The ethics and governance of stem cell clinical research in India

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Abstract

India is rapidly becoming established as a major player in the stem cell sector. However, concerns have been raised about the use of unproven stem cell therapies and the exploitation of parents for cord blood banking. This study aims to explore the nature of stem cell activities, how key stakeholders generate expectations around them and frame the ethical issues they raise, and why the biomedical governance system is unable to regulate these emerging practices. The study involved a survey, documentary analysis and qualitative interviews with key scientists, clinicians, representatives of firms and policymakers.

The thesis observes that, unlike international commentaries which largely focus on embryonic stem cell treatments, in India it is adult and cord blood stem cells which are dominant in research and clinical settings. Expectations are configured on the basis that stem cells have the potential to: solve the problem of organ shortage; help patients with ailments; provide affordable health care; and establish India as a global player. The creation of expectations is ethically problematic given the potential health risks and economic exploitation of both native and international patients. However, the ethically contested activities are justified by clinicians on the basis that the Helsinki Declaration allows to use an experimental therapy; there are many 'desperate patients' demanding these treatments; and adult stem cells are safe.

To date, the government of India appears to be unable to prevent these activities. Contrary to suggestions in previous literature and by some informants that new legislation is needed to address the problem, this thesis finds that state-led mechanisms for biomedical governance lack the ability to implement existing oversight measures. This implementation gap is partly because other forms of governance are not strong enough and partly because there are high expectations at state level aimed at establishing India as a global player in the stem cell sector.

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Contents

Chapter 1: Introduction

1.1 Introduction

Stem cells are buildings blocks of life. These cells have the capacity to develop into any kind of cells, tissues and organs, which make them an important tool in health care and biotechnology. There is extensive investment in the field of stem cell research in several countries in anticipation of cures for various presently incurable diseases and contributions to understanding basic biology. In addition, most notably, there is excitement that stem cells will be able to boost the biotechnology and pharmaceutical industries in the future. It is seen as a novel form of biomedicine which brings both health as well as economic benefits.

Countries across the world have evolved their own programmes and policies to take early advantage from stem cells (Gottweis et al., 2009; UKSCI, 2005). The global stem cell market size for stem cell therapy is estimated to reach US $96 billion by 2015, and as a result stem cell research is becoming increasingly competitive (Tiwari and Desai, 2011). Research in the US, the UK, the European Union, Asia and Asia-Pacific regions is highly supported by both public and private players (Gottweis et al., 2009; Perrin, 2005; Sipp, 2009b, 2009c; UKSCI, 2005).

In this global context, India has emerged as one of the key players in the stem cell arena, having significant activities in stem cell basic research and therapy (Bharadwaj and Glasner, 2009; Greenwood et al., 2006; Lander et al., 2008;

Sharma, 2006, 2009). However, there is a widespread perception that clinical research and therapeutic applications of stem cells in India are not governed by international rules and regulations, or more specifically that they are not in accordance with 'standard' Western ethical norms (Pandya, 2008; Sipp, 2009a). The various clinics and companies in India have been accused of making false claims relating to a wide range of stem cell treatments and even, in some cases, fake declaration of approval from governing bodies (Pandya, 2008; Sipp, 2009a). At the same time, there is considerable ambiguity and uncertainty on the issues of regulating stem cell science and ethical standards at the international level, a situation which has been characterised as a 'bioethical vacuum' (Salter, 2007; Sleeboom-Faulkner and Patra, 2008). This 'bioethical vacuum' at the international level is mainly associated with the use of human embryos in research. It was visualised that some countries have strict regulations while some have moderate ones, and in others there is no regulation at all. For instance, the policy of the UK appears to be more liberal than other European countries such as Germany and Italy (Gottweis et al., 2009). The governance mechanisms at the international level in dealing with stem cell research are therefore categorised as a 'patchwork of patchworks' (Caulfield et al., 2009).

It has been argued that India has benefitted from this vacuum for an early advantage in the area of stem cells in the guise of experimental therapy (Sleeboom-Faulkner and Patra, 2008). Various clinics in India have been able to persuade foreign as well as domestic patients to cross their respective geo-

political, commercial, ethical and moral borders for their 'novel' stem cell-based therapies (Bharadwaj and Glasner, 2009), a phenomenon alternately described in the popular media as "stem cell tourism" (MacReady, 2009) and in the academic literature, as "bio-crossings" (Bharadwaj and Glasner, 2009). In any case, such "bio-crossings" are creating growing international concerns about unproven therapies which have placed patients at health and financial risk (MacReady, 2009; Nelson, 2008a).

The international commentary has expressed concerns mainly on the use of embryonic stem cells by a New Delhi-based clinician, Dr Geeta Shroff (Basu, 2005; Bharadwaj and Glasner, 2009; Cohen and Cohen, 2010; Glasner, 2009; Khullar, 2009; Padma, 2006; Ramesh, 2005; Salter, 2008; Srinivasan, 2006). However, the use of adult stem cell in clinics also raises various concerns; for example, Life Line Hospital in Chennai has claimed that an injection of stem cells can help "improve nerve function" following spinal cord injury, yet there is no clinical evidence that this is yet possible. L.V. Prasad Eye Institute, Hyderabad has been working on corneal regeneration using stem cells for the last seven years, but was recently criticised for the transplantation procedure used by an international team of ophthalmologists (Schwab et al., 2006).

Furthermore, there is also a growing market for the banking of cord blood in India, which is largely unregulated (Pandeya, 2009). This also raises many of the same ethical issues, with concern about the safety and claims made for the benefits of cord blood banking and regenerative therapies that might arise from them, none of which are proven at present (Eaton, 2006; Kaimal et

al., 2009). The risk of infection from cord blood transplantation is also a major concern (Agarwal, 2006). These issues have been the subject of considerable public debate.

In addition to concerns about the unethical use of unproven and potentially harmful stem cell therapies, there are also problems with obtaining informed consent and the existence of financial incentives to donate eggs and embryos in stem cell research. There is growing demand for oocytes worldwide where therapeutic cloning is permitted. The recent guidelines related to stem cell research permits therapeutic cloning in India and there is a strong possibility of a rapidly developing illegal oocytes market in the absence of legislation (Waldby, 2006). This has been highlighted in IVF clinics which are an important source of embryos for research. The procedure of obtaining informed consent in India is poorly enforced (Bhatt, 2004; Glasner, 2007; Mudur, 2001; Murthy and Subramanian, 2007; Srinivasan, 2005) and India is viewed as an "embryo surplus nation" which supplies human gametes/hESCs material to Western countries (Bharadwaj, 2005; Bharadwaj and Glasner, 2009; Inhorn and Birenbaum-Carmeli, 2008). These are highly lucrative for some medical professionals and there has been resistance to regulation and monitoring (Salter et al., 2007). In some cases couples are offered free IVF in return for donating embryos for research (Salter and Waldby, 2007). As a result private IVF clinics have flourished without any regulation (Widge, 2002).

In recent years India has become a global centre for clinical trials (Maiti and M. Raghvendra, 2007; Sirinvasan, 2009; Sunder Rajan, 2006), but this has not been matched by the development of ethical oversight, as there is still a lack of binding guidelines for biomedical research on human subjects. There is no law to prevent unethical trials, and the dismal state of institutional ethics committees is also a matter of great concern (Padma, 2005; Sunder Rajan, 2006; Tharyan and Ghersi, 2008; The Lancet, 2007).

In India, clinical trials are conducted through a regulated approach following guidelines laid down by the International Conference on Harmonization (ICH) and the World Health Organization (WHO) (ICMR, 2006; Maiti and M. Raghvendra, 2007). All clinical trials are subject to the approval of an ethics committee at an institutional level, but according to a survey conducted by the Indian Council of Medical Research (ICMR) these committees are not functioning well as they lack standard operation procedures and their composition is not in line with Good Clinical Practice (Bhatt, 2004). However, in principle, India is bound to ICH through amendments to Schedule Y of the Drugs & Cosmetics Act 2005. To strengthen the governance of clinical trials, India launched a Clinical Trials Registry in July 2007. However, it appears that it is also unable to streamline the procedure of clinical trials given the growing number of deaths of research participants during clinical trials (Cressey, 2012; Sinha, 2012).

The governance problems that plague IVF clinics and clinical trials have a direct link with stem cell governance, as IVF clinics are potential suppliers of

embryos for stem cell research and the legitimate application of stem cells in clinics requires clinical trials (Bharadwaj and Glasner, 2009; Lander et al., 2008; Slater et al., 2007).

Public medical research in India is funded by a number of agencies including the Department of Biotechnology (DBT) and the ICMR. In the case of stem cell research both the DBT and the ICMR, along with the Drug Controller General of India (DCGI), act as governing bodies. Both the DBT and the ICMR have been involved in the preparation of guidelines for the regulation of stem cell research, which play an important role in setting norms for research and governing the ethical conduct of investigators, but they have no statutory power to punish anyone for unethical conduct. A major issue highlighted in academic work on stem cells in India is that no single apex body exists for the governance of stem cell research and there have been institutional and bureaucratic disputes over jurisdiction. It is argued that the presence of so many agencies with an interest in this area has created confusion and demonstrates that India has no coherent national policy, leading to a perception that the development of stem cells in India is progressing in a regulatory vacuum (Bharadwaj and Glasner, 2009; Salter et al., 2007).

As far as the use of stem cell in clinics is concerned, it was observed that the governance mechanisms in this area have so far proved ineffective in preventing the rapid growth of clinical research programmes and clinics that make unproven claims of success using stem cells, but lack authorisation and supervision (Jayaraman, 2005). This has led to calls for more formal oversight

and statutory regulation for unproven stem cell-based therapies (The Times of India, 2008).

1.2 Rationale for the research

To summarise the problems described above, the clinical development and use of stem cell therapies in India including private cord blood banking appear to be currently proceeding in a largely unregulated fashion. Several examples have been cited in academic and media commentary of clinical activities proceeding without proper review and oversight, and clinics and hospitals offering unproven stem cell-based therapies to patients. In addition, despite slim chances of the use of cord blood for the self, various firms are attracting expectant parents to preserve their child's cord blood. These events are likely to exploit patients and expectant parents, and place them at health and financial risk.

How though do key stakeholders involved in stem cell research in India perceive these issues? How do they respond to the various criticisms and justify their work? Alternatively, are there significant differences *within* the stem cell community in India in terms of how stem cell research and the ethical issues it raises are framed? There is little published research on these questions. Secondly, how has the Indian government responded to the challenges around stem cells and the charge of experimental work proceeding unregulated? The problem of ensuring effective regulation is compromised by

statements from both the Health Secretary and the Director of the ICMR, who emphasise that there should be no bureaucratic hurdles in the way of scientific knowledge and it is the medical profession, rather than government, who should be left to ensure ethical conduct in relation to stem cell research (Pandya, 2008). However, signals are mixed in that the government has also recently revised their guidelines in a way that suggests the use of stem cells for therapy is to be discouraged. There is little work on how the complex Indian bureaucracy of biomedical governance works in practice and why this existing system has been unable to check ethically problematic stem cell practices. To date no study has addressed these vital issues comprehensively, which have global implications.

1.3 Previous studies

At a global level in the area of stem cells, developments in India sparked attention in late 2001 when two research laboratories were selected for National Institute of Health (US) funding to do further research work on their existing human embryonic stem cell lines. Most of the social science studies in this initial period focused on the regulatory framework in India dealing with human embryonic stem cell research which existed at the time (Knowles, 2004; McLaren, 2001; Walters, 2004). Later studies have analysed India's strengths and weaknesses in the stem cell area and its potential contribution to a promissory global stem cell bio-economy, along with the problem of

inadequate governance mechanisms in regulating stem cell clinicians (Jayaraman, 2005; Lander et al., 2009; Padma, 2006; Salter et al., 2007; Salter, 2008; Sharma, 2006, 2009). Some studies have analysed the complexities surrounding the proliferation of embryonic stem cell research and therapy, such as various social and cultural factors and linkages between IVF clinics and stem cell research (Bharadwaj and Glasner, 2009; Glasner, 2009; Gupta, 2011). The work of Aditya Bharadwaj and Peter Glasner could be cited as a comprehensive study especially related to embryonic stem cells in India. Recently, they published a book entitled, *Local Cells, Global Science; The rise of embryonic stem cell research in India*, which provides a more complex analysis of the nature of the stem cell governance framework in India against the background of India's distinctive configuration of politics, economy and culture (Bharadawj and Glasner, 2009). In addition, a few studies related to growing 'stem cell tourism' in different parts of the world have raised concerns about unregulated stem cell clinical activities in India (Cohen and Cohen, 2010).

Most of these studies have focused on the development of embryonic stem cell therapy in India and associated ethical and governance concerns related to its proliferation. In contrast, only a few studies have studied the proliferation of therapies based on adult stem cells (Patra and Sleeboom-Faulkner, 2010; Sleeboom-Faulkner and Patra, 2011). The proliferation of private cord blood banking in India has also not been paid much attention in previous studies.

These studies have observed that India has no laws to oversee various stem cell activities and that is why many clinicians are free to do whatever they want; they blame the incapacity of the DBT-ICMR guidelines for unregulated stem cell activities since these have no statutory power (Bharadwaj and Glasner, 2009; Cohen and Cohen, 2010; Glasner, 2009; Patra and Sleeboom-Faulkner, 2009, 2010; Sleeboom-Faulkner and Patra, 2011; Salter, 2008).

While acknowledging their valuable contribution in understanding the complexity of the stem cell sector in India, my study argues, however, that the observations of these studies are limited on certain accounts. For instance, they have not investigated the different modes of governance dealing with medical practices in India of which stem cell clinical activities are one part. In addition, although highlighting the high expectations of stem cells in India (Patra and Sleeboom-Faulkner, 2010), existing studies have not analysed the basis of these expectations from the perspectives of key players and their implications for ethics and governance.

This study will provide valuable evidence of the ethical issues raised by the clinical development and use of stem cells in India. In order to do so, it will map the main stem cell activities in India, and investigate how key players who are associated with the development of stem cells frame both the need for stem cell research (and, where relevant, therapy) and the ethical concerns they have raised. In addition, it will help in understanding the main problems with the existing stem cell governance framework. This will be of direct relevance to scientists, clinicians, companies, regulators and policymakers in

both India and other countries, given the new cross-national collaborative partnerships emerging in this area.

1.4 Framework for the research

The proliferation of biomedicine has attracted great attention from various disciplines of social sciences. It is very difficult to conceptualise the development of biomedicine in a single narrative. For some, it is a great invention of modern society which not only helps in alleviating various suffering of human beings but also is an area which has enormous potential to make a significant contribution in knowledge-based economy (Rose, 2006). However, at the same time, it is also visualised in terms of a failure to address infectious diseases such as AIDS, tuberculosis and tropical diseases with which the majority of the world population is afflicted (Rose, 2006). The argument here is that biomedicine has largely neglected the 'poor man's disease' (Rose, 2007). Others believe that the proliferation of biomedicine has resulted in the commodification of human organs and tissues (Waldby and Mitchell, 2006). Authors who have studied biomedicine using the concept of 'biopower' suggest that biomedical development is one of the ways to exercise social power on individuals and populations (Raman and Tutton, 2010; Rabinow and Rose, 2006; Rose, 2001). In doing so it has extended its jurisdiction from mere disease control to solving common life problems such as birth, menopause, baldness etc. These kinds of developments resulted in the corporatisation of

biomedicine, which is reflected by the heavy investment from nation-states and the private sector in biomedical ventures (Clark et al., 2003; Rose, 2006).

Over the years we have witnessed several innovations in biomedicine in the form of genomics, pharmacogenetics, regenerative medicine, xenotransplantation, gene therapy and the recent one in the form of stem cells. Sociologists argue that the rhetoric of constructing expectations has played an important role in the development of these novel forms of biomedicine (Brown and Michael, 2003; Hedgecoe and Martin, 2003; Martin et al., 2008a; Wainwright et al., 2008). Various studies in sociology of expectations observe that expectations discourse helps to attract various necessary resources and allies for any science and technological innovation. This analytical approach is useful for analysing the construction of expectations around a science and technological development in question and for examining the specific mechanisms through which expectations are configured.

Similarly, the concept of ethical boundary-work (Frith et al., 2011; Hobson-West, 2012; Wainwright et al., 2006a) provides an opportunity to analyse in depth how key players associated with particular ethically-contested areas of science and technology, have constructed boundaries between ethical/unethical or legitimate/illegitimate. In the case of growing stem cell activities in India, this concept is useful to understand how key players legitimise or, alternatively, critique ethically-contested activities.

The governance of stem cell activities in India has been previously examined by Bharadwaj and Glasner (2009), Patra and Sleeboom-Faulkner (2009, 2010), Salter et al. (2007), Salter (2008) and Sleeboom-Faulkner and Patra (2011). They have mainly focused on the mandates of the DBT-ICMR guidelines, which are in place to govern stem cell research and therapy. However, they have not looked at the overall biomedical governance dealing with research and medical practices in India and how it works in practice. Therefore, it is meaningful to analyse the different modes of biomedical governance under which stem cell flourishes in India, (or which might in theory be a possible mechanism for governance) and why they are not capable of implementing existing oversight mechanisms. In political science, Pierre and Peters (2000) have provided a framework to understand different modes of governance (i.e. governance as hierarchy, governance as networks, governance as markets and governance as communities). The framework developed by these authors is useful for analysing the whole range of institutions and relationships which could potentially be involved in the process of governing.

Against this backdrop of research framework, this study formulates the following research aims and questions.

1.5 Research aims and questions

The overall aim of this study is to analyse the nature of stem cell activities in India, how key players from science, clinical practice, private firms and

government justify or challenge the need for specific activities and frame the ethical issues they raise, and how arrangements to govern stem cell activities work in practice. This study has outlined four sub-aims to fulfil the overall aim.

1. To map the current development of stem cells in India in terms of basic research, clinical activities and cord blood banking.
2. To analyse the configuration of expectations around stem cells by different key players.
3. To examine how key players construct boundaries between ethically legitimate/illegitimate activities.
4. To investigate the potential for different modes of governance around stem cell research and its clinical practice, and their capacity in implementing existing oversight mechanisms.

1.6 Structure of the thesis

This chapter has highlighted that the unproven clinical applications of stem cells have raised major ethical issues including governance concerns and the research framework within which these issues will be investigated in this study.

Chapter 2 therefore discusses the sociology of medicine in general and India, in particular including the theoretical framework of sociology of expectations, ethical boundary-work and the analytical approach developed by Pierre and

Peters (2000) in political science to understand different modes of governance and policy implementation. In addition, this chapter also discusses scientific governance including stem cell governance at global level and the theoretical understandings of sociology of bioethics which is useful to investigate various ethical issues which are raised with the application of stem cells in clinics, such as informed consent.

The thesis is informed by the approach of Science and Technology Studies. Data collection and analysis are discussed in Chapter 3.

The overview of various stem cell activities is highlighted in Chapter 4. The rationale behind different activities of stem cells is examined in Chapter 5. That chapter explores the expectations discourse of key players, i.e. scientists, clinicians, the representative of firms, and policymakers.

Chapter 6 analyses the various ethical issues associated with the development of stem cells in India and the construction of ethical boundaries by key players. The different modes of governance in relation to stem cell research and therapy are examined in Chapter 7. That Chapter also analyses the problem with the existing governance mechanism.

Chapter 8 pulls together the empirical findings of the study and attempts to link ethics, expectations and governance including the policy implications of this study. In addition, that Chapter also highlights the strengths and weaknesses of the study and the avenues for future research.

Chapter 2: Literature Review

2.1 Introduction

Stem cell research is one of the major aspects of biomedical research, which is developing on a global basis with promises to treat various debilitating diseases (e.g. Parkinson's disease, Alzheimer's disease, retinal degeneration, muscular dystrophy, spinal cord injuries and diabetes mellitus, etc.) for which no effective treatment has yet been developed.

Stem cell as a novel form of biomedicine is filled with high expectations similar to other areas such as nanotechnology, personalised medicine, biobanking etc. However, the use of stem cells in research and therapy has been a matter of great dispute around the world and raises significant ethical, legal, social and economic issues; and consequently poses challenges to govern this emerging technology.

This study as highlighted in Chapter 1 aims to explore the nature of stem cell activities, how key stakeholders generate expectations around them and frame the ethical issues they raise, and why the biomedical governance system is unable to regulate these emerging practices. In order to fulfil this aim it is necessary to have an understanding of various issues associated with the development of stem cell. Simultaneously the sociological understanding of biomedicine, including India, is also warranted. This chapter therefore analyses the ethical, legal, social and economic issues associated with the proliferation of stem cells in section 2.2. The sociology of biomedicine in

general, and in India in particular, is discussed in sections 2.3 and 2.4 respectively. Section 2.4 also analysed the social science literature on stem cells in India. As highlighted in Chapter 1, this thesis also aims to analyse expectations rhetoric, ethical framing and existing governance regimes with respect to stem cells in India. This thesis therefore discusses the analytical approach related to expectations in section 2.5. Section 2.6 explores the understandings of sociology of bioethics. Similarly ethical boundary-work and governance is discussed in sections 2.7 and 2.8 respectively.

2.2 Stem cells and underlying issues

2.2.1 Scientific issues

Stem cells offer hope to understand basic biology and, most notably, in treating various debilitating diseases and abnormal conditions of the human body. However, there are many scientific challenges before stem cells materialise such hopes in practice (Corrigan et al., 2006; Hyun, 2006; Liddell and Wallace, 2005; Wilson, 2009). James Wilson[1] argues that:

> "Despite advances, our understanding of the biology of hESCs and iPS cells remains thin with regard to clinical safety and utility. Controlled incorporation of transplanted stem cells into host tissues and organs remains a major challenge. Questions

[1] James Wilson, who led the gene therapy clinical trial in 1999 during which the 18-year-old Jesse Gelsinger died, now warns stem cell scientists not to repeat that mistake. See Hayden (2009).

about engraftment, rejection, and toxicity abound. Steps involved in transformation of hESCs, iPS cells, or their derivatives into tumor cells (and strategies to ablate any tumors that might arise) need further investigation" (Wilson, 2009: 728).

