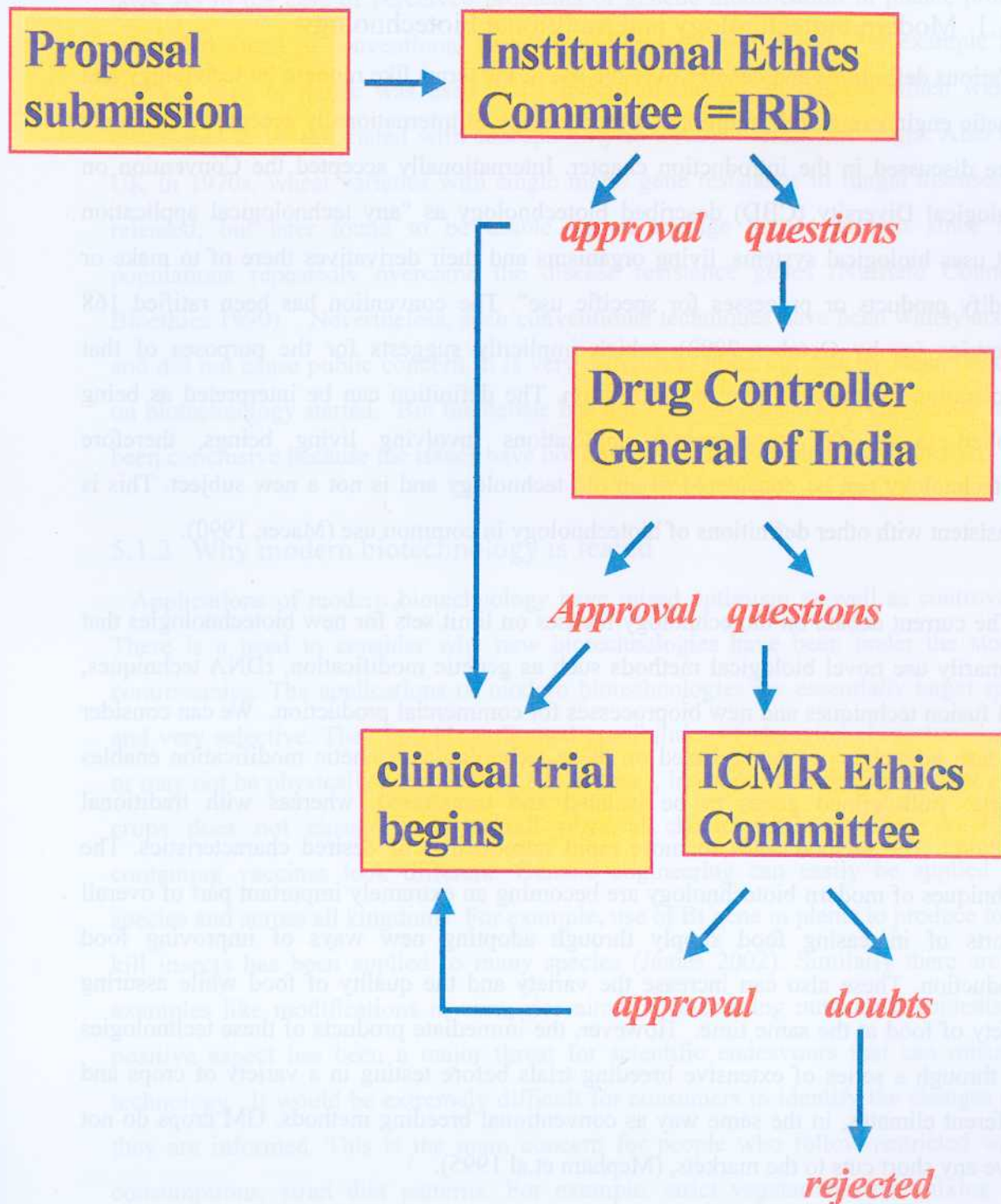
approval   *doubts*

rejected

Figure 24: Schematic representation of the approval of the clinical trials in India