The single stem cell lines can be used for many patients in stem cell therapy and there is risk for transmission of infection if that cell lines is infected (Braude et al., 2005). The premature use of stem cell therapies could potentially put patients at risk, similar to premature application of gene therapy (Martin, 2006; Wilson, 2009).

2.2.2 Ethical issues

The ethical debate in stem cell research is mainly associated with the sources of stem cells (Longstaff et al., 2009). Among the primary sources of human stem cells, i.e. the human embryo, umbilical cord, placenta, amniotic fluid, adult tissues and organs, the extraction of stem cells from the human embryo involves the on-going controversy about the moral status of human embryos and challenges to other fundamental values and beliefs (Hayes et al., 2006).

In the stem cell debate, one of the major controversies is whether the early embryos should be treated as a person. In order to derive embryonic stem cells, embryos must be destroyed around 5-7 days after fertilisation i.e. at blastocyst stage. This raise question of whether it is right to do so (Corrigan

et al., 2006). The controversy surrounds around the concept of respect for persons and it is argued that, a foetus should also be treated as a person similar to babies, children and adults (Corrigan 2006 et al., 2006). However, others believe that embryos have either no particular moral status or they have an intermediate status: "they are not the moral equivalents of infants, nor are they simply clumps of cells like any other tissue sample that can be used and discarded at will" (Fukuyama, 2005: 195).

The other matter of ethical concern is whether to use 'spare embryos' for research. The proponents of using embryos in stem cells argue that 'spare embryos' from IVF clinics could be used in research. They believe that there is nothing wrong with using those embryos which are not going to be implanted (Outka, 2002). This line of argument is accepted in some countries where the creation of an embryo for the sole purpose of research is prohibited. The creation of an embryo is regarded as immoral as it treats the embryo as a commodity in comparison to IVF embryos. The purpose in this case lies in having a child but, due to difficulties in implantation, this aim cannot be fulfilled naturally. These embryos are treated as 'spare' or 'surplus' embryos. However, the use of IVF embryos is not acceptable to many people on various religious and moral grounds. Opponents use the Kantian argument that persons must be treated as ends rather than as means (Darr et al., 2004). This suggests that a person's life cannot be sacrificed to accomplish some greater good (Darr et al., 2004).

Apart from philosophical debates about using embryos in research, there are apprehensions that embryos will be also used as a commodity similar to human organs and other tissues. In Science and Technology Studies (STS), various studies have shown the increasing linkages between biomedical advances and the market (Andrews and Nelkin, 2001; Rose, 2007; Sunder Rajan, 2006; Waldby and Mitchell, 2006). Human organs and tissues have been treated as commodities on a large scale in recent decades. However, the commercialisation of body parts is not a new phenomenon. It had already started during the Renaissance with the growing interest in anatomy (Andrews and Nelkin, 2001). The experiments in organ transplantation techniques in the 1960s accelerated the phenomenon further. Organ transplantation was based on the concept of 'a gift'. However, in reality it works under commercial interest; more specifically, organ transplantation at large is a blend of altruism and commerce (Scheper-Hughes, 2000; Waldby, 2002). Andrews and Nelkin stated that "body parts are extracted like a mineral, harvested like a crop, or mined like a resource. Tissue is procured – a term more commonly used for land, goods and prostitutes" (Andrews and Nelkin, 2001: 5). However, it could not resolve the ever-growing demand for organs and tissues in the wake of a more vulnerable ageing population worldwide, which forced the development of other alternatives. In recent years, the development of stem cell technologies is seen as one of the novel sources to fulfil the growing demand for organs and tissues (Waldby, 2002). This new source is different from the living donors as it is procured from the

early human life, i.e. the embryo, and results in a new form of 'tissue economy' (Waldby and Mitchell, 2006). "It shifts the source of tissue from a whole organ to a tiny collection of cells, and from an unarguably human person to an entity whose status regarding the human community is the subject of bitter contestation" (Waldby, 2002: 313). The 'spare' embryos, those produced during the IVF process, are viewed as a good source of stem cell technologies. However, it is also facing the same problem as organ donors, as availability of eggs is a matter of concern and in this direction a country like the UK has started an incentive to donate eggs for stem cell research. This step is viewed as a departure from the previous policy and a practice of altruistic donation (Roberts and Throsby, 2008). Drawing from Foucault's notion of 'bio-politics' it can be argued that this 'incentive' scheme is a new way of managing life in the name of well-being of the population (Rose, 2001), which further leads to commodification and commercialisation of body parts.

2.2.3 Legal issues

Legal issues in stem cell are basically related to the destruction of human embryos in conducting research and the use of human foetal tissues. It is very much linked to the ethical consensus in different countries and accordingly the legislation is formulated. The lack of ethical consensus has resulted in different regulations across the world, which has been described as a 'patchwork of patchworks' (Caulfield et al., 2009). In the US, most of the

states permit embryonic stem (ES) cell research that requires destruction of human embryos, but the federal law has prohibited such types of research. Only by 2009 did the federal government allow research on embryonic stem cells by using public funds (Nasaw, 2009). Some states in the US prohibit reproductive cloning but allow cloning for therapeutic purposes (Robertson, 2001; UKSCI, 2005). German law bans the embryo research and embryo cloning within states but allows the importation of stem cell lines derived from human embryos. Both the US and Germany were criticised for their double standards (Wang, 2006). In the UK, through The Human Fertilisation and Embryology Act 1990, it was made legal to conduct research on human embryos up to 14 days after fertilisation. Reproductive cloning in the UK is prohibited through the Human Reproductive Cloning Act 2002 (Wang, 2006). Australia allows ES stem cells by using surplus IVF embryos but bans therapeutic cloning. China is more focused on clinical application of stem cells than basic research. As for therapeutic cloning, production of human embryonic stem cell lines is legal. Different countries have different regulations (Gottweis et al., 2009).

2.2.4 Social and economic issues

The IVF clinics have emerged as one of the major sources for 'raw materials', i.e. surplus ova, embryos and oocytes, for stem cell research (Gupta, 2011; Waldby, 2008). There is a growing unregulated market in many countries (both in developed as well as in developing countries) for these reproductive

materials, which is considered to be exploitative for impoverished females. Females have become the 'reproductive labour' in the stem cell bio-economy. The procurement of oocytes is a painful process. It requires hyper-stimulation of the ovary followed by surgery (Dickenson, 2005). Waldby (2008: 21) argues that the whole procedure "involves pain, abdominal inflammation, possible renal failure and infertility, venous thrombo-embolism and cardiac instability." However, given the financial incentives, many young women and girls are attracted towards fertility clinics to 'harvest' their oocytes (Waldby, 2008). There is a strong possibility of economic exploitation of poor women across countries in the era of global bio-economy, against this backdrop (Dickenson, 2005).

Another key social issue associated with stem cell is that it will not be of benefit to the poor as it may be highly cost-intensive. In addition, there is the possibility that stem cell will significantly increase the average life span, which might have several social impacts. For instance, inter-generation family disputes and pension payments might increase considerably (Liddell and Wallace, 2005).

Despite various underlying issues highlighted above, in many countries stem cells are being used frequently in research and clinical settings. However, a few countries have banned the research using human embryos and its therapeutic applications given that it is considered as an immature therapy, except bone marrow adult stem cell transplantations. In countries like India and China, along with bone marrow stem cell transplantations, embryonic

stem cell, adult stem cells i.e. neural stem cell, cardiac stem cells, liver stem cells etc. are being used in the treatment of various diseases. Patients both domestic and internationally are flocking to these countries in the hope of curing their disease. Stem cell-based treatment is considered as a money-making endeavour rather than an effort to help patients.

Stem cell is a part of that biomedical enterprise which is highly complex. Biomedicine is analysed differently across different disciplines and between different authors. The next section has attempted to pull together various understandings of biomedical development, which is helpful in understanding the contextual development of stem cell.

2.3 Sociology of biomedicine

The development of biomedicine is shaped by different actors, i.e. the state, industry, scientists, society etc. (Baronov, 2008; Bellett, 1992; Clark et al., 2003; Conrad, 1992; Singer, 1992). It is viewed as a human social construct which involves choices about how to spend time, energy and resources (Bellett, 1992: 364). Biomedical science is now more under the control of bureaucracies and private corporations than its own norms (Bellet, 1992), as given by the fact that there are different rules and regulations in different countries to regulate the same form of science worldwide.

The emergence of biomedicine was viewed differently by different sections of society. For some, it generates great hope in curing diseases and afflictions,

while others warn of the dangers of treating human life as an object, for example, by using human embryos in fertility treatments and research. Many politicians, academicians, corporations and private investors are of the view that it results in a new and highly lucrative bio-economy; on the other hand there are apprehensions that this affects the development of basic sciences because of profit-oriented services. The focus of biomedicine is more on 'elite' disease rather than 'poor' disease (Rose, 2007). In this way it serves only the interests of the dominant class of society (Singer, 1992).

Bellett (1992: 364) has narrowed down the debate about biomedicine into two 'voices' and stated that: a) it is characterised by having a strongly hierarchical culture of managerial interventionists with instrumental values and a competitive market model of society that wants to convert all research into a centrally controlled and efficient producer of marketable products and b) it is used as an agent of social control. Thus biomedicine has brought so many complexities and tensions between science, market and society.

Given the complex nature of biomedicine, Baronov (2008) has attempted to analyse its development ontologically. This study has shown that, as an institution, biomedicine was shaped by a distinctive arrangement of scientific-material, symbolic-cultural, and social factors. Thus the emergence of biomedicine is manifold: (a) biomedicine as a scientific enterprise; (b) biomedicine as a symbolic-cultural expression; and (c) biomedicine as an expression of social power.

2.3.1 Biomedicine as a scientific enterprise

The post-war period (1945-1975) was seen as the emergence of biomedicine. It was claimed that, "since World War II, biology and medicine have come together, both institutionally and intellectually, in a hybrid practice that is neither syncretic nor synthetic" (Keating and Cambrosio, 2003: 1). During this period, the transformation of biology and medicine took place in the contextual development of physiology and bacteriology. This development became an important resource for the organization, diagnosis, and treatment of human disease and established linkages among laboratories, hospitals, and dispensaries including public health organisations. As a result, modern, professional medicine, i.e. biomedicine, was 'invented' (Quirke and Gaudilliere, 2008).

The 'invention' of biomedicine brought about significant changes in the medical system, including the conduct of research and governance of medicine. Specifically, the changes could be seen in the form of heavy investment in research, fundamentally increased level of inquiry in biology and medicine and a strong linkage between laboratories and clinics. The post-war period was described as a new "way of knowing" in terms of biomedicine, where a new system of relations developed between science-technology (biology) and medicine (Keating and Cambrosio, 2003; Quirke and Gaudilliere, 2008).

The 1960s was viewed as a turning point for biomedicine as patient expectations and demands for new medical procedures and drugs increased.

This led to the development of various diagnostic instruments, along with new ways of diagnosing disease and method of drug discovery. The invention of new scientific methods (empirical and experimental) facilitated further 'advancement' and the establishment of biomedicine in society. According to David Baronov, biomedicine has introduced radical new ways of thinking and knowing. Firstly, it brought a seismic shift in attitudes from a traditional reliance on "God's will" with the development of controlling power over nature and, secondly, new epistemological developments associated with empiricism and rationalism (Baronov, 2008). As a result, significant advancement in medical knowledge took place.

It is argued that institutionally, biomedicine is being reorganised not only from the top down or the bottom up but from the inside out (Clark et al., 2003). This institutionalisation is taking place through the development of institutional infrastructures (i.e. technical, informational, organisational etc.) through the combination of computer and information technologies (Clark et al., 2003). Clark et al. (2003), in their study related to the proliferation of biomedicine in the US, have observed that from 1890 to 1945 was the period of transformation within American medicine. This period witnessed not only the professionalisation and specialisation "of medicine and nursing, but also the creation of allied health professions, new medico-scientific, technological, and pharmaceutical interventions, and the elaboration of new social forms" (Clark et al., 2003: 164). After World War II, a massive increase of investment could be seen in both the public and the private sectors. The production of

medical knowledge and intervention of goods and services has expanded rapidly. Contemporary biomedicine sector in the US is a multi-billion-dollar industry (Baronov, 2008). In the last 50 years, the US health sector has increased from 4% to 13% of GNP, and it is projected to exceed 20% by 2040 (Clark et al., 2003). Similar kinds of development in biomedicine were seen in Britain and France after the Second World War; however, it was not at the level of the US (Quirke and Gaudilliere, 2008). Quirke and Gaudilliere (2008) stated that the development of biomedicine in the post-war era resulted in the shifting of state focus from public health concerns towards biomedical research. However, there were differences between the mode of expansion of biological and medical research in Britain and France; while the British built on an older and stronger tradition of university-based research, the French preferred a model of full-time research under the umbrella of government agencies (Quirke and Gaudilliere, 2008: 447).

After having been established in the US, Britain and France, biomedicine has started to expand in other parts of the globe, where it developed within different national contexts in the background of changing relationships between laboratories, clinics and public health establishments (Quirke and Gaudilliere, 2008). However, Quirke and Gaudilliere (2008: 251) argued that, "individual national patterns have had a relatively limited influence on biomedicine. The moral and political economy of the post-war period stimulated the rapid internationalization of biological research."

2.3.2 Biomedicine as a symbolic-cultural expression

The notion of biomedicine as a scientific enterprise has highlighted its universal claims that its principles and methods could be applied across different cross cultural settings (Baronov, 2008). However, Baronov (2008) and Lock and Gordon (1988) argue that it is very much a product of particular social and cultural conditions.

From the perspective of biomedicine as a scientific approach, all disease symptoms are categorised as universal in nature and applicable to all in the same way across the society. Nonetheless, the social constructionist approach challenges the notion of disease as culture-free (Baronov, 2008). King (1954: quoted in Baronov, 2008) stated that, "diseases are not things in the same sense as rocks, or trees, or rivers. Disease represents patterns or relationships, which are not material. The problem then becomes, how real is a pattern, what is the ontological status of a relationship?" (p.199).

Thus it can be argued that disease is not a universal phenomenon across society and it varies with respect to time and space. This approach questions the universal pattern of diagnosis and treatment of disease (Brown, 1995). Payer (1988: quoted in Baronov, 2008: 243) asserted that, "the same clinical signs may even receive different diagnoses. Often, all one must do to acquire a disease is to enter a country where that disease is recognized – leaving will either cure the malady or turn it into something else."

Symbolic- cultural framework analyses biomedicine in a particular social context and refutes the notion of biomedicine as objective, dispassionate,

rational, and professional. It was viewed that biomedicine emerged in Western Europe and North America and at a unique time under particular social and cultural settings (Baronov 2008: 243). It emerged in Europe and spread to North America. Actually biomedicine was a cultural invention of nineteenth-century Europe, and now it has permeated across the globe (Geest and Finkler, 2004). The post-war period has witnessed the rapid transformation of scientists and medical professionals into business men, resulting in power struggles between them (Baronov 2008; Light and Levine 1998; Nye 2003).

2.3.3 Biomedicine as an expression of social power

From this conceptual perspective, biomedicine is seen as "an expression of social power that reflects structures of power and privilege within capitalist society" (Baronov, 2008: 235). The last quarter of the twentieth century has seen the different ways in which medicine and knowledge of illness came to be localised upon the individual body to exercise power. Michel Foucault in his book *The Birth of the Clinic: An Archaeology of Medical Perception* (1973) described the reshaping of medicine at the start of the nineteenth century through the interconnections of changes along a number of dimensions (Foucault, 1973). These changes include "laws and practices of assistance, shifts in the organization of medical professions and medical pedagogy, new forms of record-keeping in hospitals allowing the production of various

statistics related with morbidity and mortality, pathological anatomy and post mortem dissection and so forth" (Rose, 2007: 10).

Medicine went beyond mere treatment and curing of diseases to the management of diseases, the administration of reproduction and the maintenance and optimisation of the body. The maintenance of the healthy body became a major concern for many individuals and families. This resulted in the employment of practices such as dietetics and exercise coupled with increasing consumption of proprietary medicine and health supplements (Rose, 2007).

The extension of medical authority in this way has been seen as 'medicalization' of social problems (Clark et al., 2003). The term is defined as the process through which certain events or characteristics of everyday life become medical problems and come within the jurisdiction of medicine. Medicalization is a "process whereby more and more of everyday life has come under medical dominion, influence and supervision" (Conrad, 1992: 210). For example, fertility, birth, pregnancy, and menopause, which are normal and natural process of human life, are now being regarded as conditions of illness or disease (Peerson, 1995). It is stated that medicalization is one of the most forceful social alterations of the last half of the twentieth century (Clark et al., 2003; McLellan, 2007). Since 1985, striking changes in both the organisation and practices of modern biomedicine have been put into practice through the integration of techno-scientific innovation; Clark et al. (2003) termed this 'biomedicalization'.

Clark et al. (2003: 166) argue that biomedicalization is co-constituted through five overlapping processes: (a) major political economic shifts; (b) a new focus on health and risk and surveillance biomedicine; (c) the technoscientization of biomedicine; (d) transformation of the production, distribution, and consumption of biomedical knowledge; and (e) transformations of bodies and identities.

Biomedicalization is marked by the concentrated corporate power in the form of privatisation of research, university/industry collaborations and commodification of research. Medicine has become technomedicine, highly dependent on sophisticated diagnostic and therapeutic equipment (Clark et al., 2003; Rose, 2007). The expansion in biomedicine has resulted in a complex division of labour among specialists. Medical professionals have lost their monopoly of diagnosis and therapeutic calculation. They are/have become forced to depend upon pathological tests. Evidence-based medicine is said to have constrained the clinical judgement of the practising physician. The use of standardised, corporately framed diagnostic and prescribing procedures became essential for medicine and medical professionals. Medicine has been reshaped by its intense capitalisation. Intellectual property became a major factor for research in biotech companies and universities. Illness and health have become major fields for corporate activity. Thus, the human body has been opened up for technical innovation and economic exploitation (Rose, 2007).

Peerson (1995) argues that the individual body has become objectified in terms of localisation and configuration of disease. 'The clinical gaze' has become the important tool for measurement of human anatomy and physiological processes, both qualitatively as well as quantitatively. Biomedicine ignores the patient's subjectivity, i.e. her/his perception of illness and treatment is overlooked. There is more reliance on various medical tests (Peerson, 1995). The intensification of knowledge in biomedicine has resulted in a new power relationship between medicine and the human body. In the process of acquiring knowledge, medicine has gained importance and power over the human body (Peerson, 1995). It is evident by the fact of using the human body as 'a guinea pig' in the name of clinical trials, especially in the case of developing countries such as India (The Lancet, 2007).

The development of biomedicine in India is an interesting case to study since India is known as a place of various rich traditional systems of medicine, despite biomedicine being firmly established in contemporary India.

2.4 Sociology of biomedicine in India

In the beginning of the first millennium AD, there were three principal systems of medicine: a) Ayurveda, b) Greek, and c) Chinese. The basic principle of these systems of medicine is based on the relationship between man and nature. However, their explanations of the human body and disease are different in different medical systems. Of the three systems of medicine,

Ayurveda is viewed as a unique medicine system with a holistic approach both in terms of foundational ideas and therapeutic measures (Subbarayappa, 2001).

Ayurveda is considered as the principal system of medicine in India. However, the Siddha, the Unani and the folk medicines are also seen as a part of the Indian System of Medicine (ISM). Sometimes, even homeopathy is included to the list of ISM (Banerji, 1981; Khan, 2006; Subbarayappa, 2001); and later in the first half of the twentieth century biomedicine, i.e. a Western system of medicine, began to interact with ISM (Khan, 2006).

The co-existence of different multiple systems of medicine is viewed as a medical 'pluralism' (Minocha, 1980). However, it is argued that in the case of India there is need to go beyond the liberal pluralist predispositions and that one should consider the issues of power, domination and hegemony associated with the development of biomedicine in India (Frankenberg, 1981; Khan, 2006).

The history of Western medicine in India can be traced back to the early sixteenth century, when the first medical hospital was established by the Portuguese in Goa. Later, the British also established their first hospital in the mid-seventeenth century and a medical college in the mid-nineteenth century (Desai, 2007).

It is largely perceived that Western medicine in India evolved to address the medical needs of the military rather than local needs, and medical thought was dominated by environmental paradigm (Arnold, 2000; Desai, 2007). The

identification of the cholera bacterium (Koch 1843-1910), the discovery of the mode of malaria transmission (Ronald Ross 1857-1932), and the outbreak of the bubonic plague shifted the environmental paradigm towards germ theory in the late nineteenth century. Western medicine began to address various tropical diseases like anthrax, malaria, cholera and tuberculosis through medical services and research (Desai, 2007).

In India, however, these services and research were only confined to the "colonial enclaves" – the army, prisons, hospitals, civil stations, etc (Khan 2006: 2789). The development of biomedicine is perceived as a hegemonic weapon. Despite many revolutionary breakthroughs such as germ theory, the medical advancements did not reach the general medical professionals (whether European or Indian) (Arnold, 1996; Desai, 2007; Khan, 2006). Khan (2006) argued that, notwithstanding being a state-sponsored medical system, Western medicine never reached beyond metropolitan elites. The rest of the country had to rely solely on the indigenous system.

The situation changed a little by the late 1920s and 1930s as the idea of India getting independence had become fairly predominant (Khan, 1996). During the decades of the 1920s and 1930s the main nationalist body, the Indian National Congress (INC), became a strong force in the national politics. INC had performed well in the 1924 municipalities and district boards' election. In the 1937 provincial legislature's election, INC had attained a complete majority (Khan, 2006). In 1939 the legislative assembly of United Provinces (UP) has passed "The United Provinces Indian Medicine Bill, 1938". The goal

of the bill was to "modernize" the Indian system of medicine with the help of Western medicine. As a result, Western medicine became a top priority in the nationalist agenda. However, some sections of the society had perceived this bill as an attempt to ignore the indigenous system of medicine, i.e. Ayurveda and Unani (Khan, 2006).

After independence in the background of the Bhore Committee report (1946), the government of India expressed her firm commitment to establish Western medicine in the country (Srinivasan, 1995). While advocating the modern system of medicine once first prime minister of India, Jawaharlal Nehru said that:

> "The science of medicine would not be divided up into compartments but would be built upon solid foundations of past and present experience tested by modern scientific methods. The proper approach, therefore, should be that any system of medicine to be followed or encouraged must be modern and up-to-date and should take advantage of all the accumulated knowledge we possess" (Khan, 2006: 2,790).

Here the argument was to have a "modern" and "up-to-date medicine" system and to get government support; indigenous systems had to be "modern" and "up-to-date". It is pertinent to highlight that it was the Western medicine system which acted as the scale of measurement to test the modernity of the indigenous medicine system (Khan, 2006). Drawing on the notion of critical studies of science, medicine, knowledge and

development discourses, Khan (2006: 2,790) argued that "the whole logic of the 'uniform policy' based on 'modern scientific methods' was quite discriminatory to the indigenous systems, and it inevitably meant giving a dominant position to the system of allopath in policy formulation."

This approach was quite similar to the colonial government as they always insisted on scientific evidence on the matter of recognition to indigenous medicine (Jeffery, 1977; Khan, 2006). More explicitly in the name of scientific advances, indigenous medicine was always undermined.

It is worth mentioning that, during the same period (1920s-1940s) when INC was advocating Western medicine, the popular leader of the INC Mahatma Gandhi firmly stood for promoting the indigenous system of medicine (Srinivasan, 1995). However, at large, Gandhi was critical towards any type of medicine, especially biomedicine; Khan (2006: 2,793) argued that "his critique of biomedicine is much sharper and at a much higher grade" than the Ayurveda and Unani systems of medicine. Gandhi criticised the system of modern medicine or biomedicine in his book Hind Swaraj by stating that it increases more dependency on the doctors and undermines self-control; it weakens the mind. As he said:

> "I overeat, I have indigestion. I go to a doctor, he gives me medicine, I am cured. I overeat again, I take his pills again. Had I not taken the pills in the first instance, I would have suffered the punishments deserved by me and I would not have overeaten again. The doctor intervened and helped me to

> indulge myself. My body thereby certainly felt more at ease; but my mind became weakened. A continuance of a course of medicine must, therefore, result in loss of control over the mind" (Gandhi, 1938: 43).

Gandhi was also against the killing of animals for the medical research, as he stated that "... it is not necessary to take so many lives for the sake of our bodies" (Gandhi, 1938: 43). This argument of the most popular leader of India is very much important with respect to embryonic stem cell research in India where an attempt is being carried out to use human embryos for the sake of medical advancement (Basu, 2005).

Khan (2006) argued that the voice of dissent against Western medicine within the nationalist discourse was based on the fear that, in the name of scientific medicine, the hegemony of modern medicine will be established. The advocators of indigenous medicine were concerned for the better treatment of Indian medicine. The opposition to Western medicine, however, was never effective.

In independent India, science became an essential part of India's development, under the leadership of the first Prime Minister of India, Jawaharlal Nehru (Rao, 2008). He was a great supporter of biomedicine. Independent India has seen the establishment of several agencies to carry out medical research based on the model of biomedicine. The re-designation of the Indian Research Fund Association (IRFA), soon after independence, into the Indian Council of Medical Research (ICMR) in 1949 could be seen as a first

step in this direction. The IRFA was constituted in 1911 at the Plague Laboratory in Bombay under the chairmanship of Sir Harcourt Butler (Desai, 2007). Over the years, the ICMR played a major role in the development of modern medicine in India, including stem cells, being a principal advisory body to the Ministry of Health and Family Welfare.

It would be worth highlighting here that the Western medicine in India has a colonial root and its introduction in India was viewed as one of the efforts to strengthen colonial power similar to the development of railways, telegraphy, roads and bridges (Krishna, 2001; Kumar, 1995, 1997). It could not be simply seen as a diffusion of modern science from the central to the periphery (Baber, 2001); rather, biomedicine had also brought its underlying 'hegemonic' and 'exploitative' character in India, which was prevalent in the West (Arnold, 1993). However, there are some views that biomedicine in India did not achieve hegemony during the colonial period, though it was a dominant system of medicine (Kapila, 2010).

To sum up, it can be argued that the Western medicine during the British period only served a privileged section of the society. The question therefore, one may ask, what is the current situation of biomedicine in India, especially after the end of colonial rule? Is it still confined to the elite and privileged section of the society or has it become medicine for the common man? The answer to this question is directly linked to the stem cell proliferation.

2.4.1 Present status of biomedicine in India

Similar to the colonial period, the independent India also used science for its political dominance and justification for the Indian state (Nandy, 1988). Science was strongly driven by the Indian state in the beginning years of independence. Though the role of the state is still dominating in the promotion and proliferation of science in India, private players have also started making a significant contribution, especially after economic liberalisation since 1991.

The initial years, till the 1970s, were viewed as a happy period for science with the assumption that the future "belonged to those who made friends with science" (Visvanathan and Parmar, 2002: 2,714). Later it was realised that science is used as an instrument of dictatorship, especially during the period of emergency (1975-1977) when, in the name of population control, forced sterilisations were carried out. Similarly, due to various developmental projects, millions of people were displaced (Visvanathan and Parmar, 2002). These kinds of examples recall Ashis Nandy's argument, i.e. "in the name of science and development one can today demand enormous sacrifices from, and inflict immense sufferings on, the ordinary citizen" (Nandy, 1988: 1).

The biomedicine in India is also the part of the state-driven science project. The development of biomedicine is highly complex given the distinguished political economy of India. As a nation-state, India is characterised as an uneven innovator where more than one India exists (Bound, 2007). For instance, India is both an economic leader, where the annual growth rate is

impressive (average 7% even during global recession), and a country which has the world's largest population and number of people surviving on less than a dollar per day (Shastri, 2007). Nearly 70% of the Indian population live in its villages where the large sections of the population are deprived of basic health care facilities (The Asian Age, 2011). At the same time, in some urban areas there are world-class health care facilities, largely provided by the private sector, though these are only accessible to about one-third of the Indian population (Sengupta and Nundy, 2005). The health care system in India is full of contradictions; on the one hand there are state-of-the art medical facilities for the rich, and on the other hand access to basic health care for the poor is a distant dream. Similarly, modern medicine attracts great attention from the government of India, whereas the various issues of public health are largely neglected (Amrith, 2007). India fails to control infectious diseases such as tuberculosis, Japanese Encephalitis, diarrhoea and mosquito-borne diseases such as malaria and dengue fever. The government of India is comparatively more interested in areas such as genomics, nanotechnology, GM crops and stem cell research rather than public health.

The modern medicine is viewed as one of the causes of poverty in India. It is argued that the increasing costs of medical expenses push 40 million of the population to below the poverty line each year. At the moment, Indians are paying 80% of medical expenses from their own pocket (The Hindu, 2012). India has been unable to develop state-of-the art public hospitals which can provide affordable health care to millions, free of charge. The majority of

public sector hospitals are in the worst condition. There is always a shortage of medicine and unavailability of diagnostics tests in these hospitals. People are forced to go to private sector hospitals, despite allegations that private service providers of health care execute unnecessary pathological tests and surgical procedures (Sengupta and Nandy, 2005).

The public spending in the health sector as a proportion of GDP is only 1%, which is less than its neighbouring countries such as Sri Lanka (1.8%), China (2.3%) and Thailand (3.3), and far behind in comparison to the US and the UK (Planning Commission, 2012; The Financial Express, 2012). On the other hand the private spending on health is 4.2% of GDP (Nagarajan, 2010). There is a great reliance on private service providers, which accounts for nearly 80% of medical services in India. The recent report of the Planning Commission of India on health has expressed concern over the greater reliance on private service providers as it is beyond reach of the poor people. This report reflected that the public health care system in India has not only a shortage of adequate funding but also there is a problem with the existing health care governance system. It was stated in the report that the health care system has several structural problems. For example, there is a lack of integration between disease control and other programmes in the social sector, and the regulatory system related to drugs and medical practices is weak (Planning Commission, 2012).

Against this backdrop of political-economy of India in general and biomedicine in particular, stem cell research and its clinical activities

proliferate in India. In the next section, I critically examine how social scientists have begun to explore these developments.

2.4.2 Social science studies on stem cells in India

The proliferation of stem cell research in India has attracted attention at national and international level since the beginning of 2000s, as highlighted in Chapter 1. Given the controversies related to the use of human embryos in stem cell research worldwide, most of these studies have focused on similarities and differences in the regulatory framework adopted by different countries with embryonic stem cell research, with India as one of the case studies (Knowles, 2004; McLaren, 2001; Walters, 2004). The first major social scientific study looking specifically at stem cells in India was conducted by Brian Salter and his colleagues in 2007. They observed that India was yet to formulate strategies related to intellectual property rights, venture capitals, public-private partnership, and regulatory issues, with respect to the use of human embryos in stem cell research. Further, they highlighted problems and inadequacies in the governance regime dealing with IVF clinics which are a main source of raw materials for stem cell research as well as with the regulation of clinical trials. Since both IVF clinics and clinical trials have been linked with stem cell development, they argued that these aspects need to be addressed by the regulatory authority. They suggested that India needs to have appropriate governance mechanisms in three areas: a) the supply of oocytes and the use of human embryo in research; b) the conduct of human

embryonic stem cell research; and c) the clinical experimentation with stem cells. Brian Salter and his colleagues also highlighted the unapproved and unproven stem cell clinical practice of a controversial clinician, Dr Geeta Shroff. Overall, Salter et al. (2007) focused on the scientific strengths of India in general and stem cells in particular along with the limits of governance regimes existing at the time with respect to stem cells. They depicted that Indian stem cell research, including clinical practices in the country is proliferating in a governance vacuum since India has non-binding guidelines which have no statutory power.

However, they did not pay attention to the specificities of institutional arrangements in stem cell science in India. For instance, what is the main focus of various public and private players in stem cells such as research laboratory, firms, and hospitals? Second, it appears that this study was based on secondary sources, as they do not mention any field work in India. A later study conducted by Bryn Lander and her colleagues in 2008 attempted to fill this gap (Lander et al., 2008). They mapped the current state of stem cell research in India at the time and highlighted the various activities in stem cells at different research institutes, companies, hospitals and clinics. Lander et al. (2008) have argued that India has the capability to harness the potential of stem cells to address various chronic diseases from which a growing number of the population suffer, and observed that India can make a significant contribution to the emerging stem cell knowledge economy. The study also highlighted the lack of a robust stem cell regulatory framework in

India and expressed concern that there is considerable potential of exploitation of patients against the background of inflated expectations surrounding stem cells. However, finally, they concluded that, similar to impressive progress in information technologies and biotechnology, India could be an important contributor in stem cells, especially in its clinical applications. The study was based on interviews with key players working at research institutes, private companies, universities, hospitals and clinics including policymakers, bioethicists, intellectual property experts and science journalists. The interview study was supplemented with relevant policy documents, academic literature and bibliometrics analysis.

The findings of Lander et al. (2008) were important in the sense of understanding the overall status of stem cell research in India. However, they were also limited in certain respects. For example, though their research highlights the possible exploitation of patients in the context of high expectations associated with stem cells and poor regulations, it was unable to provide a more nuanced understanding of the rhetoric surrounding expectations and its ethical implications.

Both studies described above largely attempted to explore the overall status of stem cell research in India and highlighted the problem with the existing regulatory regime. They did not analyse in depth the interconnections between socio-cultural and economic factors and the proliferation of stem cell related research and therapy in India. This interconnection was examined by Bharadwaj and Glasner (2009). They conducted an ethnography study in

New Delhi and Mumbai to understand the rise of embryonic stem cell research in India and attempted to investigate how social and culture factors shape the proliferation of embryonic stem cell research and practice in India (Bharadwaj and Glasner, 2009). Their study showed a strong linkage between IVF clinics and embryonic stem cell research and they argued that the proliferation of embryonic stem cells in India is inextricably intertwined with IVF clinics, infertile couples, patients and a lax regulatory framework. The study was largely based on interviews with the same controversial clinician, Dr Geeta Shroff (whose claims regarding stem cell therapy became the subject of media coverage), and IVF experts, patients, donors and policymakers. In this study, the clinical services offered by Dr Shroff were portrayed both as a 'miracle', as in helping patients in their sufferings, as well as 'maverick', as her treatment modality is neither peer reviewed nor approved by regulatory authority. Though Bharadwaj and Glasner (2009) blame the powerlessness of existing stem cell guidelines and poor regulatory framework related to IVF clinics and clinical trials for unregulated proliferation of stem cell treatments in India, at the same time they argue that India is challenging Western dominance not only economically but both ethically and politically, since many foreign patients are travelling to India for an ethically-contested therapy which is not approved in the West. The phenomenon of overseas travel for stem cell therapy is termed 'stem cell tourism' and many studies have raised concerns about this growing

phenomenon in India, especially the unproven use of embryonic stem cells (Cohen and Cohen, 2010; Murdoch and Scott, 2010; Sipp, 2011).

Most of the studies highlighted above have focused on the therapeutic application of embryonic stem cells; they did not pay much attention to investigating the adult stem cell-based treatments in India. Only recently have Patra and Sleeboom-Faulkner (2009, 2010, 2011) analysed the proliferation of adult stem cells in clinical settings. Their work was based on an ethnography study, including participant observations, case studies and semi-structured interviews with stem cell researchers, clinicians and hospitals (both public and private), firms, policymakers, patients and their family members in locations such as New Delhi, Mumbai, Kolkata, Bangalore and Cuttack. Their main focus of research was to investigate how patients are being 'recruited' for an experimental therapy through a phenomenon termed 'bionetworking'. They conceptualise bionetworking as a network of key individuals from research and health organisations to 'recruit' patients strategically for unproven stem cell therapy. For instance, the majority of the patients are 'recruited' through false testimonials of 'cured' patients. Patra and Sleeboom-Faulkner (2009, 2010, 2011) stated that this bionetworking exploits the lax regulatory system for financial gain and put patients at health and financial risks. Similar to other studies, they also argued that unproven stem cell treatments proliferate in India because of the ineffective DBT-ICMR stem cell guidelines, as these guidelines have no statutory power to punish anyone in the case of transgression.

It is worth highlighting here that in both studies (Bharadwaj and Glasner, 2009; Patra and Sleeboom-Faulkner, 2009, 2010, 2011) data was collected by a native speaker unlike Lander et al. (2008). The richness of these studies (Bharadwaj and Glasner, 2009; Patra and Sleeboom-Faulkner, 2009, 2010, 2011) in terms of more in depth sociological analysis of stem cell developments in India compared to Lander et al. (2008) suggests that native competency plays a crucial role in qualitative research. Ganga and Scott (2006), while studying international migration in Nottingham (UK) and Paris (France)[2] have observed that, to a large extent, social proximity (similar ethnic, national, religious, linguistic and cultural heritage) between researchers and participants assists in data collection through interviews. This suggests the significance of native language skills and native understanding of the surrounding politics and culture in data collection, especially through qualitative interviews.

The existing studies on stem cell research in India have made a valuable contribution to understanding the proliferation of stem cell research and therapies in India. However, these studies have important limitations. First, though they highlight that patients are being attracted through the creation of hope and hype, and there is a high expectation of stem cells, these studies have not analysed the basis of hope and hype, or more specifically the generation of expectations. Second, these studies have not paid attention to

[2] Ganga and Scott (2006) have analysed "the case of an Italian researcher interviewing Italian migrants in Nottingham (UK) and a British researcher interviewing British migrant in Paris (France)".

analysing the ethical implications of expectations and how various key players justify or challenge stem cell activities in India. Furthermore, they do not analyse the ethical issues in great detail associated with those stem cell clinical services which are being offered by many clinicians such as Dr Shroff. More specifically, how do different actors comprehend these and other recent stem cell practices? Third, none of the studies described above have investigated the different modes of governance dealing with medical practices in India, of which stem cells are one part. Focusing on the limits of a specific set DBT-ICMR guidelines introduced to regulate stem cells, they neglect the relationship between stem cell medical and the wider governance regimes which are in place to govern general medical practitioners.

In Chapter 1, the growing activities around stem cells are highlighted and one of the aims of this thesis is to analyse the expectations discourse of key players in the background of various activities of stem cells. This can be studied through an analytical approach provided by the social studies of expectations. The next section critically analyses this approach in greater detail.

2.5 Sociology of expectations

In recent years, scholars in STS have begun to examine the significance and dynamics of expectations in the development of a particular science and technology regime (Brown and Michael, 2003). The sociology of expectations

shows- how visions of the future are used to mobilise resources and in the formation of socio-technical networks. Expectation studies in science and technology provide a valuable framework to study the rise and fall of a particular science and technology area and help in analysing its success and failure.

In sociology of expectations studies, since the late 1990s various studies in different areas of science and technology have been conducted with varied aims and objectives, most notably in the areas such as xenotransplantation and stem cells (Brown and Michael, 2003), pharmacogenetics (Hedgecoe and Martin, 2003), biobanking (Tutton, 2007), haematopoietic stem cell research (Martin et al., 2008a), cord blood banking (Brown and Kraft, 2006) regenerative medicine (Wainwright et al., 2008), and anti-aging medicine (Mykytyn, 2010). Most of these studies have investigated the articulation of hopes, visions and promises in shaping of the particular research areas or technology. For instance, the study of Brown and Kraft relating to the banking of cord blood stem cells elucidated that extensive advertisements directly to the expectant parents as a future investment for their child have helped in the establishment and proliferation of private cord blood banking firms over the years (Brown and Kraft, 2006).

Scholarship in sociology of expectations has argued that a strong vision in terms of potential capability of a particular technology is necessary to draw attention of the public, funders and policymakers for social and financial support and a favourable policy regime (Borup et al., 2006; Brown, 2003;

Martin et al., 2008b; Petersen, 2009). Furthermore, a 'future' is deliberately created to marshal resources and the support of different actors for the development of a particular techno-scientific venture and the direction of research especially for emerging technologies where actual products or services are yet to be manifested (Brown and Michael, 2003).

However, the 'creation of future' is not a simple or linear process; it is highly contested, since varied promises lead to contested claims and counterclaims with regard to potential of a given area of science and technology, both in technical and social aspects. During the whole exercise of creating a positive future, some claims get accepted while some get rejected. Brown and his colleagues in their study of *Contested Futures* seek to "understand how it is that some futures come to prevail others, why once seemingly certain futures happened to fail, how other futures are marginalised as a consequence of the dominant metaphors and motifs used in everyday life, and the consequences of particular framing of the future" (Brown et al., 2000: 4). The futures are mainly contested in terms of their time-frames (i.e. when will the desired futures be secured?) and varied interests of key actors. In addition, possible risks and uncertainties associated with a given technology also lead to contested futures. For instance, the translation of research findings from lab to clinic have always been a contentious issue in the area of biomedical research in relation to potential capability, safety and possible risks associated with a given technology. In the past, the case of gene therapy and stem cells presently can be a good example of contested futures (Martin,

2006; Wilson, 2009). Here, expectations play a vital role in diluting various contentious issues and in the alignment of various actors towards 'shared futures' (Martin et al., 2008a).

Analysing the 'translation' of haematopoietic stem cells (HSCs), Paul Martin and his colleagues develop the idea of 'communities of promise', which provides a useful framework to study how different actors are assembled in the background of high expectations for a particular technological development. This study illuminates how a particular 'imagination' has the capability to not only pull heterogeneous actors to work together but also it can attract new players in given science and technology ventures. For example, in the initial stages of HSCs' development, mainly scientists and clinicians were involved but later, with the identification of the CD34 marker, other players such as firms also enrolled themselves in HSCs' development as CD34-based HSC-separation promised to treat various haematological disorders (Martin et al., 2008a).

The studies have shown that expectations discourse is not only limited to attracting various resources and the alignment of various actors, in the form of 'hope' rhetoric, but it also helps in the generation of capital, even when there is no actual product. The proliferation of cord blood banking, especially those which are private in nature, appears to be a good example for the same. It is observed that "the creation of commercial cord blood banks...marks the capitalization of human tissues within a future-oriented 'regime of hope' (Martin et al., 2008b: 127). This development is viewed as a

shift from 'regime of truth' (proven evidence and established practice) to 'regime of hope' in present bio-economy, where hope itself becomes a marketable product, termed 'capitalization of hope' (Martin et al., 2008b). The interesting thing about this 'regime of hope', which has been observed by Paul Martin and his colleagues, is that, it is not geographically confined and it has a tendency to capture different countries and locations, which is conceptualised as a new 'geography of promises' (Martin et al., 2008b). Arguably, "this geography illustrates the spatiality of a regime of hope focused initially on the US and the UK, but with Asia and the near East closely following" (Martin et al., 2008b: 134). For instance, private blood banking had been established during the 1990s in the West (Brown and Kraft, 2008; Martin et al., 2008b) and has spread in countries such as in India in the beginning of the 2000s (Singh, 2009; The Hindu, 2001).

The majority of studies in the sociology of expectations discussed above have concentrated on Western settings and do not pay attention to the nature of expectations in different cross-cultural settings. In addition, these studies limit their analysis of expectation discourse at the level of specific actors, *viz.* only scientists, clinicians and entrepreneurs, and overlook the role of nation-states and governments in expectations rhetoric. Only a few studies have compared the nature of vision and hype in different cross-cultural settings, most notably the comparative study of *Biocapital* in the US and India (Sunder Rajan, 2006), which attempted to investigate the varied nature of expectations in these two countries. In the US it is largely the corporate sector

that engaged in the articulation of *vision and hype* while in the case of India it is the state itself, for the major part, playing a leading role in the creation of expectations. In India, the majority of biotechnology R&D is supported through government funded laboratories; therefore, it is quite natural for the Indian state to actively participate in expectations discourse. However, the study of Sunder Rajan illuminates a fundamental difference between the vision and hype of the US and India. The vision and hype in the former case is embedded in 'salvation' rhetoric, i.e. a particular biomedical research has the capability to 'save life'; while in the latter case it is dominated by 'nationalist' discourse where there is a desire to be a global player. Sunder Rajan (2006: 126) further argues that, in contrast to the US, "the speculative capitalism in India is far less developed in relation to manufacturing capitalism, which suggests that sales and profit, rather than the conjuration of futures, are likely to be the driving dynamic of the Indian biotech and pharmaceutical industries." More clearly this argument reflects that futures vision circulates in the generation of capitalism (speculative) in the US. Drawing on the observation of Paul Martin and his colleagues in the case of proliferation of cord blood banking (Martin et al., 2008b), it can be argued that the 'regime of truth' is dominant in India compared to the 'regime of hope'. However, the concept of 'geography of promises' reflects that this regime has now started to change. Similarly, Sunder Rajan (2006) also illustrated that, in the desire to go global, India has started to lean towards the speculative/hope regime, which is a more market-oriented approach. The above discussion informs us

that visionary promises need to be analysed at the nation-state level as well. Vision and hype as a 'nationalist discourse' might have serious implications for ethics and governance, as in the case of Indian stem cells it was often argued that, the Indian stem cells rush ahead in the background of weakened regulations (Padma, 2006).

The studies highlighted above largely investigate the role of positive expectations in the shaping of new technologies; for instance, how hope, hype, and promises are used as rhetoric to draw the attention of various necessary allies and marshal resources. In contrast to positive expectations, recently the role of pessimistic discourse has been analysed as another approach to sustain resources and to interact with various actors (Tutton, 2011). Richard Tutton highlights that "in addition to projecting optimistic scenarios, firms advance much more pessimistic images of futures that they wish to avoid: possible failures, disappointments and financial losses" (Tutton, 2011: 411). Examining the pessimistic projections in company filings to the US Securities and Exchange Commission, he observes that, along with positive visions and hopes, the narratives such as fears and uncertainties are playing an important role in future-making endeavours (Tutton, 2011). Similar to this study, while establishing the link between sociology of metaphors and sociology of expectations using avian flu as a case study, Nerlich and Halliday (2007) have argued that negative expectations can also play a performative role to draw attention and to mobilise actions and resources in certain directions. The study of Nerlich and Halliday conceptualises negative

expectations in terms of 'fear' and they attempted to highlight that negative expectations in the form of 'fear' force actors to take preventive actions against avian flu in the UK (Nerlich and Halliday, 2007). Therefore, it can be inferred that not only positive but negative expectations have a decisive role in shaping the direction and outcome of science and technology ventures.

Irrespective of whether the future is conceptualised in positive or negative terms and whether or not a particular vision materialises in practice, the key point is that narratives of expectations help to legitimize and 'sell' investments in the technology in question (Brown, 2003; Sunder Rajan, 2006; Tutton, 2011). The legal protection of 'forward looking statements' made by companies in the US reflects how visions are important for the contemporary biocapital regime. The Private Securities Litigation Reform Act 1995 of the US illustrated that "the issuers of such statements (usually corporate investors relations departments) are not liable in case of the failure to fulfil a promise or predictions made within the statement" (Sunder Rajan, 2006: 132). Given this protection to visionary statements, biotech companies sell their visions as actual tangible products (Sunder Rajan, 2006; Tutton, 2011).

While the literature on the sociology of expectations contains a number of important insights, from the standpoint of questions relating to the ethics of stem cell research, it is limited by its methodological orientation. So, the majority of studies focused on investigating questions such as: a) how is the future created in the present through various visionary statements?; b) who are the main actors involved in promising ventures?; c) how do different

actors in a given sector construct the future as per their institutional settings?; d) how are consumers configured in the mis-selling of particular visions? (Martin et al., 2008b). Indeed, it is implied that there is nothing particularly problematic in the 'business of expectations'. Expectations are seen as one of the essential components for a 'successful innovation' as expectations speak about the capacity of a technology in solving many existing problems (Mensink and Birrer, 2010). Mensink and Birrer (2010: 37) stated that, "If we were to only act when we are completely sure, there would be no innovation." A few studies in this field even highlight the role of bioethics in the creation and preservation of expectations (Hedgecoe and Martin, 2003; Hedgecoe, 2004; Hedgecoe, 2010). In sum, the majority of social studies of expectations confined themselves only at the level of analysing the role of expectations (the positive as well as the pessimistic approach) in the development of a technology (Brown, et al., 2000; Hedgecoe, 2004; Tutton, 2011). The growing literature in this area, does not address the ethical and social implications if a particular set of expectations fails to achieve the promised results. Yet, high expectations may result in the proliferation of immature and unproven applications of technologies and can have serious impacts on patients (Petersen, 2009, 2011). Moreover, in a situation when there is a legal protection to inflated promises in countries such as the US, the situation becomes more complicated. It can be argued therefore that there is a need to study the ethical and social implications of heightened expectations as well, which is largely overlooked in the social

studies of expectations (Petersen, 2009). In addition, if a state were involved in expectation rhetoric then it might affect implementation of existing regulations. This aspect is also not paid attention in the sociology of expectations.

In addition to analyse the expectations rhetoric of key players who are associated with the development of stem cells, the aim is also to investigate the construction of ethical boundaries of different key players and the raised ethical issues in the background of growing activities of stem cells and expectations attached with these activities. It would worth to examine previous work related to sociology of bioethics.

2.6 Sociology of bioethics

Bioethics emerged in the late 1960s to study the ethical problems in medical research and biomedical sciences. It evolved from the field of medical ethics when established principles failed to answer some of the emerging philosophical questions associated with the advancement of biomedical sciences (Bhardwaj and Macer, 2003; Sherwin, 2011). In recent years it has come to be viewed as a mechanism to protect vulnerable populations from exploitation in the course of being research subjects and to resolve wider social conflicts and ethical dilemmas which arise with new developments in the area of medicine (Salter and Jones, 2002).

Van Rensselaer Potter is credited with coining the term 'Bioethics' in 1971 in his book, *Bioethics: Bridge to the Future* (Reich, 1994). Potter characterised bioethics as "a new discipline that combines biological knowledge with a knowledge of human value systems ... I chose bio- to represent biological knowledge, the science of living systems; and I chose -ethics to represent knowledge of human value systems" (Potter 1975: 2297-2299; cf. 1971: 2 cited in Reich, 1994). The emergence and establishment of bioethics was coupled with the development of biomedicine and biotechnology. After the Second World War, significant changes in the conduct of research and governance of medicine took place with the increasing involvement of human subjects in medical research. This led to the formation of the Nuremberg Code[3] (1947) and the 1964 Helsinki Declaration to protect human participants in biomedical research following the abuses of the Nazi death camps. Further, the development of recombinant DNA technology in the early 1970s opened up the possibility of 'genetic manipulation' of plants and animals, including human beings. These developments raised major ethical and social issues. To address these issues, a series of discussions and academic programmes was started; as a result of these efforts, by the late 1970s bioethics had become firmly established as a discipline in the West (Engelhardt et al., 2009). Much Anglo-American bioethics is based on certain basic principles developed by

[3] The Nuremberg Code was formulated in Nuremberg, Germany after the judgment in a trial where 23 scientists and clinicians where accused of the killing and murder of human participants during the medical experiments in the concentration camps (Shuster, 1998).

Tom Beauchamp and James Childress in their book, *Principles of Biomedical Ethics* (2001), first published in 1979 (Petersen, 2011); so-called principlism.

2.6.1 Principles of bioethics

Within principlism there are four basic principles which can be used to help make moral decisions in health care practice: a) Autonomy; b) Beneficence; c) Nonmaleficence and d) Justice (Beauchamp and Childress, 2001). These principles primarily aim to protect patients from possible exploitation during biomedical research such as clinical trials and therapeutic interventions. *Autonomy* is based on the principle of 'respect for persons' and emphasises that patients/individuals should make their decision without any interference from outside while encountering any biomedical research or therapeutic interventions. *Beneficence* argues for the overall benefit of a patient by improving her/his quality or length of life. *Nonmaleficence* advocates that there should be no harm to a patient; and finally *Justice* addresses the equal distribution of health care services. Although these principles are viewed as essential guides to protect human subjects in biomedical research, there are various critiques on the grounds that they ignore important social, religious and cultural considerations while applying these principles and are dominated by a Western-centric approach, especially of the US (Petersen, 2011; Ryan, 2004). In addition, these principles themselves are subject to internal conflicts (Sutrop, 2011). For instance, there is always a confrontation on "whether respect for the autonomy of patients should have priority over professional

beneficence" (Wolpe, 1988: 45); more specifically, whether a patient knows better than a physician what is good for her/him.

Various studies within multiculturalism, feminism, disability rights, and sociology have highlighted the limitations of bioethics principles by offering more rigorous sociological studies of bioethics (Azetsop and Rennie, 2010; Fox and Swazey, 1984; Petersen, 2011; Ryan, 2004; Sherwin, 2008; Turner, 2003). In particular it has been argued that there is a gap between bioethical principles and 'lived experience' in clinical settings (Hegoecoe, 2004). In addition, it has been suggested that the principles of bioethics mainly deal with the decision-making process and doctor–patient relationship and they largely overlook the ethical implications of specific technologies (Petersen, 2011).

2.6.2 Social studies of bioethics

The main argument made by scholars working on the sociology of bioethics is that for bioethicists there is a need to understand the social contexts in which a particular ethical issue emerged.

The principle of autonomy has been given foremost importance amongst the four principles of bioethics in the majority of bioethical discourse and it is seen as one of the most important tools to protect human subjects and patients (Azetsop and Rennie, 2010; Corrigan, 2003; Helsinki Declaration, 2008). This principle advocates that individuals should have control over the decision-making process, as to whether to participate as a research subject or

allow any therapeutic interventions (Helsinki Declaration, 2008). Beauchamp and Childress state that "... the core idea of personal autonomy is an extension of political self-rule to self-governance by the individual: personal rule of the self while remaining free from both controlling interferences by others and personal limitations such as inadequate understanding, that prevent meaningful choice" (Beauchamp and Childress 1989: 68, quoted in Corrigan, 2003: 770).

This highly individual centric approach has been a matter of criticism worldwide since it ignores certain cultural, social and institutional environments which might have influence on the decision-making process of a particular individual (Corrigan, 2003; Kara, 2007). Azetsop and Rennie (2010) highlighted that various cultures, such as the Jewish, Confucian and African, perceived human beings not only as individuals but also the part of society to which it belongs. In Tonga, a South Pacific island, there was an opposition to a genetic database of the population on the basis that it has not taken the consent of the extended family (Burton, 2002; Corrigan, 2003). Similarly, in India, family and the largely patriarchal nature of the society have influenced medical decision making (Kumar, et al., 2012). Apart from socio-cultural factors, the economic status and the level of literacy also have an impact on the decision-making process, which is also not given proper attention while ensuring the principle of autonomy (Bhan et al., 2006; Dein and Bhui, 2005; Kumar, et al., 2012). It is argued that in India poor people

take part in clinical trials with ritual informed consent in order to avail free treatment (Srinivasan, 2009).

2.6.3 Autonomy and informed consent

'Respect for autonomy' is meant to be ensured through the mechanism of 'informed consent', which was established as a key principle in biomedical research and therapy after the Nuremberg Trials in 1946, popularly known as the Nuremberg Code. Subsequently, informed consent was given prime importance through international guidelines formulated by organisations such as the World Medical Association (Helsinki Declaration 1964) and the Council for International Organisations of Medical Sciences (CIOMS) (Boulton and Parker, 2007). Informed consent is conceptualised as;

> "consent that is voluntarily given (or refused) in response to a prior, explicit disclosure, detailing the nature, risks, costs, benefits and side-effects of a proposed course of action (perhaps with a specification of the risks, costs, benefits and side effects of alternative courses of action, or of taking no action at all). Informed consent is something much more specific than 'simple' consent in that it involves specific obligations to inform patients and research subjects about the nature, risks and side effects of a proposed course of action" (Manson, 2007: 300).

Informed consent initially started with the emphasis on research ethics but later also extended to clinical ethics (Manson and O'Neill, 2007). However, both in the case of research as well as in clinical settings, it has been observed that the individual centric approach is problematic not only in developing countries such as India and China, where an individual is highly dependent on her/his family to make free and informed choices, but also in Western countries such as the US and the UK, where an individual appears to be more independent in terms of her/his decision-making process (Corrigan, 2003; Dein and Bhui, 2005). It has been argued that various social aspects and largely paternalistic and autocratic clinical settings have a profound influence on the procedure of informed consent, by and large, everywhere. Dein and Bhui (2005) have argued that, for ethnic minority groups in the UK, the individual centric approach of informed consent is not meaningful since, even after living in the UK for many years, they still adhere to their own culture and traditions where other family members have an impact on their decision. In addition, an individual centric approach is problematic in certain research areas such as genetics and genomics, where information provided by a particular individual may have an impact on other family members (Boulton and Parker, 2007). In the UK, events in the past decade have called into question the assumption that informed consent is embedded in Western medical practice. For example, the Alder Hey 'scandal' of organ retention in the UK was seen to reflect the paternalistic and autocratic nature of the medical community, where organs or tissues of dead children were retained

without the informed consent of parents (Dyer, 2000; Leith, 2007). Furthermore, the widely-publicised death of Jesse Gelsinger during a gene therapy clinical trial in the US suggests that there is a need to go beyond 'informed consent' as an ethical mechanism in biomedical research and to recognise that even fully 'informed consent' does not always guarantee to protect patients from possible harm (Savulescu, 2000; Wilson, 2009).

The procedure of informed consent also needs to be seen in the background of high expectations associated with biomedical research and therapy. The study of Larry Churchill and his colleagues with respect to gene therapy illuminates that inflated promises of potential therapy can have an impact on the functioning of informed consent (Churchill et al., 1998). In the current era of biocapital, there is an immense pressure on researchers for funding and 'breakthroughs' and this leads to exaggerated claims and high expectations. It attracts patients for an immature therapy, especially those who are terminal and desperate. The gene therapy in the past and the growing phenomenon of 'stem cell tourism' are good examples for the same (Petersen and Seear, 2011). Biomedicine, which is an integral part of biotechnology venture, often proliferates on the basis of 'hope' and 'high expectation' and it is not surprising to see the dilution of informed consent against this backdrop (Churchill et al., 1998).

It is often highlighted that the level of literacy can have a profound impact on the procedure of informed consent, especially in those developing countries, where the level of education is comparatively low compared to developed

countries (Bhutta, 2004; Marshall et al., 2006). Whilst studying the informed consent procedure in India, it is observed that the low level of literacy often affected the functioning of informed consent as, for most of the research subjects or patients, it is very hard to understand information sheets (Bhan et al., 2006; Jhanwar and Bisnoi, 2010; Nirmalan et al., 2004). However, it is not the case for only illiterates; in a recent study in the UK confined to cancer trials, a similar problem was observed. It was found that the language of the information sheet was over-complicated, poorly structured and too technical, and participants find that it is difficult to understand (Armstrong et al., 2012).

The above discussion reflects that the functioning of informed consent is subject to various social and cultural factors. This is the reason behind the formulation of the International Ethical Guidelines for Biomedical Research Involving Human Research Subjects in 1993 by the Council for International Organisations of Medical Sciences (CIOMS) and the World Health Organisation (WHO). It highlighted the limitations of the Declaration of Helsinki in developing countries and argued to consider particular cultural values and multiple health care systems while applying universal ethical standards.

2.6.4 International guidelines and terminally-ill patients

International guidelines, whether it is the Helsinki Declaration or CIOMS guidelines, mainly aim to protect human research subjects. Given the mandates of these guidelines, especially with regard to

experimental/unproven treatments, it appears that, for terminally-ill patients who have exhausted all treatment options, these guidelines are unable to provide enough safeguards against possible exploitation. For instance, the CIOMS guidelines stated that "persons who have serious, potentially disabling or life-threatening diseases are highly vulnerable. Physicians sometimes treat such patients with drugs or other therapies not yet licensed for general availability because studies designed to establish their safety and efficacy have not been completed. This is compatible with the Declaration of Helsinki, which states in Paragraph 32: "In the treatment of a patient, where proven...therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new...therapeutic measures, if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering.' Such treatment, commonly called 'compassionate use', is not properly regarded as research, but it can contribute to on-going research into the safety and efficacy of the interventions used" (CIOMS, 2008: 65-66). Though these guidelines put emphasis on informed consent before doing so, nevertheless, given the complexity in the proper functioning of informed consent, there is no guarantee that a particular patient will be not exploited (Bhutta, 2004). Moreover, the 'compassionate use' seems to be complicated, given that no single mechanism could be developed worldwide. In the European Union significant variations have been observed regarding the regulatory mechanism dealing with 'compassionate use'. For example, in four countries

(Hungary, Ireland, Sweden and the UK) there are no formal regulatory systems, yet in other countries there are legislations, which are not uniform and are varied both in content and comprehensiveness (Whitfield et al., 2010).

It resonates from the above discussion that there is a discrepancy at world level to address the disease conditions for which there are no treatment options available. This suggests that the international community largely fails to develop a uniform mechanism to address the use of unproven therapies on terminally-ill patients. However, many countries have state-sanctioned professional regulations, such as the General Medical Council (GMC) UK and the Medical Council of India (MCI), which have enough statutory power to punish a clinician, if the profession feels that the intervention of particular medical practice is unjustified.

In addition to certain limitations of these international ethical guidelines, many countries are reluctant to implement these guidelines on certain grounds. Recently, in October 2008, the US Food and Drugs Administration (FDA) made the decision to abandon the Declaration of Helsinki for international clinical trials and it has ruled that, instead of the Helsinki Declaration, the International Conference on Harmonisation of Good Clinical Practice (GCP) will act as a regulatory standard for the clinical trials conducted outside the US (Goodyear, 2009; Kimmelman et al., 2009). The rationales behind this step are: a) the Helsinki Declaration is subject to frequent

revision, which creates confusion;[4] and b) any future modification might be inconsistent with the US laws and regulations. It should be worth highlighting here that the US FDA was working on the idea to refuse the Helsinki Declaration since 2001 after the revised version of the Declaration in 2000 which put more restrictions on placebo-control trials in developing countries (Kimmelman, et al., 2009). This restriction is viewed as an impediment to prove the efficacy of a new drug (Wolinsky, 2006). However, the step of the US FDA has met with criticisms as unwillingness to fully implement the Helsinki Declaration offers less protection to research participants and more protection to the pharmaceutical industry[5].

Similar to the US FDA, the European Commission has also rejected the revised versions of 2000 and 2004 of the Helsinki Declaration and has adhered to the 1996 version of the Declaration, which is comparatively less stringent (Wolinsky, 2006).

It appears that international communities are largely unwilling to adhere to a stringent ethical document in the background of financial and industrial interest and 'scientific' arguments, especially in dealing with clinical trials in developing countries. This reflects that ethics is negotiated on several counts

[4] The Declaration of Helsinki to date has been revised eight times after its formulation in 1964.

[5] Requirements in the latest version of the Declaration of Helsinki but are absent in GCP are: a) Investigators to disclose funding, sponsors, and other potential conflicts of interest to both research ethics committees and study participants; b) Study design to be disclosed publicly (e.g. in clinical trial registries); c) Research, notably that in developing countries, to benefit and be responsive to health needs of populations in which it is done; d) Restricted use of placebo controls in approval process for new drugs and in research done in developing countries; e) Post-trial access to treatment; f) Authors to report results accurately, and publish or make public negative findings (Kimmelman et al., 2009: 14).

in a particular context. The sociological point of view informs us about the concept of ethical-boundary work (Frith et al., 2011; Hobson-West, 2012; Wainwright et al., 2006a).

2.7 Ethical boundary-work

The idea of ethical boundary-work is developed from Thomas Gieryn's concept of boundary-work (Gieryn, 1983). The concept of boundary-work focuses on the construction of boundary between science and non-science, which is defined as the "attribution of selected characteristics to the institution of science (i.e. to its practitioners, methods, stock of knowledge, values and work organization) for purposes of constructing a social boundary that distinguishes some intellectual activity as non-science" (Gieryn, 1983: 782). Recently, this concept has been used to analyse the construction of a host of boundaries between 'ethical'/'unethical' or 'legitimate'/'illegitimate' practices in areas related to biomedicine such as stem cells and infertility clinics and animal research field (Frith et al., 2011; Hobson-West, 2012; Wainwright et al., 2006a).

Originally the concept of ethical boundary-work was proposed by Steven Wainwright and his colleagues to "explore how scientists draw the boundaries of ethical scientific activity" (Wainwright et al., 2006a: 735). The ethical boundary-work argues that non-science, in the form of ethics, is an integral part of science to maintain its image, unlike Gieryn's boundary-work, which focuses on the demarcation of science from non-science. Furthermore,

ethical boundary-work "differentiates between scientists, enhances the authority of 'non-science' (e.g. regulatory bodies) and de-privileges science" (Wainwright et al., 2006a: 735). However, Hobson-West (2012) questions that the use of language 'de-privileges science' as it echoes that science and ethics are fixed domains and are engaged in some kind of battle for authority. She argues that reference to 'non-science' (society or regulation) is "more likely to be just one point on the route towards the overall positioning of scientists and biomedical research as legitimate" (Hobson-West, 2012: 12-13). By quoting Gieryn,[6] she attempted to highlight that, similar to science, the boundaries of ethics might be also flexible and seemingly both are 'co-constructed' (Hobson-West, 2012).

The US FDA decision to abandon the Helsinki Declaration for overseas clinical trials and the adaptation of a comparatively less stringent ethical document for the same could be seen as an example of flexible boundaries of ethics. This step of the US FDA also illustrates that ethics is subject to 'scientific' and commercial interest. It can be argued, therefore, that science and ethics are flexible and 'co-constructed' in the background of commercial interest.

It would be interesting to investigate in this preceding context, how various players in India are constructed ethics or legitimate their activities. This is one of the main focuses of Chapter 6. The Chapter 1 highlights that unproven clinical activities of stem cell have raised not only ethical concerns but also governance concerns. This informs us to investigate the existing biomedical

[6] "'Science' is no single thing: its boundaries are drawn and redrawn in flexible, historically changing and some-times ambiguous ways" (Gieryn, 1983: 781).

governance framework in India and to analyse why it fails to regulate those stem cell activities which are not proven. The next section of this chapter discusses different conceptual framework of governance including the approach of scientific governance and existing stem cell governance regime in different countries.

2.8 Governance

Science has travelled a long distance from Mertonian norms to Mode 2 knowledge. Arguably, science has transformed from *public good* to *financial good* (Jacob, 2009). It has become a business enterprise and attracted great interest from governments and industries across the world, given its enormous power in nation building. During 2007, for example, the US spent US $377 billion and China invested US $102 billion on research and development in science (Hasan et al., 2012). In the 2009-2010 union budget, India has increased its R&D budget by 17% (US $5.8 billion) (Jayaraman, 2009). Over the years science promises to solve various problems of society related to health, hunger and livelihood. However, the development of science and technology has also raised several ethical, legal and social issues; for instance, the BSE crisis in the UK, commercialisation of GM crops in India as well as Europe, and on-going concerns about nuclear power in different parts of the world, including India. The debate around stem cell research can be seen in this wider context in which various issues associated with these

scientific developments have forced different nation-states to accommodate societal concerns. How this interaction between government and society in the broadest sense (to include a variety of organised stakeholders from industry, the professions and civil society) should be conceptualised is an important question for investigating the way in which the domain of stem cell research and therapy in India is governed.

2.8.1 Defining governance

The term 'governance' is used in a variety of ways and has a variety of meanings. Governance is conceptualised in a wide range of disciplines such as sociology, political science, public policy and international relations, which is one of the reasons behind the different notions of governance which is influenced by the particular disciplinary approach. Governance is seen as a set of relationships between government and its citizens which can be variable from a state-centric approach to a societal-centric approach (Howlett et al., 2009). Kooiman (1993) perceived governance as an interaction between government and society. He refers to governance as "arrangements in which public as well as private actors aim at solving problems or create societal opportunities, and aim at the care for the societal institutions within which these governing activities take place"(Kooiman, 2000: 139). Rhodes (1997: 15) conceptualises governance as a new process of governing which "refers to self-organising, inter-organisational networks characterised by interdependence, resource exchange, rules of the game and significant

autonomy from the state." For Richards and Smith (2002: 2), "governance is a descriptive label that is used to highlight the changing nature of the policy process in recent decades. In particular, it sensitized us to the ever-increasing variety of terrains and actors involved in the making of public policy. Thus, it demands that we consider all the actors and locations beyond the 'core executive' involved in the policy making process."

Various international organisations such as the World Bank and United Nations Development Programme (UNDP) conceptualise governance in different ways. The World Bank perceives governance as an exercise to manage a country's social and economic resources for development; on the other hand the UNDP relates governance to sustainable human development (Kitthananan, 2006). These varieties of meanings of governance compel us to analyse governance in great details. The following section discusses some approaches of governance including scientific governance.

2.8.2 Analysing governance

2.8.2.1 The propositions

Gerry Stoker has set out five propositions for better understanding of the governance theory. According to Stoker (1998) these five propositions are: a) Governance refers to a set of institutions and actors that are drawn from but also beyond government. This proposition challenges the highly government centric approach. It informs about the involvement of private and voluntary institutions in service delivery and the decision making process;

b) Governance identifies the blurring of boundaries and responsibilities for tackling social and economic issues. This proposition blurs the boundaries between state and other private actors. It shifts the responsibility from the state to different stakeholders. The problem underlying this proposition is that it becomes very difficult to fix any responsibility on either state or other actors in the case of failure of any policy decision; c) Governance identifies the power dependence involved in the relationship between institutions involved in collective action. The idea here is that, in the governance mechanism, where multiple institutions are involved, no single organisation can easily command, though one institution can play a dominant role. This proposition resonates that governance is an interactive process, based on collective action. However, it is argued that dependence on others often results in a lack of co-ordination; d) Governance is about autonomous self-governing networks of actors. The formation of self-governing networks is one of the fundamental features of governance. It is perceived as more effective than government imposed regulation. It not only influences the policy of the government but also takes over the business of government. However, the dominance of certain elite actors and the problem related with accountability poses a limitation to this proposition. The critics argue that self-governing networks work for their own interest rather than for society at large. The intervention of government therefore becomes inevitable to steer and guide the networks; e) Governance recognises the capacity to get things done, which does not rest on the power of government to command or use

its authority. This proposition sees government as able to use new tools and techniques to steer and guide the activities of different groups.

2.8.2.2 The 'old' governance and 'new' governance approach

These two perspectives of governance were highlighted by Peters (2000). The 'old' governance focused on the capacity of the government to govern the economy and society while the 'new' governance focused on either the self-steering capacity of societies or the interaction between state and society at various levels (Peters, 2000; Raman, 2002). These two approaches can be characterised as a state-centric approach and a society-centric approach, respectively (Kitthananan, 2006).

2.8.2.3 Governance as structure and as process

Beyond this perspective of 'old' and 'new' governance, Pierre and Peters (2000) have postulated the governance *as structure and as process*. They have discussed four structural arrangements of governance: a) Governance as hierarchies; b) Governance as markets; c) Governance as networks; and d) Governance as communities.

2.8.2.3.1 Governance as structure

a) Governance as hierarchies

This structure of governance is based on the assumptions that "governance conducted by and through vertically integrated state structures is an idealized model of democratic government and the public bureaucracy" (Pierre and Peters, 2000: 15). It is a top-down approach. Here the idea is that state

governs society through the mechanism of command and control by imposing law and regulation and never gives up its legal right to other institutions. In the backdrop of increasing globalisation and liberalisation, however, critics argued that this form of state-led governance is no longer relevant (Pierre and Peters, 2000). It is contended that translation organisations such as the EU and WTO influenced the policy decision of nation-states (Pierre and Peters, 2000). However, Pierre and Peters (2000) emphasised that these institutions actually serve the interests of the nation-states and are dominated by their interests. Therefore, various transnational institutions are actually indirectly dominated by the interests of states. Furthermore, "governance through hierarchies still plays an important role in a surprisingly large number of national and institutional contexts" (Pierre and Peters, 2000: 18). For instance, in Britain, central government still has political control over local authorities in the form of audits. Similarly in Germany, regional and local authority has control over public services. However, this power is at the discretion of the government and can be resumed at any time (Pierre and Peters, 2000). In India, though, local bodies; Panchayats in rural areas and Municipalities in urban areas are recognised by the 73rd and 74th constitutional amendments; it is argued that enough powers are not devolved to these local authorities by the national government (Steytler, 2005).

b) Governance as markets

In this governance framework, the market is seen to be a dominant factor and the most efficient way of governing resource allocation. It is believed that the

market-led governance is free from politics and hence can empower citizens in the same way as consumers. In the case of public services, similar to the market situation, they provide for citizens to choose services directly and there is no dependency on elected or government officials for the same. However, this form of governance is dominated by self-interest of actors and it is seen as a problematic. Pierre and Peters (2000) argued that this form of governance is problematic "because of the atomistic and anonymous nature of the market and its actors" (p. 19).

c) Governance as networks

This form of governance is based on the network of a wide variety of actors in a given policy sector. It is contended that, "policy networks facilitate coordination of public and private interests and resources and, in that respect, enhance efficiency in the implementation of public policy" (Pierre and Peters, 2000: 20). However, policy networks of actors are more aligned towards self-interest rather than the collective interest of society. In addition, these policy networks have influence on the state policies which can be viewed as anti-democratic. One of the main drawbacks of this form of governance is to maintain proper co-ordination between the state and policy networks. The common interests of varied actors tend to challenge the domination of the state and the state feels that its policy initiatives are obstructed by policy networks. In sum, it can be argued that policy networks play an important role in policy implementation.

d) Governance as communities

Here the idea is that communities can deal with their common problems with a minimum intervention from the state. It is argued that the care of children and elderly people can be organised in a more efficient manner by the communities themselves. The supporters of this form of governance believe that the bureaucratic structure is too complicated to deal with these types of issues. Pierre and Peters (2000: 21) argued that "communitarian governance builds on a consensual image of the community and the positive involvement of its members in collective matters. The state is believed to be too big and too bureaucratic to deal with these issues". However, this form of governance is also limited on account that individuals are not always ready to sacrifice their personal interest for the common good at community level.

2.8.2.3.2 Governance as process

The above discussion of different ways of governance has shown the structural arrangements of governance. Governance as structure (hierarchies, markets, networks and communities) is based on the assumption that, for a 'right' form of governance, there is need to manage structural arrangement. In contrast, governance as process emphasises outcomes rather than structural and institutional arrangements. The governance as a process perspective is concerned more about interactions among structures rather than structures themselves. Governance is conceived as a process of steering and coordination of a given sector where states dominate. However, this approach does not discard institutional arrangements entirely as it is

important to decide the roles of the state. This perspective of governance argues that "states are still indeed capable of 'steering' society; only now its authority is less based on legal powers and more due to its control over critical resources" (Pierre and Peter, 2000: 23).

Out of a variety of notions of governance, for Pierre and Peters, the hierarchy mode of governance is still dominant. While discussing the *different ways to think about governance*, Pierre and Peters (2000: 25) argue that "the role of state is not decreasing as we head into the third millennium but rather its role is transforming, from a role based in constitutional powers towards a role based in coordination and fusion of public and private resources". Against this backdrop of state-led governance, the next section has attempted to investigate whether in the governance of science as well as the state dominates.

2.8.3 Analysing scientific governance

In STS discourse, governance is conceptualised as both a top-down and a bottom-up approach, as reflected from various studies. Irwin (2008) argued that governance is not simply a matter of a nation-state and a defined set of bureaucratic institutions; rather it encompasses a wide range of actors, which includes scientific organisations, consumers, industry, markets, and pressure groups. It was viewed as a step away from the traditional *government* approach (a top-down legislative approach to regulate the activities of people and institutions) to *governance* (a bottom-up approach which encompasses

more participation of different stakeholders in the decision-making process). More specifically, 'governance' is the replacement of traditional 'powers over' with contextual 'powers to' (Lyall and Tait, 2005: 3). It is a step in which the divergent public views are translated into a policy-making process. According to Gottweis (2005) the concept of governance minimises the dominant-state role in society.

It does not mean, however, that the 'traditional' form of governments or governmental institutions has no more relevance in governing science. This relevance still exists and is playing a crucial role in the policy-making process across nation states. 'Traditional' governments continue to play a vital role in the development of science and technology (Gottweis, 2005). Salter and Jones's conceptualisation echoes the dominant role of state in governance, especially of scientific governance, as they argued that, "Governance is the general process of accountability used by governments to monitor and shape those areas of economic and social activity for which they are responsible. Regulation is a specific form of governance that is characterised by standard setting, monitoring and, where necessary, corrective intervention of defined areas of activity" (Salter and Jones, 2002: 810). Some scholars believe that science still requires a hierarchical mode of governance, i.e. "conventional command and control style regulation" (Lyall et al., 2009: 2). The controversial technological developments such as stem cells, GM crops, and nuclear power and many more which have raised profound ethical, social and safety issues might be the reason to advocate state-led governance. It has

been observed that most of the science policies worldwide rely on legislation (Lyall et al., 2009). The stem cells science is a good example for the same, which is governed by legislation in most countries.

2.8.4 Governance and stem cells

Stem cells as a promising scientific venture have attracted considerable attention at government level worldwide. However, the same science is dealt with differently in different countries, which informs us that, in the governance process, the state still plays a leading role and a particular governance mechanism is subject to a particular political system. It can be better understood by Sheila Jasanoff's comparison of biotechnology debates in the UK, Germany and the US. In her concept of *'National Styles of Regulation'*, she stated that, "Regulation, it emerged, displayed distinctively national characteristics, leading to observable differences in the timing, priorities, forms, and stringency of interventions. Scientific evidence was shown to carry different policy environments, its interpretation conditioned by home grown traditions of legal and political reasoning and habits of deference or scepticism toward expert authority" (Jasanoff, 2005: 17). The *'National Styles of Regulation'* informs us that governance of science varies across different political systems.

In the case of stem cell governance this variation is significantly observed. There is a considerable ambiguity and uncertainty on the issues of governance of stem cells. The international and regional jurisdiction policies

and practices are highly varied along with public opinion. The diverse religious and cultural norms shape the stem cell policies globally (Caulfield et al., 2009). The legal governance framework varies from strict to moderate and finally no regulation at all (Table 1).

Table 1. A small sample of how regulations governing human ES cell research differ from country to country:

Country	Imported lines	Deriving new human ES cell lines from excess IVF embryos	Deriving new lines through nuclear transfer
Italy	Allow	Prohibit	Prohibit
Germany	Allow	Prohibit	Prohibit
United Kingdom	Allow	Allow	Allow
Ireland	Prohibit	Prohibit	Prohibit
Denmark	Allow	Allow	Prohibit
Canada	Allow	Allow	Prohibit

Source: Caulfield et al. (2009)

For example, the restrictions on stem cell research in Germany are much more stringent than in the US (Gottweis, 2002). These policy variations exist not only across nation-state level but within the jurisdiction of a single nation-state. For example, in the US different states have different rules for gametes, embryos and the derivation of new Human Embryonic Stem cell lines, and

their uses. This disparate approach on the same issue is termed a 'patchwork of patchworks' (Caulfield et al., 2009). The legal variations across different countries lead to the exploitation of patients by a phenomenon, characterised as 'stem cell tourism' where patients seek unproven therapies across the border countries where there is a lack of proper legislation to govern stem cell research and therapy (Caulfield et al., 2009; Ryan et al., 2010). This demands a harmonisation of policy across the world, at least at the level of research standards and clinics. The initiative of the International Society for Stem Cell Research, International Stem Cell Banking and European Human Embryonic Stem Cell Registry has been seen as an effort to harmonise policies across countries (Caulfield et al., 2009). However, these efforts are so far not effective, given the politicisation of stem cell science globally. Brian Salter argued that, in the case of stem cell science, "a range of cultural values support, oppose, or are indifferent to its progress, and these have to be politically negotiated by states and institutions with an interest in promoting it" (Salter, 2007: 278).

It is clear from the above discussion that stem cell governance across the world is greatly influenced by particular social and cultural factors. This suggests that despite the dominance of state-led governance other forms of governance are playing an important role in policy formulation. Against this backdrop it would be interesting to see as per thesis aims-what is the existing mechanism of stem cell governance in India and more importantly why it fail to regulate experimental stem cell based treatments?

2.8.5 Governance and policy implementation

Pierre and Peters (2000), while analysing the different modes of governance, have attempted to understand the capacity of government to steer society i.e. the competence of government to formulate policy and its implementation. It is reflected from their state-centric approach of governance that the policy implementation is highly dependent on other modes of governance. They argued that policy networks and civil society play an important role in the implementation of public policy. They either help or obstruct the implementation process which is subject to their co-ordination with the state and their own interest.

Makinde (2005) has observed that the involvement of different stakeholders in the policy-making process is one of the essential components for successful policy implementation. In addition, various social, cultural and economic factors also affect the implementation of policies. It is argued that when these factors do not take into account at the level of policy formulation, it often results in implementation gap (Makinde, 2005). It appears that, to address the implementation gap, public consultation has been become major thrust in many countries while formulating policies, especially for controversial issues in science and technology (Marchant and Askland, 2003).

In recent years, we have witnessed public consultation on sensitive issues (e.g. GM crops, stem cell) to accommodate various societal concerns in developing governance framework in developed as well as developing countries (Irwin, 2006; Padma, 2010; Shankar, 2011; The Economist, 2010).

However, the credibility of public consultation is often questioned on the issue such as the wider participation of the general public and the procedure of public consultation itself (BBC, 2003; Durodie, 2003; Gill, 2010; Gray, 2010; Irwin, 2006).

2.9 Summary and discussion

The aim of this Chapter was to examine various issues associated with the proliferation of stem cell biomedicine which reflects that there are many unresolved ethical, legal, social and economic issues attached with its development. The other aims were to discuss the sociology of biomedicine in general and India in particular in order to understand the contextual development of stem cells in India. The various understandings of biomedicine reflect that biomedicine is used largely as a commercial enterprise and exercising power on citizens. The discussion related to Indian biomedicine shows that primarily it serves the wealthy and influence population of the society and various important public health issues which affects the large section of the society are largely ignored by the government of India. The growing activities of stem cell in India are also a part of this biomedical venture and therefore it can be argued that stem cell also carries the similar characteristic of biomedicine which has been discussed in this Chapter. To examine the current development of stem cell including expectations discourse, ethical construction and existing governance regime

this Chapter has discussed analytical approach of sociology of expectations, sociology of bioethics including ethical boundary-work and different approaches to understand governance framework. The data chapters 4-7 is analysed using these frameworks.

Chapter 3: Methods

3.1 Introduction

The aim of this thesis is to explore the issues related to ethics and governance with the proliferation of stem cell in India from the perspective of key stakeholders using an interpretive approach. The study seeks to analyse the nature of stem cell activities in India, how key players from science, clinical practice, private firms and government justify or challenge the need for specific activities and frame the ethical issues they raise, and how arrangements to govern stem cell activities work in practice. The study involved a survey, documentary analysis and qualitative interviews with key actors, including scientists, clinicians, representatives of firms and policymakers. Following the discussion of key literature pertinent to this study in Chapter 2, this chapter describes the philosophical standpoint of the research and the methods which have been adopted in the designing and execution of this study. More specifically, this chapter attempts to justify the rationale underpinning the choice of a qualitative research strategy and methods.

3.2 Philosophical approach

The theoretical approach adopted in this study was informed by various STS literatures as described in Chapter 2 and beyond. Based on recent trends, the

ontological position in STS could be considered as *constructivism*, which means that reality is the outcome of social processes. The underlying assumption in STS is that "science and technology are thoroughly social activities" (Sismondo, 2010: 10). Within STS, there is a greater thrust to investigate the constitution of scientific knowledge and technological artefacts. Science is seen as an active and socially-situated process, and scholars argue that it should be studied as such (Sismondo, 2010). Epistemologically, this informs us that knowledge is not value-free, rather socially constituted; therefore, the phenomenon under consideration should focus on questions such as 'what counts as knowledge?' and 'how are facts constructed?' (Bijker, 1993; Sismondo, 2010;). Bryman (2008: 13) notes that "an epistemological issue concerns the question of what is (or should be) regarded as acceptable knowledge in a discipline." The underlying assumption of STS suggests that epistemologically (the nature of knowledge) it is more close to *interpretivism*, which emphasises analysing the subjective meaning of social action. This approach demands the analysis of "the perceptions and actions of social actors" (Bryman, 2008: 18) which are essential to understanding any social reality.

However, critics argue that there is a danger in adopting a constructivist approach (highly human-centric perspective) entirely, as it ignores the materiality of the social world (Murphy and Dingwall, 2003). It can be argued, therefore, that the construction of reality is subject to the external

environment, which needs to be taken into account while applying this approach.

3.3 Research design

This project is informed by the philosophy of qualitative research. The reason behind using qualitative research is that it provides an opportunity to study experiences and views of participants or stakeholders in a chosen study. Qualitative research emphasises the interpretation of meaning in a given social world. It is based on the assumption that meaning is socially constructed. There is no single reality; rather, there are multiple interpretations of reality which are flexible and change over time. Qualitative research provides a framework to understand this reality in a particular social context in a given time (Merriam et al., 2002). Qualitative research is not only helpful in exploring experiences and views of different stakeholders but it is also useful in analysing the inconsistency and conflicts of views of various stakeholders (Jaye, 2002). It is especially suited for finding the answers to questions such as how, why and in what way (Hancock, 2002). The qualitative research method helps in understanding the world. Hancock (2002) argues that it provides an opportunity to know a) why people behave the way they do; b) how opinions and attitudes are formed; c) how people are affected by the events that go on around them; d) how and why cultures have developed in the way they have; and e) the differences between social groups.

Against the back drop of this conceptual framework, this research seeks to investigate the views of different key players associated with stem cell development in India. Using qualitative research methods provides more flexibility than quantitative research in this type of research where the main aim is to explore experiences and views of different key players. This study puts more emphasis on words rather than numbers (Miles and Huberman, 1984). However, simultaneously this study acknowledges that choice of any methodology "should depend on the nature of what we are trying to describe, on the likely accuracy of our descriptions, on our purposes, and on the resources available to us; not on ideological commitment to one methodological paradigm or another" (Hammersley, 1992: 163).

In the background of both epistemological and ontological consideration of STS combined with the nature of study under investigation, a qualitative research strategy, therefore, was most suitable for the data collection.

The basic interpretive approach was applied to explore ethical and governance issues, especially the framing and/or understandings of ethics and problems with the existing system of governance from stakeholders' perspective and the expectations rhetoric of different key players with respect to stem cells. The reason is that the interpretive approach provides an opportunity to explore "the complex world of lived experience from the point of view of those who live it" (Schwandt, 1994: 118). This approach is helpful in understanding how participants construct the meaning of a phenomenon or a situation. Merriam et al. (2002) argue that basic qualitative study helps "to

discover and understand a phenomenon, a process, the perspectives and worldviews of the people involved, or a combination of these" (p.6). This approach is based on the assumptions that constructions and interpretations are subject to change over time and qualitative researchers seek to understand various interpretations in particular time and contexts (Hancock, 2002; Merriam et al., 2002). Data for this research approach are collected through interviews, observations or documentary analysis (Merriam et al., 2002).

3.4 Data collection and analysis

For this study, the empirical data were collected and analysed using a survey, documents and semi-structured interviews. The choice of methods was pragmatic in terms of their suitability to address the research aims and questions of the thesis. A survey was conducted to map the stem cell activities in India. The documents were used to investigate existing policy and regulatory regime related to stem cells in India and also to analyse how different key players framed their expectations regarding this line of research as well as the emerging ethical and governance issues related to the proliferation of stem cell therapy in clinics. In addition to various documents, semi-structured interviews were also conducted to have a more nuanced understanding of stakeholders' perspectives for the same.

3.4.1 Survey

A survey was conducted to map the current basic research, clinical activities and cord blood banking. It was helpful to analyse the various activities which are being undertaken by a range of public and private organisations, including hospitals, clinics, universities and private companies. In addition this survey was useful to identify individuals to interview. The survey was web-based and involved detailed internet searches of all leading Indian medical research centres, laboratories, hospitals, clinics and stem cell companies. The data obtained from this survey provided an overview related to the focus of the basic research, type of service offered, stem cell used, disease target, and principal investigator.

3.4.2 Documentary analysis

In qualitative research some of the commonly used documents are diaries, letters, autobiographies, media outputs, visual forms (such as photographs) and official documents derived from both the state and the private organisations (Bryman, 2008). According to Altheide (1996), a document can be any symbolic representation that can be retrieved or recorded for analysis. Documents are viewed as an invaluable source of data in qualitative research to reveal underlying social reality (Bryman, 2008; Hoepfl, 1997; Scott, 1990). However, the available documents are subject to scrutiny on the basis of four criteria (Scott, 1990: 6): a) *Authenticity* (Is the evidence genuine and of

unquestionable origin?); b) *Credibility* (Is the evidence free from error and distortion?); c) *Representativeness* (Is the evidence typical of its kind, and, if not, is the extent of its untypicality known?) and d) *Meaning* (Is the evidence clear and comprehensible?).

3.4.2.1 Collection of documents

This thesis has used media outputs and official documents of various government and private organisations. Documents are viewed as an important "source to understand culture – or the process and the array of objects, symbols, and meaning that make up social reality shared by members of a society" (Altheide, 1996: 2). As far as media outputs are concerned, various national and international newspapers were used including science magazines, television programmes and the internet. The media have been influential in shaping public attitudes of new emerging technologies, especially the promises of technologies to address various issues related but not limited to the environment and health and illness.

For conducting media analysis there is no standard method described; it is subject to the researcher's interest and relevance (Altheide, 1999). Although documents have an independent existence, their meaning and significance depend on researchers' perceptions and questions (Altheide, 1999), and this makes sampling a prominent issue. The choice of sources, publications and time-period is crucial as it can have an effect on data generation.

3.4.2.2 Sampling

For this study, documents since 2001 were chosen, since 2001 was the year when India's two research centres were selected by the National Institute of Health (USA) for embryonic stem cell funding, among ten institutions world-wide (Bharadwaj and Glasner, 2009: 60). Most importantly, the government of India started taking the initiative for the development of stem cell research in the year 2001 when, for the first time, the Department of Biotechnology issued draft guidelines to govern stem cell research in the country (Salter et al., 2007).

Collection of media documents was done with the help of setting up a Google Alert with a search term 'stem cell research in India'. This helped me to monitor day-to-day newspaper articles, web pages and blogs, and to track newspaper articles as it was easy to look at various newspapers daily only for the news specifically related to stem cell in India. In addition to Google Alert, the widely-used on-line media database Nexis was also used for more comprehensive news items. With the help of both Nexis and Google Alert a corpus of 480 news articles was produced. All new articles were downloaded in rich text format into Microsoft Word for further in depth study. The articles were read and re-read to look for overlap in coverage of newspapers and more importantly, to find out the most suitable news items for the purpose of the study. Finally 73 news articles were selected for in-depth analysis, most notably the news items published in India's leading newspapers, *The Times of India*, *The Hindu*, *The Indian Express* and science magazines *Biospectrum*

India, *Express Healthcare* and *Express Pharma*. These were analysed in more detail along with news coverage of some key international daily and news agencies such as *The Washington Post*.

In addition to newspaper articles, this study also analysed policy and legal documents published by various government agencies, which are related to stem cell basic research and its clinical practices; for instance, guidelines formulated by the Indian Council of Medical Research (ICMR), the Department of Biotechnology (DBT) and the Drug Controller General of India (DCGI) and various legislations dealing with clinical practices in India including the Medical Council of India (MCI) Act. The documents from private organisations such as stem cell firms, which were available on-line, were also examined. All documents were available on-line; therefore, it was very easy to use this method in the study.

3.4.2.3 Analysing documents

The documents, especially newspaper articles, were useful in gaining information regarding various activities of stem cells including locations and key players. This was not only helpful for Chapters 4-7 but also for the selection of interviewees. I have used the data from newspapers mainly to analyse how various media reports portrayed the proliferation of stem cell in India, especially in terms of expectations of stem cells. This study has not done widely popular discourse analysis in qualitative research for the same reason since the aim was not to do so. The policy documents published by the

government of India were helpful to understand the existing biomedical governance system in general and stem cell in particular.

Although this thesis and many other studies have used documents for data generation, and it was worthwhile as far as my purpose of study, using documents as a standalone method is not so popular in qualitative research. It is argued that, if using documents solely, a researcher is placed at some distance from real people (Miller and Alvarado, 2005). Instead, it is argued that documents can be used in combination with other methods to increase the comprehensiveness and legitimacy of any single study as the strengths of one method can compensate for the weaknesses of another method (Patton, 2002). For Patton (2002), combining both interviews and documents is therefore worthwhile as it can help to overcome potential weaknesses of the methods on their own; the researcher may get distorted data from the interview due to personal prejudice, while available documents might not be complete or accurate or authentic (Bryman, 2008; Patton, 2002).

3.4.3 Qualitative interviews

The interview is one of the most widely-used methods in qualitative research (Britten, 1995; Bryman, 2004). Qualitative interviews are viewed "as an opportunity to explore how informants themselves define the experiences and practices that are the object of the research" (Murphy and Dingwall, 2003: 82). It is argued that interviews (as *interactionism*) provide a trustworthy understanding into people's experiences (Silverman, 1993).

Interviews are a way to gather facts about reality, whether that reality exists internally in the interviewees' mind or externally in the world (Murphy and Dingwall, 2003).

Despite popular use of qualitative research interviews in examining the social reality, it is argued that there is no surety that informants will reveal true information and the data from interviews might be socially and contextually constrained (Dingwall and Murphy, 1998). This notion depicts that representation of truth is questionable in qualitative interviews and hence the data from interviews should not be examined under the framework of true and false; rather, it should be viewed as informants' perspective on a particular phenomenon (Dingwall, 1997).

Several types of qualitative research interviews are described, which include structured, semi-structured and unstructured (Esterberg, 2002). Qualitative researchers mostly prefer the use of a semi-structured interview (sometimes called in-depth interview) because of its flexible nature (Barbour, 2008) as it allows interviewees to express their opinions and ideas in their own words (Esterberg, 2002). The semi-structured interview follow an open and informal interview style (Hardon et al., 2004). It is neither a free conversation nor highly structured. It focuses on certain themes rather than on exact questions (Kvale, 1983). The flexible and interactive nature of semi-structure interviews paves the way to obtain 'insider accounts' (Hammersley and Atkinson, 2007: 97) of a given social phenomenon from the respondents' perspective.

The semi-structured interview therefore is justified to achieve the aims of this study.

3.4.3.1 Sampling

In qualitative research, sampling is viewed as a very complex issue (Coyne, 1997). Johnson and Waterfield (2004) stated that the sampling strategy in qualitative research does not look to accomplish statistical representativeness; rather, it strives for diversity within the study population. According to them, "the sample must be sufficient to generate depth rather than breadth and may comprise a small number of participants or just one" (Johnson and Waterfield, 2004: 124). Sample size depends upon the research questions and aims of the study and the type of data to be collected. Curtis et al. (2000) argued that is why often purposive sampling is employed rather than probability sampling. However, Murphy and Dingwall (2003: 105) argued that, "using nonprobability sampling methods in qualitative research is best seen as a pragmatic compromise between breadth and depth." Therefore it can be argued that in qualitative research there should be a balance between depth and breadth of sample size.

This study has employed purposive sampling. The analysis of documents was very helpful to select informants. In addition, prior contact with some of the key players during a meeting was very useful for sampling (Devers and Frankel, 2000). The potential respondents are selected from four different groups: a) scientists – involved in basic research; b) clinicians – engaged in

clinical research and medical practice using stem cell; c) firms – involved in basic research, product development and cord blood banking; and d) regulators, government agencies, members of ethics committees and National Apex Committee for Stem Cell Research and Therapy.

3.4.3.1.1 Scientists

Scientists who are involved in stem cell basic research and cord blood banking were approached for interview. Interviews with scientists aimed to investigate the current status of stem cell basic and clinical research and their expectations of stem cells, as well as their views on the ethical and regulatory problems relating to stem cells in India and the problems of maintaining and enforcing ethical standards.

Given the nature of this research and its aims, purposive sampling was desirable. With the help of survey and media analysis, most of the respondents were selected. Around 15 scientists were contacted via email for interview. Of these, five scientists expressed an interest to take part in the research project. It is worth highlighting that I had prior contact with two scientists, during my M. Phil when I did an on-line survey for the dissertation.

3.4.3.1.2 Clinicians

In India, as described in Chapter 1, there are significant numbers of hospitals and clinicians offering stem cell based treatments. Given the prominent

ethical and governance issues related to various stem cell based therapies, I was comparatively more interested to interview as many clinicians as possible. Again, newspaper coverage has helped me to select clinicians. In India, as in many other countries, medical services are being offered by both the public and the private sectors. The approach was, therefore, to make contact with clinicians serving in both public and private sectors. An e-mail was sent to 35 clinicians; of these, 11 clinicians responded and showed willingness to take part in the study.

3.4.3.1.3 Firms

Many firms are active in stem cell research and cord blood banking. Before starting my field work, I was not very sure whether this group of people would respond to my e-mail as my effort to enrol them in an on-line survey for my M. Phil in India was largely unsuccessful. However, the participation in UKNSCN/UKTI Indian stem cell mission seminar in London (15th March 2010) helped me to establish prior contact with representatives of stem cell firms. The full credit goes to one of my supervisors, as he suggested to attend this meeting; it provided me with valuable information about various firms in India and simultaneously I was able to get personal contacts with representatives of firms. I would like to stress here that only by attending this meeting did it become possible to arrange interviews with this largely unapproachable group. In total, I2 firms were approached through e-mail; of these seven firms were responded to take part in this study.

3.4.3.1.4 Regulators/policymakers/members of ethics committees/NAC-SCRT

With the help of official documents, I selected a few people to contact for the interview. Again, a prior meeting with a regulator during a one-day workshop in India has helped me to approach this group of people. I selected ten people to contact via e-mail; of these three agreed to take part in the research project. One policymaker/regulator got in touch with the help of another respondent. In this case, therefore, 'snowball sampling' was used.

3.4.3.2 Justifying sampling

In total, I conducted 27 interviews. It appears to be a relatively small number. However, all these interviews were conducted with key persons. For instance, although I conducted interviews only with five scientists, all these are leading scientists in the area of stem cells. One of the scientists has received NIH funding for his existing embryonic stem cell lines. Similarly, another scientist has an international reputation. The embryonic stem cell lines, which are derived from her, have passed the eligibility criteria from the UK stem cell bank and are now available for researchers to conduct further research. Similarly, in the case of firms, I have conducted interviews with those firms which have invested a significant amount in stem cell R&D and are recognised as leading firms in the stem sector of India. The majority of the firms which were interviewed were invited by the UK National Stem Cell Network (UKSCN)

and the UK Trade and Investment (UKTI) in 2010 in the UK to foster possible international research collaboration and business in the area of stem cells. This suggests the importance of these firms. One of the firms is also the beneficiary of NIH funding to work further on embryonic stem cell lines. In the case of policymakers, although I conducted interviews with only four, including one ex-policymaker, all of them are key informants since they are in charge of either the stem cell division in the DBT or in the ICMR or are a member of the newly-constituted National Apex Committee for Stem Cell Research and Therapy. Similarly, an ex-policymaker is a key person in biomedical policy areas who has been involved in the biomedical policymaking process in India for 30 years. Clinicians who were interviewed are also known as leading medical practitioners in India and are often quoted in media reports related to stem cell coverage. Some of them are associated with the state-of-the art hospitals of the country.

Although I conducted interviews with important key persons, I could not arrange an interview with Dr Geeta Shroff, a clinician who is always quoted in various academic writings and media reports, and with the officials of the Medical Council of India (MCI) and the Drug Controller General of India (DCGI). Dr Shroff refused my invitation by saying that she has no time, and officials of both the MCI and the DCGI did not respond to my mail. In the case of the MCI, the reason was that, at the time of my field work, the MCI was in crisis as its president was arrested on corruption charges. However, my data collection has not been affected because of the availability of significant

studies related to Dr Shroff's work (see Chapter 1) and the role of the MCI and the DCGI. In addition, through interviews with other policymakers I was able to get valuable information about the MCI and the DCGI.

3.4.3.3 Conducting interviews

Informants were contacted by e-mail with a brief introduction of the project (see Appendix I and Appendix II). The interviews were conducted in India during the period June 2010-January 2011 and again during September-October 2011. All interviews were carried out face-to-face in respondents' offices and for which I had to travel a lot given the huge geographical area of India. In general, each interview was around 40-50 minutes; however, in some cases it was more than one hour and in one case it was only 15 minutes. The conduct of interviews with clinicians was more challenging as most of them fixed an appointment at their clinics and during this time patients were also in the queue. In the midst of our conversation some clinicians tended to talk with their patients and support staff. The flow of the interview got interrupted as a result. I believe that conducting an interview in this environment has affected my data collection. Sometimes I felt guilty that patients were waiting for their number for several hours while I entered clinicians' offices to conduct my interview.

Most of the interviews were recorded using a digital recorder with the permission of interviewees. It has been argued that, in qualitative research,

the *way* of saying matters as much as *what* people say. The taping of the interview allows for more in-depth analysis of *what* people say (Bryman, 2004). However, three interviewees refused permission to record the conversation. In that case I noted down their response.

The interview guide before going into the field was very helpful in conducting interviews. However, I faced some difficulties in conducting interviews especially because of weather and traffic. In addition, I encountered difficulties in fixing appointments with policymakers.

My local supervisor in India is based in New Delhi (Northern region) who is affiliated to Jawaharlal Nehru University. It was quite natural therefore for me to go New Delhi and report to him. I reached New Delhi in the last week of May in 2010. May is the hottest month in India in the Northern region. The average temperature in this month is usually around 32-40°C and it was not the ideal time for conducting interviews in New Delhi. However, I started contacting my informants who were based in New Delhi through e-mail. Initial days were very disappointing as, for my first interview; I had to wait for one month. The reason was that most informants were on holidays during the summer time. This suggests that timings of starting field work play an important role in data collection. Then I decided to contact those informants who were based in the Southern region of India, i.e. Chennai, Bangalore, etc. (most of the stem cell activities are in this region). The response was overwhelming and, within eleven days, I conducted eight interviews in Chennai and Bangalore. However, conducting interviews in various cities in

India is always very challenging because of traffic. Within a city I had to spend 2-3 hours in traffic to reach respondents' office. In Mumbai, because of heavy traffic I missed my appointment with a clinician. And for another appointment I had to wait for one week.

To fix an appointment with policymakers was very difficult as no-one responded to my mail. My local supervisor had helped me in getting hold of a policymaker by inviting her for a one-day workshop at Jawaharlal Nehru University. I took this opportunity to talk to her personally about my project and fixed an appointment. For other policymakers I had to make a telephone call to arrange an interview.

3.4.5 Interview guide

Interviews were conducted using the philosophy of the semi-structured interview, which allows freedom for the informants to express their views on the topic under investigation. The interview guide was developed before going into the field for the data collection; it includes the key themes and questions (see Appendix III). Questions were mainly prepared according to the actors, i.e. scientists, clinicians, the representatives of firms, and policymakers; however, certain general questions were also asked to every actor. Questions were refined throughout the data collection process.

3.4.6 Analysing interview data

The analyses of interview data started first with the transcription, i.e. the written translation of a recorded interview. All interviews were transcribed by me. Although it was a laborious and time-consuming task, this exercise helped in bringing me closer to the data in terms of identifying key themes and in-depth analysis of various narratives of research participants (Bryman, 2008). I conducted interviews and transcriptions simultaneously as there was some time between interviews. The initial transcriptions were very helpful in refining questionnaires further. For emergent themes, transcripts were analysed by content and then coding was carried out (Strauss, 1987; Weber, 1990). Emerging themes were named and the data obtained from different stakeholders were collated and included in each of the themes. The analysis of interview data is presented in Chapters 4-7.

This study has taken into account the ethical issues associated with the conduction of qualitative research.

3.5 Ethics

Ethical issues in qualitative research are one of the most important aspects (Orb et al., 2001) which cannot be ignored as they directly related to the integrity of the research work (Bryman, 2004). There is an imperative to ensure the anonymity, privacy, confidentiality and informed consent with

respect to the participants in the research process (British Sociological Association 2002; Daymon and Holloway, 2002).

This project was designed as per the University of Nottingham's ethical guidelines and, after approval from the university, field work interviews were conducted in India. The relevant ethical issues which were taken into account are described below.

Empirical data were collected using face-to-face interviews and recorded using a digital voice recorder with the permission of the interviewee. As per the current research code of conduct guidelines, the interviews will be retained for seven years. Research participants were asked for written consent for the recording to take place. The permission was also taken to use their quotations taken from their answers for the reproduction in my thesis and any subsequent papers derived from my thesis.

The topic of my research was ethically sensitive given that its aim was to explore the ethical and governance issues with the help of participants' perspective. In an ethically sensitive area, there is a greater emphasis to take care of research participants who are particularly vulnerable in terms of age, mental or physical health etc (Bryman, 2008). In my case, there was no such issue as I did not conduct interviews with any vulnerable groups. My informants were leading scientists, clinicians, representatives of firms, and policymakers. However, given the increasing unethical clinical activities in stem cells, there was a possibility of self-incrimination of respondents (Cowburn, 2005) if, during interview, they had told of certain unethical

routine procedures they performed . Hence, those types of questions which could potentially incriminate the informants were avoided.

In addition, participants were assured that their responses would be kept confidential and also their identifications were anonymised. Their reference in the data chapter was highlighted as per the occupational role which they play, such as scientists, clinicians etc. Participants were informed of their right to withdraw from the study at any time without giving explanation.

3.6 Conclusions

This chapter has described the methods and philosophy which were used in the execution of the study. The chapter has attempted to explain the rationality for choosing the methods to fulfil the aims of the study. In doing so, the chapter has highlighted the merits and limitations of the adopted methods. The data gathered through using a survey, documentary analysis and qualitative interview are analysed in Chapters 4-7.

Chapter 4: Stem Cell Science in India: An Overview

4.1 Introduction

This chapter analyses the status of stem cell research and therapy in India. This chapter is based on a survey, media articles, science magazines, existing academic literatures, hospitals'/institutes'/firms' websites and the reports from the different departments of the government of India. The data from the interview with different stakeholders enriched this chapter with up-to-date development in recent years.

The proliferation of stem cell research and therapy in India can be traced back to the beginning of the 1980s. After performing its first successful allogenic bone marrow transplantation (a type of stem cell transplantation) on 20 March 1983 (Chakraborty et al., 2009), India geared towards the development of biotechnology, leading to the establishment of the Department of Biotechnology (DBT) in early 1986 (Natesh and Bhan, 2009; Salter et al., 2007). However, other scholars such as Bharadwaj and Glasner have viewed that the rise of India in stem cell research can be best traced to the middle of the twentieth century, when science had been assigned to technological innovation (Bharadwaj and Glasner, 2009). Whatever the circumstances or reasons, the various studies depict that India is emerging as a global player in the field of stem cell research and therapy (Bharadwaj and Glasner, 2009; Glasner, 2009; Sharma, 2006, 2009; Sleeboom-Faulkner and Patra, 2008), given that its two research laboratories were selected for the US National

Institute of Health (NIH) funding for the existing stem cell lines, from which they derived in 2001.

The NIH funding could be seen as one of the important factors for accelerating stem cell research in India. In 2000, in the area of stem cells, there were very few authored papers by the Indian scientific community, but by the beginning of 2007, there were nearly 100 authoring papers (Chakraborty et al., 2009; Tiwari and Desai, 2011). Indian scientists published 412 papers related to stem cell research during the period 2006-2010. Out of these, there were 142 internationally collaborated papers with the researchers from countries such as the US, Japan, France, Canada and the UK (Tiwari and Desai, 2011). India is placed amongst the top 10 countries of the world in term of publication (McMohan et al., 2010; Tiwari and Desai, 2011).

In this preceding context, this chapter attempts to explore the nature of stem cell activities in India. In doing so, section 4.2 analyses the development of stem cell basic research. In India, there are significant numbers of hospitals and clinics engaged in stem cell based treatments. Section 4.3 therefore explores the therapeutic applications of stem cells. In recent years, umbilical cord blood banking has flourished significantly in India. The activities and nature of cord blood banking are examined in section 4.4. In addition to these activities, some academic institutions are involved in knowledge production through various short and long term courses, training programmes and research at doctoral level. The status of knowledge production is discussed in section 4.5. For a successful innovation, linkages of various sorts among

different players in a particular sector are viewed as one of the key components (Tiwari and Desai, 2011). It was argued that, for a translational research field, like stem cells, a high degree of linkages between basic and clinical research is the need of the hour (Lander et al., 2008). Section 4.6 investigates the different kinds of linkages in the Indian stem cell sector; and, finally, the last section deals with the summary and discussion.

4.2 Stem cell basic research

In India, basic research in stem cells is being carried out largely by the government funded research laboratories. These research laboratories are supported by the different government agencies such as the Department of Biotechnology (DBT), the Council for Scientific and Industrial Research (CSIR), the Indian Council of Medical Research (ICMR), the Department of Science & Technology (DST) etc.

Among them, DBT is playing a major role and every subsequent year it has expanded its support to more research programmes by increasing funding. From the 8th five year plan (1992-1997) to the 11th five year plan (2007-2012), the DBT's budget has been increased by 16 times (from US $44 million to US $3.6 billion), of which stem cells share 30% of the total budget. Currently, DBT is supporting around 55 programmes in different aspects of stem cell research (Patra and Sleeboom-Faulkner, 2010).

In India, the focus is mainly on the adult stem cells. Different institutions are engaged in different areas of adult stem cell research. In comparison to adult stem cells, even after the 'favourable' environment compared to the West, a few research laboratories are focusing in the area of embryonic stem cells (Tiwari and Desai, 2011). Some of the research laboratories are also engaged in research on umbilical cord blood cells. The major programmes in stem cells include differentiation of pancreatic progenitor cells to insulin secreting cell, isolation of multi-potential adult progenitor cells from bone marrow and their clonal expansion, use of banana lectins for stem cell preservation, hematopoietic stem cell (HSC) for haplo-identical HSC transplantation, use of limbal stem cells for ocular surface disorders, isolation and characterization of mesenchymal and liver stem cells, cardiac stem cells, in vitro differentiation of human embryonic stem cells to neural and non-neural lineages, etc. (Patra and Sleeboom-Faulkner, 2010).

Some of the centres in India have developed state-of-the-art technology in the field of stem cells. For example, Centre for Stem Cell Research (CSCR), Vellore has succeeded in the creation of induced pluripotent stem (iPS) cells. In media commentary, this is portrayed as a path breaking research, where adult stem cells are reprogrammed to behave like embryonic stem cells. India is the fifth country after Japan, the US, China and the UK, which has developed this technology (Menon, 2009; Tiwari and Desai, 2011). The main goal of CSCR is to develop stem cell based therapies and to understand basic mechanism of human disease. It has set up four aims for the stem cell based

research and therapy[7], namely: a) to have a scientific faculty involved in basic research that will have translational potential, mostly with adult stem cells at present; b) to develop a training programme for students and scientists who will contribute to the manpower required for this field in the country; c) to develop cellular and animal models of diseases to test hypotheses generated from our understanding of stem cell biology, and d) to do clinical trials with stem cells produced under current good manufacturing practice (GMP) conditions (Tiwari and Desai, 2011). The CSCR is more interested in translation research with the help of the Christian Medical College (CMC), Vellore.

India has recently established the Institute for Stem Cell Biology and Regenerative Medicine (inStem), with the investment of US $50 million in Bangalore. It is viewed as a major boost for stem cell R&D in India (Sachitanand, 2009).The major focus of inStem is basic research. However, it will work in close collaboration with the clinician of CMC, Vellore. A scientist at inStem informs:

> "Currently we have only basic research here and we interact with the clinicians at CMC, Vellore, where a lot of translation work is going on. inStem basically aims to conduct basic research on problems of clinical importance" (Scientist, 3).

[7] http://www.cscr.in/, [Accessed April 30, 2011].

The narration of the scientist reflects that the government of India is making effort to bring scientists and clinicians on a common platform to work together.

The National Centre for Biological Sciences (NCBS), Bangalore is conducting research in embryonic as well as adult stem cells. Its three human embryonic stem cell (hESC) lines had fulfilled the eligibility criteria for funding from NIH, USA, in 2001. However, these cell lines are still not available for the researcher to conduct further research (Tiwari and Desai, 2011). The main focus of the work here is to study the role of neurotransmitters, more specifically the role of serotonin in depression, stress and psychosis as informed by the scientist during field visit (Scientist, 2).

A multidisciplinary research institute, Jawaharlal Nehru Centre for Advance Scientific Research (JNCASR), which is also in Bangalore, has derived two human embryonic stem cell (hESC) lines from the discarded embryo. These cell lines are available through UK stem cell bank to carry out further research. The Bangalore Assisted Conception Centre (BACC), Bangalore and the NCBS were also a part of this collaborative project (Inamdar et al., 2009). The JNCASR website highlights that "this project will be part of the International Stem Cell Initiative 2 (ISCI) project to identify the common genetic changes that occur in hES lines on prolonged culture. This will be the first time that India is represented on an ISCI project"[8]. Similar to JNCASR, the scientists at the National Brain Research Centre (NBRC), Manesar are also

[8] http://www.jncasr.ac.in/newsview.php?id=51, [Accessed April 30, 2011].

conducting research in the area of embryonic stem cells (Sharma, 2006). However, they are more active in neural adult stem cells.

For diabetes, the National Centre for Cell Sciences (NCCS), Pune is involved in animal and preclinical analyses of bone marrow stem cell injections for pancreatic regeneration. The scientists of the NCCS are in the process of establishing a team of clinicians, scientists, and patients to act as a platform for the trial related to diabetes (Lander et al., 2008; Tiwari and Desai, 2011).

The Centre for Cellular and Molecular Biology (CCMB), one of the constituent national laboratories of CSIR, based in Hyderabad, has established a stem cell facility centre in association with DST and the Nizam's Institutes of Medical Sciences (NIMS), Hyderabad. The facility centre aims to work in both the basic and applied research. For applied research, NIMS will provide patients to CCMB (The Financial Express, 2009; Tiwari and Desai, 2011).

Scientists at the stem cell laboratory of the National Institute of Immunology (NII) New Delhi are working on bone marrow derived adult stem cells. A scientist at NII stated that:

> "I am working on bone marrow derived stem cells i.e. mesenchymal and hematopoietic stem cells. I am also interested in differentiating them [mesenchymal and hematopoietic stem cells] into other kinds of tissues" (Scientist, 1).

The Central Leather Research Institute (CLRI), Chennai, which is one of the leading centres in leather technology, has been focusing on the engineering tissue by seeding scaffolds with stem cells. The main aim of CLRI is to conduct basic research and with the collaboration of private sectors further develop their research findings (Lander et al., 2008).

In contrast to public research laboratories, hospitals in India are engaged in both the basic as well as clinical research. The majority of the hospitals are offering direct therapy to the patients, more specifically the private hospitals; however, a few public hospitals are also engaged in the therapeutic applications of stem cells.

Public hospitals are mostly involved in basic/clinical research in stem cells. The All India Institute of Medical Sciences (AIIMS), New Delhi, which is India's premier research intensive public hospital, set up a Stem Cell Facility for this purpose in 2005. During a field work visit, a clinician at this centre informed that:

> "The stem cell facility at AIIMS was established for the purpose of doing basic and clinical research and we are trying to see its [stem cell] role in degenerative areas like cardiac, neurological, epithelial surface, eye and skin" (Clinician, 7).

AIIMS is also engaged in the research on umbilical cord blood banking. It has developed an in-house umbilical cord blood bank for the same reason (The Hindu, 2009).

Similar to the AIIMS, the other hospitals/medical institutes such as the Post Graduate Institute of Medical Sciences (PGI), Chandigarh, the Sri Venkateswara Institute of Medical Sciences (SVIMS), Tirupati and the Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI), Lucknow are conducting basic and clinical research in the different areas of stem cells. A clinician at PGI, Chandigarh stated that:

> "We are doing a few clinical trials using bone marrow mononuclear cells in several disease conditions such as heart attack, stroke, spinal cord injury and diabetes. In addition to these, we do lot of basic research related to stem cells" (Clinician, 4).

In addition to these, a not-for-profit hospital, the L.V. Prasad Eye Institute (LVPEI), Hyderabad is also active in research and development for the stem cell based therapy. LVPEI is conducting both basic and clinical research in the area of stem cells, specifically in limbal stem cells.

Sankara Nethralaya, an eye hospital based in Chennai, is conducting research in the area of corneal and retinal stem cells. Recently, it has develop synthetic gel to grow stem cells cornea and also obtained an international patent for this technology (The Times of India, 2010). It can be seen as an indicator of growing scientific strength in the field of stem cells, along with publications.

In contrast to research laboratories and hospitals, a few firms are doing basic research along with clinical research. The Reliance Life Science Pvt. Ltd (RLS), Mumbai is conducting research in embryonic and adult, as well as cord blood

stem cells. RLS is actively involved in developing the stem cell technology in India, as per information provided by the company's representative during the field visit (Firm's representative, 6). RLS is developing a wide range of novel research-led, autologous and allogenic cell therapies and tissue engineered products. Under the Regenerative Medicine initiative, RLS has set up several groups to work in the areas of embryonic stem cells, ocular stem cells, haematopoietic stem cells and skin and tissue engineering. It is interested in developing stem cell based therapies in the areas of cardiac disorders, neural degeneration, spinal cord injury, metabolic disorders like diabetes, ophthalmic diseases, hematological diseases, oncological diseases, burns and wound management, diabetic and venous ulcers, skin pigmentation disorders, orthopaedic and cartilage disorders.

RLS is conducting clinical trials for diseases conditions such as stable vitiligo, Parkinson's disease, non-healing diabetic ulcers, spinal cord injury and autologous stem cell conjuctival graft using stem cells. Recently, RLS has developed a few stem cell products: a) ReliNethra to cure corneal blindness; b) ReliHeal – G (biopolymeric hydrogel wound management product), which claims to be useful in early wound healing and c) CardioRel for heart attack (Bisserbe, 2010; Tiwari and Desai, 2011).

RLS has started the ReliCord™ programme for umbilical cord blood banking. There are two types of services being offered under this programme: a) ReliCord 'S' Sibling Donor Program, and b) ReliCord 'A' Allogenic, voluntary donor program. It has recently launched the Relicord 'M' program for cord

blood banking service, which stores umbilical cord derived from mesenchymal stem cells (Tiwari and Desai, 2011).

RLS does not offer any stem cell services directly to the patients. It conducts basic research for the development of stem cell based products. In addition, it is also involved in clinical trials and for which it has collaboration with different hospitals. The long term plan of RLS is to commercialise stem cell based therapies through hospitals across the country (Tiwari and Desai, 2011).

The Stempeutics Research Pvt. Ltd is another important firm in India primarily engaged in developing stem cell based products. It has invested US $ 7.5 million in the clinical research of stem cell and planning to invest more money in near future[9]. Stempeutics is a group company of the Manipal Education and Medical group in India which is basically based in Bangalore. However, it has also set up its subsidiaries in Manipal (India) and Kuala Lumpur (Malaysia). The Stempeutics stem cell facility centre in Malaysia has been given the Bionexus Status by the Malaysian Biotechnology Corporation. BioNexus Status provides certain exclusive rights to the companies as stated within the BioNexus Bill of Guarantees. For instance : a) freedom of ownership; b) freedom to source funds globally; c) eligibility to receive assistance for international accreditation and standards, and d) a strong intellectual property regime. In Malaysia, the Stempeutics also has got approval from

[9] http://archive.biospectrumasia.com/Content/110509OTH9451.asp [Accessed May 02, 2011].

National Pharmaceutical Control Bureau, which allows Stempeutics to go in nearly 20 other countries which are under the purview of the Organisation of Islamic Conference without conducting any further clinical trials (Biospectrum, 2011, Tiwari and Desai, 2011).

Stempeutics mainly focuses on adult stem cell research, although they are also interested in embryonic stem cell research but it is a long-term goal only, according to a representative of Stempeutics who said that:

> "We do research on embryonic stem cell on a small scale considering the potential for embryonic stem cells in the future but it is not our short-term or mid-term goal; this is our long-term goal. As for our short-term and mid-term goals we are focusing on adult stem cells" (Firm's representative, 4).

In adult stem cells, Stempeutics is basically involved in mesenchymal stem cells (MSCs) derived from sources such as bone marrow, adipose tissue, Wharton's jelly and dental pulp. Presently, the main focus of Stempeutics is on MSCs derived from bone marrow, which is now at the stage of clinical trials. The MSCs derived from other sources like, Wharton's jelly, adipose tissue and dental pulp are confined at the level of laboratory only (Tiwari and Desai, 2011). The above representative of Stempeutics informed that:

> "We are conducting four clinical trials, two in India and two in Malaysia; all are from bone marrow derived MSCs, so we have crossed the basic research and pre-clinical levels and we are at the human clinical trial stage, whereas the other

projects, that is MSCs from Wharton's jelly, adipose tissue and dental pulp, are at the research level" (Firm's representative, 4).

The clinical trials are basically for the four disease conditions such as: a) Mayocardial Infarction; b) Critical Limb Ischemia; c) Cerebral Stroke, and d) Osteoarthritis. The clinical trials related to Myocardial infarction and Critical Limb Ischemia are being conducted in India and the rest (related to Cerebral Stroke and Osteoarthritis) in Malaysia (Firm's representative, 4). The trial in India, for Critical Limb Ischemia (CLI), which was started in 2009, is considered India's first true stem cell trial approved by the regulatory authority (Jayaraman, 2009). It completed the initial phase I/II clinical trial in April 2010 and will soon launched a product named 'Stempeucel-CLI' (Tiwari and Desai, 2011).

Furthermore, Stempeutics recently obtained approval for the phase II clinical trial for chronic obstructive, liver cirrhosis, pulmonary disease, osteoarthritis and diabetes mellitus from the Drug Controller General of India (Tiwari and Desai, 2011).[10]

Stempeutics has filed thirteen patent applications in India and six PCT applications. It has recently received a patent in India on *"An in vitro human embryonic model and a method thereof"* for the potential application in toxicological studies and drug screening. Stempeutics is in the process of

[10] http://www.stempeutics.com [Accessed April 22, 2012].

launching its products in the European and North American markets (Tiwari and Desai, 2011).

The Nichi-In Centre for Regenerative Medicine (NCRM) is also seen as one of the leading firms in the stem cell sector in India. It is an Indo-Japanese joint-venture firm mainly focusing on autologous adult stem cells; more specifically limbal, haematopotic, mesenchymal liver and corneal endothelial precursors stem cells. It has collaboration with various public and private institutes in Japan. The institute in Japan helps NCRM in stem cell basic research. It has linkages with different hospitals in the country for research and clinical application of stem cells (Tiwari and Desai, 2011). A representative of the NCRM explained his activities:

> "We are providing basic research and cell processing services to the hospitals. We provide an autologous bone marrow stem cell isolation service to the hospitals; we don't deal with fetal cells, we don't deal with embryonic stem cells, we don't use animal material or anything, also we don't use allogenic material" (Firm's representative, 2).

However, the work of NCRM as a stem cell service provider was a matter of criticism in 2008 because of its nexus with the Life Line Hospital, Chennai, which offers unproven therapy to the patients (Pandya, 2008). It seems that after this criticism NCRM suspended its services to the Life Line Hospitals as per the information provided on the company website, viz. *"our services were*

provided to this institute (Life Line Hospital) until 29th Feb 2008".[11] This type of nexus is termed 'bionetworking', which is conceptualised as a network of plurality of actors in biotechnological ventures. It facilitates the selling of stem cell services as an experimental therapy (Patra and Sleeboom-Faulkner, 2009; Sleeboom-Faulkner and Patra, 2011).

The Advanced Neuro-Science Allies (ANSA), a stem cell research and development company based in Bangalore, also focuses on adult stem cells similar to the above-mentioned firms. Their main thrust is on mesenchymal adult stem cells. ANSA has done some clinical trials at a small level for the disease conditions like multiple sclerosis, Parkinson's disease, cerebral palsy and traumatic brain injury as per information provided by the co-founder of the company (Firm's representative, 7). Currently, researchers at ANSA are working on diabetes type 1. ANSA's long-term plan is to produce stem cell products and services at an affordable cost so that poor people in India can get benefit from the stem cell technology.

4.3 Stem cell clinical applications

In India, significant numbers of public and private hospitals are involved in the clinical applications of stem cells. They are offering various kinds of stem cell based therapies to the patients for a wide range of incurable diseases using adult stem cells. Only, The Nu Tech Mediworld is offering embryonic stem cell

[11] http://www.ncrm.org/media/pm12jun07.htm [Accessed May 10, 2011].

treatments. Stem cell based treatments have attracted a significant number of local and international patients towards various hospitals the so-called 'stem cell tourists' (Cohen and Cohen, 2010). The projected market of stem cell therapy in India is worth US $8 billion by 2015 (The Indian Express, 2012). However, the therapeutic applications of stem cells in India have raised several ethical issues in the absence of regulatory approval and clinical evidence.

AIIMS has done a few stem cell transplantations for some disease conditions over the years. The first use of stem cell in 35 cardiac patients by the clinicians at AIIMS was reported in the media and science magazines in 2005. The stem cell injection was given to these patients between February 2003 and January 2005 (Biospectrum, 2005). However, these stem cell transplantations were criticised on ethical and safety grounds since AIIMS failed to provide any proof of the ethical clearness and the experimental and clinical study prior to applying this therapy to the patients (Pandya, 2008). For example, the Deputy Director-General of the ICMR Dr Vasantha Muthuswamy had argued at that time, "We are only a block away from AIIMS and we did not know this was happening there. If the nation's premier medical institute did not ask our permission for such therapy, how can we blame private clinics for what they do?" (Jayaraman, 2005). There was also a report that AIIMS did not fully inform the patients about the pros and cons of stem cell treatments. Following the widespread criticisms, AIIMS made an announcement about the abandonment of this kind of treatment. It appears that AIIMS is now moving

in this area cautiously as it has recently dropped two stem cell trials related to muscular dystrophy and motor neuron disease because of poor patient response (Krishnan, 2009).

LVPEI has treated 750 patients as told by the director of the Institute during a field work visit (Clinician, 8). It is worth to highlight here that many patients were treated free of charge (Lander et al., 2008; Tiwari and Desai, 2011; Vemuganti and Sangwan, 2010). However, in 2006, the stem cell transplantations procedure at LVPEI came under scrutiny when a team of international ophthalmologists criticised the existing stem transplantation procedures, where human and/or animal materials were being used for the limbal stem cell growth (Schwab et al., 2006). These ophthalmologists had reviewed all the clinical trials worldwide between the period July 1, 1996 and June 30, 2005, including LVPEI clinical trials. The use of bioengineered ocular surface tissue in transplantation procedures was basically examined during this review. It was observed that the "current investigational protocols rely on the use of animal and/or donor human tissue products and thus carry the potential to induce xenogenic microchimerism in recipients or disease transmission through contamination with bacteria, viruses, or other infectious agents, such as those responsible for transmissible spongiform encephalopathy" (Schwab et al., 2006: 1,734). In response to this report, a clinician at LVPEI had admitted the 'potential risk'; however, he denied any adverse effects of stem cell transplantations in his patients (Gulf Times, 2007).

The most 'notorious' hospital in India is The Nu Tech Mediworld, which has attracted great attention at national and international platforms for its unproven embryonic stem cell treatments. This is a private stem cell clinic run by an obstetrician Dr Geeta Shroff in New Delhi. She claims to have treated more than 800 patients from 35 different countries using embryonic stem cell for the ailments such as Parkinson's disease, eye disorders, diabetes, cardiac problems and spinal injuries. Dr Shroff also stressed that none of her patients have shown any side effects. She has filed a patent, claiming that "terminal disease and other disorders or conditions that may be treated or ameliorated according to the present invention include, without limitation, cancer, liver and kidney disorders, nervous system disorders, skin disorders, autoimmune disorders, genetic disorders, eye disorders, musculoskeletal disorders, fertility and reproductive disorders and cardiovascular disorder" (Tiwari and Desai, 2011; WO 2007141657 20071213). In her patent application, around 80 diseases are listed which might be treated by this new medical technology (Sipp, 2011; Tiwari and Desai, 2011). It is worth to mention here that, she never published her findings in peer-reviewed journals. However, she has filed a patent (Cohen and Cohen, 2010; Khullar, 2009; Tiwari and Desai, 2011). In a recent meeting at the 2nd Annual World Stem Cells & Regenerative Medicine Congress Asia 2010 in South Korea, Dr Shroff explained her method of treatment and the clinical results of 108 patients suffering from spinal cord using human embryonic stem cell (Dash, 2011; Pandeya, 2010). However, in the absence of any peer review, stem cell experts across the world are

sceptical about the claims made by her (Cohen and Cohen, 2010; Khullar, 2009). In December 2010, there were reports in the media that Drug Controller General of India (DCGI) had asked Dr Shroff to explain her claims to have successfully treated patients and to show whether she has an approval from any regulatory body (Pandeya, 2010). Similar action was also taken from the government of India in 2006 when an inquiry was set up against Dr Shroff's stem cell treatments. There was promise from the Ministry of Health that strict action would be taken once the inquiry report came out. However, Dr Shroff still continues with her work (Cohen and Cohen, 2010; The Hindu, 2006).

The Chaitanya Stem Cell Centre is part of Chaitanya Hospital, located in Pune. As per the information on the hospital website, it claims to treat more than 92 patients using patients' own bone marrow stem cells with a success rate of 70%. This centre offers therapy for a wide range of diseases including spinal cord injury, diabetes, stroke, autism, liver diseases and motor neuron diseases. The hospital offers different 'medical tourism packages' for different diseases[12]. Its' website reflects that, this hospital is using stem cell as a standard mode of treatment. However, during a field work visit, the hospital management stated that it is still an experimental therapy (Clinician, 9). It can therefore be argued that, through false claims, this hospital is exploiting the patients. The website is fully loaded with patients' experience, which is a kind of 'informal advertisement' and is violating the medical code of ethics as per

[12] http://www.chaitanyastemcell.com/index.php [Accessed May 04, 2011].

the Medical Council of India. The Chaitanya Stem Cell Centre is also involved in a stem cell clinical trial in collaboration with Reliance Life Sciences, Mumbai[13].

A hospital in India is offering stem cell therapies in combination with India's traditional medicine Ayurveda, named Crystal Hospitals Ltd. This hospital is based in Mumbai. Its website highlights that 500 patients have been treated with the combination of stem cells and Ayurveda. The hospital has a slogan for stem cell based therapy, i.e. *"Ayurveda" of Allopathy*. Apart from making claim for treating most of the untreatable diseases, it also promises to reduce age by 10 to 20 years and enhancement of beauty by the stem cells. Crystal Hospitals Ltd has collaboration with Ree Laboratories Pvt. Ltd, another biotechnology company engaged in stem cell banking and treatment. Ree Laboratories provides stem cells to Crystal Hospitals for the treatments (Sipp, 2011).

Sir Ganga Ram Hospital, a private hospital based in New Delhi, is involved in stem cell research and therapy. It was reported that nearly 60 patients were treated at this hospital using stem cells by the beginning of 2011 (Jha, 2011).

The Fortis Hospital in Delhi offers stem cell treatments for arthritis, bone regeneration, cartilage regeneration, non-healing wounds and chronic pain. In the beginning of the New Year 2011, Fortis Hospital drew the attention of the media after the treatment of an Iraqi national using stem cell injection.

[13] http://ctri.nic.in/Clinicaltrials/pubview2.php [Accessed May 04, 2011].

However, the ICMR raised concern over the unproven therapy offered by the Fortis Hospital since it is still an experimental therapy and has not been authorised in India (Chatterjee, 2011).

The Life Line International, Chennai, The Medanta Medicity, Gurgaon, Apollo Hospitals, Narayana Hrudayalaya, Jain Institute of Vascular Sciences (JIVAS), BGS Global Hospital in Bangalore, The Sion Hospital in Mumbai and PGI Chandigarh, among others, are also offering stem cell therapy for various disease conditions, basically using adult stem cells.

A few banking firms also jumped in the clinical applications of stem cells. For example, International Stem Cell Services Ltd (ISSL) is basically a stem cell banking company located in Bangalore. In recent years, it started offering various stem cell based treatments for the disease conditions such as Buerger's disease (critical limb ischemia), chronic liver and kidney failure, osteoarthritis, muscular dystrophy, myocardial infarction and spinal cord injury. ISSL has also conducted clinical trials for some of the above-mentioned disease conditions as per information provided by the representative of firms during field work (Firm's representative, 5).

4.4 Umbilical cord blood banking

There are significant numbers of multinational firms in India who are involved in cord blood banking. Most of them are offering private banking where they charge US $1,500- US $2,000 to the expecting parents to preserve their child's

cord blood. Given the high birth rate in India the projected market of private cord blood banking is worth of million dollars.

Life Cell International in India is one of the leading cord blood banking firms; it started functioning in the year 2004 in collaboration with CRYO-CELL International Inc. and is based in Chennai. The company has invested US $4 million. It has about 50 centres in different parts of India. LifeCell has so far collected over 25,000 cord blood units. However, the representative of the company during an interview felt that, given the population of India, this collection is very low (Firm's representative, 3). It charges close to US $1,500 for preserving each unit of cord blood component for a period of 21 years. The transplant centre of the company is set up at Sri Ramchandra Medical College, Chennai. It has accreditation from the American Association of Blood Banks (AABB). Life Cell has tied up with Hindustan Lever Limited for cord blood banking for its employees. The employees pay half the amount and the rest is paid by the company. Life Cell has similar collaboration with Starcom and India Inc. (Ilic, 2006).

StemOne Biologicals Pvt. Ltd was first established in 2005 as Cord Life Biotech Pvt. Ltd. It is basically involved in private cord blood banking. In recent years, it has expanded in the area of stem cell based research and therapies as well. StemOne Biologicals has collaboration with the NCRM for cryopreservation. It has collected around 1,500 cord blood units.

Cryobanks International India is a joint venture between Cryobanks International USA and RJ Corp India, based in Gurgaon near Delhi. It was

established in 2006. Cryobanks International India offers services for the private as well as the public cord blood banking. It has also shown interest in the development of stem cell therapies for cardiac disease and diabetes. Its website shows that it has collected 15,000 samples of cord blood stem cells.[14]

CordLife Sciences India Pvt. Ltd is located in Kolkata. It was launched in 2006. It is part of the Cordlife group, which is considered to be Australasia's largest network of private cord blood banks. Apart from India, it is also operating in China, Hong Kong, Singapore, Philippines and Indonesia. It has a storage capacity of up to 150,000 cord blood units.

Cryo-Save India was established in 2009. It is based in Bangalore. It is a subsidiary of Cryo-Save, Netherlands. Cryo-Save is working in 40 countries. In India, it has collected around 7,000 samples of the cord blood in urban areas. Given the opportunity of more business in rural areas, it is in the process of expanding its business in the rural areas of different parts of India. At the beginning, it targeted rural areas of Northern and Western parts of India (Vijay, 2011).

The Jeevan Blood Bank and Research Centre is located in Chennai. It is a not-for-profit blood bank established in 1995. It started its stem cell umbilical cord blood unit in 2010 as per the information provided during the field visit (Firm's representative, 1). The nature of this bank is both public and private. However, the majority is 'public' in nature. It has so far collected 500 samples

[14] http://www.cryobanksindia.com/cryobanks-india.html [Accessed May 05, 2011].

of cord blood donated by the general public. Jeevan is interested to expand its inventory size but there is a problem of funding, as one of its scientists stated that:

> "we are working towards an inventory size of 30,000 because only with that kind of size do we have a hope that we might be able to issue cells to people who require them; but our major problem is that we have not had adequate funding, rather I would not say adequate funding but we have no funding, in terms of help from the government whether at the state or central level" (Firm's representative, 1).

The Regenerative Medical Services (RMS) Pvt. Ltd was started in 2007. It is basically a cell therapy division of Satyan Interchem Pvt. Ltd. Satyan Interchem Pvt. Ltd. is a pharmaceutical and specialty chemicals supply company located in Mumbai. The subsidiary of RMS, Babycell India, is involved in cord blood banking. RMS has collaboration with Sewan Cellontech, South Korea for the transfer of technology.

StemCyteTherepeutics India (SCIPTL) is a joint venture between StemCyte Inc. (USA), Apollo Hospital Enterprises Ltd and Cadila Pharmaceuticals Ltd, headquarters located in Ahemdabad. It was established in 2007. The company is interested to build a cord blood inventory of the ethnically diverse Indian population with the storage capacity of 25,000 cord blood samples. SCIPTL is also interested to conduct some clinical trials related to stem cells based therapies.

Nanog India Pvt. Ltd is a Pune based cord blood company. It is a subsidiary of Nanog International, Italy. Nanog India has alliance with the Stemone Biologicals for laboratory facilities in India.

Pacific Stem Cells, Hyderabad; Tran-Scell Biologics Pvt. Ltd, Hyderabad; Histostem; Karnataka Stem Cell, Bangalore; Advanced Cell Therapeutics, Mumbai; and IQRA Biotech Services, Lucknow are some of the emerging players in the business of cord blood banking in India.

4.5 Knowledge production

The universities are emerged as the main centre of knowledge production in India. They are producing knowledge in two ways, firstly through basic research and secondly by starting courses related to stem cell (Tiwari and Desai, 2011). The school of life sciences at Jawaharlal Nehru University (JNU), New Delhi has started basic research on multipotent adult progenitor stem cell as informed by a Prof of the school during field visit (Scientist, 4). Similarly, The University of Delhi in collaboration with the Indian Institute of Nuclear Medicine and Allied Sciences, New Delhi is conducting research to study the basic mechanisms of stem cell function (Lander et al, 2008). At the University of Hyderabad, scientists are engaged in neural stem cell research (Tiwari and Desai, 2011). The Special Centre for Molecular Medicine, Jawaharlal Nehru University, has started teaching on 'Stem cell research and its application in human health' in its pre-PhD course (Tiwari and Desai, 2011).

Similarly Guru Gobind Singh Indraprastha University, New Delhi, in the curriculum for the Masters of Technology degree has included the topic 'Stem cells in health care' (Greenwood et al., 2006; Tiwari and Desai, 2011). The Department of Zoology at the University of Madras, Chennai, has started a one-year PG Diploma programmes in 'Molecular cell biology and stem cell technology' (Tiwari and Desai, 2011).

Some firms have established linkages with universities for the production of knowledge. For instance, Nichi-In Centre for Regenerative Medicine, Chennai has started the doctorate programme on stem cells in collaboration with Acharya Nagarjuna University, Guntur. The university gives recognition of the doctorate programme of this firm. Similarly, Life-Cell has established the 'Tri Cell' stem cell centre to understand haematological diseases using stem cells.

In addition to universities and firms several medical colleges are also engaged in knowledge production of stem cells such as AIIMS, New Delhi, PGI, Chandigarh, SGPGI, Lucknow, CMC, Vellore, SVIMS, Tirupati, etc. (Tiwari and Desai, 2011).

4.6 Linkages

The government of India has taken some steps to establish linkages between basic and clinical research. The mandate behind the establishment of inStem is very much in this direction. inStem will work in collaboration with the clinicians of CMC, Vellore. inStem has already started some collaborative

research programmes with overseas institutes such as the Institute for Integrated Cell Material Sciences, the University of Kyoto, Japan. The National Centre for Biological Sciences (NCBS) is a part this collaborative research programme. In addition, inStem has also signed a Memorandum of Understanding with the US-based, California Institute for Regenerative Medicine to start a collaborative research project (Tiwari and Desai, 2011). It is interested in promoting a public-private partnership with the help of another newly established institute, the Centre for Cellular and Molecular Platform Technologies (C-CMAP), Bangalore in order to bring bench side research to bed side.

The DBT has launched the city cluster programme. The main aim of this programme is to share information and to explore collaboration between the basic researchers and the clinicians. Delhi, Bangalore, Vellore, Pune and Hyderabad are included in the city cluster programme. The city cluster programme facilitates linkages between public and private players. For instance, the stem cell city cluster programme at Bangalore consists of the Indian Institute of Sciences (IISc), NCBS, Manipal Hospital, CMC, Vellore and a local company (Tiwari and Desai, 2011).

The different hospitals, firms and research laboratories have established linkages with different national and international organisations. They have linkages with various research laboratories and stem cell firms (Tiwari and Desai, 2011).

For the basic research, LVPEI has recently started a collaborative project with the University of Sheffield, UK. This collaborative project aims to develop biocompatible materials for stem cell transplantation. The biocompatible materials are being developed by the researchers of Sheffield University and their clinical evaluation is being conducted at LVPEI. It is hoped that, if successful, these synthetic materials will be safer and more affordable than the human amniotic membrane which is currently being used for the growth of limbal stem cells. This project is being funded, under the scheme "R&D for Affordable Health Care in India". The scheme was launched in July 2010 by the DBT in collaboration with the Wellcome Trust, UK to support R&D projects for the development of innovative health care products at affordable costs.

Fortis Healthcare (India) Ltd has collaborated with California-based TotipotentRX Cell Therapy Pvt. Ltd for the stem cell clinical trials, at selected Fortis hospitals. The main focus is on stem cell clinical research for disorders such as diabetes, cancer, cardiovascular disease, and neurological ischemia (The Economic Times, 2011).

CCMB is engaged in a collaborative cardiac stem cell transplantation project with NIMS, The Madurai Kamaraj University and The Wellcome Trust Sanger Institute UK (Tiwari and Desai, 2011).

There seems to be strong linkages between various hospitals and firms in India. RLS has collaboration with AIIMS, New Delhi, and Aditya Jyot Eye Hospital, Mumbai, for clinical trials. For cardiac stem cells it is working with Sir Hurkisondas Nurrotumdas Hospital, Mumbai by establishing a stem cell

research laboratory. RLS provides its services to hospitals for the extraction of stem cells from bone marrow (Dutta, 2006, Tiwari and Desai, 2011).

RLS is also working with different government research laboratories such as NCCS, Pune and NCBS, Bangalore. NCCS, Pune has provided storage facility to embryonic stem cell lines of RLS. Similarly, NCBS, Bangalore has also collaborated with RLS for stem cell facilities (Tiwari and Desai, 2011).

Stempeutics has established its linkages with different hospitals and research institutes. It is not directly involved in any kind of stem cell based therapies similar to RLS; rather it offers various stem cell based services to its collaborating groups. Stempeutics has signed a MoU with India's leading pharmaceutical company, Cipla for marketing of its stem cell products (Tiwari and Desai, 2011). Under this collaboration Cipla is investing up to US $ 10 million in Stempeutics for research and development of stem cell products. In return Cipla will get marketing rights.

Similar to other players NCRM has collaborated in both basic research and therapeutic application of stem cells with different hospitals and research centres. NCRM provides services such as stem cell isolation and NK cells expansion for stem cell based treatments to hospitals based on MoU. The responsibility of NCRM is limited to this stage only. Hospitals further conduct clinical assessment, harvesting and application of stem cells (Tiwari and Desai, 2011).

ISSL has a MoU for banking and therapy with St Theresa Hospital, Bangalore Apollo-BSR Hospital, Bhilai, Tirupti Nursing Home, Bangalore and Sita Bhateja

Multispecialty, Bangalore. It appears that St Theresa Hospital is its main stem cell therapy centre.[15]

4.7 Summary and discussion

It seems that, in India, a lot of activities are going on in the area of stem cells both at the research as well as translational level. In addition, a few academic institutions also started courses on stem cells to understand the basic stem cell science. The government of India is highly supportive of stem cell based research, shown by the increasing budget and different programmes over the years. Recently, new research institutes exclusive for stem cells have been established with government support. The initiatives have been taken to promote collaboration between the basic researchers and clinicians. The leading institutes are working in close associations with each other through city cluster programmes. In addition, the various centres have been able to develop networks in the US, the UK, Japan, Korea etc. and started collaborative research programmes. This could be viewed as a good indicator for the linkages among different actors in the emerging stem cell sector and will perhaps help in the flow of knowledge. Some efforts have also been taken by the government of India to bring both the public and the private players to a common platform which might be helpful in stem cell transplantation.

[15] http://www.internationalstemcellservices.net/stem-cell-therapy.html [Accessed June 21, 2011].

In India, the majority of the research institutes are focusing on adult stem cell research. Only a few scientists are conducting research on embryonic stem cell. It appears that India is unable to develop those 'state-of-the-art' technical skills which are required in embryonic stem cell research. It is pertinent to highlight that, the embryonic stem cell lines, which received NIH funding in 2001, are still not available for researchers. There were reports in the media that the cell lines of NCBS have petered out (The Economic Times, 2007). However, the scientists at JNASCR are able to develop and characterise a few stem cell lines, which are available through the UK stem cell banks.

Similar to research institutes, most of the firms of Indian origin are also involved in adult stem cell research. RLS in the beginning started research in embryonic stem cell but it seems that it is now focusing only on adult stem cells and cord blood banking. Firms in India are interested in the development of stem cell based products. However, some of them are indirectly involved in the therapeutic applications of stem cells in the form of providing services to various hospitals and clinicians. This has been a controversial issue which is seen as a nexus for unproven stem cell treatments.

In India, the majority of foreign origin stem cell firms are engaged in private cord blood banking. The future market of the private cord blood banking is worth millions of dollars, having 25 million births per year in India. It seems that, for this potential market, multinational firms are attracted towards India.

Hospitals in India are offering stem cell therapy for a wide range of diseases. The majority of the hospitals are using the patients' own stem cells derived from bone marrow, i.e. adult stem cells. Only a few hospitals, such as The Nutech Mediworld, are said to treat patients using embryonic stem cells. Some of the hospitals are also treating patients with stem cells from cord blood. However, the overall clinical development and private cord blood banking in India have raised major ethical concerns with respect to patients' safety and their economic exploitation in the absence of peer-reviewed and legitimate clinical trials. Only in the year 2009 did the regulatory authority approve the first 'true clinical trials' in the country; before that several claims were made by different hospitals and individual practitioners to treat/cure patients using stem cells. The clinic based at New Delhi started stem cell treatments at the very beginning of the 2000s using embryonic stem cells and still continues in the venture without having any clinical evidence or publication in any peer-reviewed journals.

The unproven clinical applications of stem cells are directly linked to the existing governance framework and raise an important question as to how various unethical clinical activities flourish in India. This suggests to analysing the raised ethical and governance issues. However, before analysing these issues some other important questions need to be addressed in order to have more nuanced understandings of stem cell proliferation in India. In this area the government of India has invested a substantial amount in basic research. Private players have also made a significant contribution in stem cells. The

significant investment coupled with increasing activities in this area compels us to investigate why the Indian government and various private players have so much interest in stem cells. The clinical activities of stem cell also raises question on similar line that how has it become possible for Indian clinicians to attract several patients for an experimental therapy. It would be meaningful therefore to analyse the expectations of different players with respect to this emerging area.

Chapter 5: Expectations of Stem Cells in India

5.1 Introduction

The discussion in the previous chapter has shown that significant activities are taking place in the area of stem cells in India. Both the public and private sectors have made noteworthy investments in the stem cell venture. New institutes and several new programmes in stem cells have been started in recent years.

Stem cells in India are part of its ambitious biotechnology programme which was described as the next big thing after the software revolution (Bharadwaj and Glasner, 2009). The development of stem cells in India could be seen as a part of its exercise to capture the global biotech market. Various key players and media reports highlighted the potential of stem cells to find answers to some of the pressing questions in biomedical research as well as to cure various debilitating diseases for which there are no treatment options available (Sharma, 2006; Sharma, 2009; The Hindu, 2010; United News of India, 2009). However, there are a number of concerns with respect to unproven stem cell therapeutic applications that are being offered by some of the clinicians and hospitals in India (Biospectrum, 2011; Pandya, 2007). In addition, activities in private cord blood banking have also increased substantially in recent years raising legitimate concerns about its future promises, especially for self-use' i.e. autologous (Kaimal et al., 2009).

In India, therefore, it can be argued that, on the one hand, there are great hopes associated with stem cells; on the other hand, there are fears as well. This chapter of the thesis aims to examine how the different key players in the stem cell sector, such as scientists, clinicians, representative of firms and policymakers, articulate hopes and fears associated with the proliferation of stem cells. This will be examined through the theoretical framework provided by the sociology of expectations (Borup et al., 2006; Brown and Michael, 2003; Hedgecoe and Martin, 2003). This chapter, however, is not limited only to analysing the 'dynamics of expectations', it will also focus on how the future of stem cells is being created in India by different key players and through media and the internet. It has been observed in various social studies of expectations that, in the innovation process, especially for an emerging area of science and technology, the 'creation of futures' is essential to mobilise necessary resources. The chapter will try to investigate on what basis various key players are attempting to mobilise resources for stem cell innovation.

This analysis largely focuses on discussing real-time present expectations of stem cells in India rather than its temporal pattern (Brown et al., 2006) since the Indian stem cell sector is in its early stages of innovation. The discussion in this regard will prepare the ground to analyse explicitly the ethical and governance issues in the next chapters of the thesis, which are, I argue, inextricably intertwined with the real-time current expectations of stem cells.

The growing numbers of studies in the sociology of expectations have mainly discussed, as highlighted in Chapter 2, the role of hope, hype or we can say positive expectations as a performative force, while they largely ignored the role of pessimism, fear or negative expectations in shaping a particular area of science and technology. However, expectations studies acknowledged that fears and risks have a significant influence in technological development (Borup et al., 2006). In a few studies, it was recently analysed that a pessimistic approach or fear can also have the capacity to mobilise the future into the present (Nerlich and Halliday, 2007; Tutton, 2011). I will therefore examine both positive and negative expectations of stem cells in India. Stem cells promise different potential applications ranging from basic research to translational research, including cord blood banking and accordingly different key players might have different expectations (Sunder Rajan, 2006). This chapter investigates whether expectations varied as per different potential applications of stem cells and also tries to analyse whether there are any similarities or differences in expectations discourse between and within the different key players and how these are being institutionalised in different communities of promise, and how expectations vary between different groups.

In doing so, based on interview data and media coverage including the promotional websites of different firms, clinicians and hospitals, I analyse positive expectations of stem cells in section 5.2 as per their different potential applications, and also discuss the expectations of different key

players. Similarly, negative expectations are discussed in section 5.3. The role of media and internet in creating expectations is highlighted in section 5.4. In addition, each section also examines how different key players construct India's strength at the global level, and finally the last section deals with summary and discussion.

5.2 Positive expectations of stem cells

There are high expectations of stem cells across the world (Boseley, 2011; Keller, 2005; Kitzinger and Williams, 2005; Wainwright et al., 2006b). In a report jointly published by The American Association for the Advancement of Science (AAAS) and the Institute for Civil Society, it was argued that:

> "Human stem cell research holds enormous potential for contributing to our understanding of fundamental biology. Although it is not possible to predict the outcomes of basic research, such studies will offer the real possibility for treatments and ultimately for cures for many diseases for which adequate therapies do not exist" (Chapman et al., 1999: iv).

Similarly in a document published by the Government Office for Science, UK, it was expected that, "stem cells have the greatest potential in the field of regenerative medicine, and could see widespread application by the early-mid 2020s" (Government Office for Science, 2010: 18). In this document, it was

also emphasised that there is a great potential for stem cells to transform medicine (Government Office for Science, 2010). As we have seen in the previous chapter, India is also geared up to take potential advantage of stem cells, which is quite similar to the development of the US and the UK. This section aims to discuss the positive expectations of stem cells related to different potentials of stem cells in basic research, clinical applications and cord blood banking, and attempts to analyse on what basis different key players in India are creating a future for stem cells. It will help in a more nuanced understanding of expectations of stem cells in India.

5.2.1 Expectations of stem cell basic research

Many scientists and policymakers are optimistic about stem cells in terms of their use in basic research. It would be interesting to analyse how they portray future prospects of stem cell basic research. The DBT-ICMR guidelines for stem cell research and therapy 2007 also recognise the importance of stem cells for understanding basic biology, which in turn is expected to contribute to understanding how to deal with various debilitating diseases. In 2006, and again in 2009, the principal scientist of the DBT, who is mainly involved in the policy-making process of stem cells in India, published two papers in peer-reviewed journals. These papers, though mainly discussing the overall status of stem cell research in India, also reflected the high expectations of stem cells in the country at government level (Sharma, 2006, 2009). The DBT is currently supporting a large number of stem cell

programmes in basic research, which was highlighted in the previous chapter. During the field work visit, it was observed that scientists in India are very excited about stem cells and they feel that stem cells will be useful in solving the various problems of medical science and will help in regenerating damaged cells, tissues and organs. A scientist illustrated that:

> "any organs damaged by a natural wear and tear process or by some toxic effect of some drugs or by infection, the organs need to be replaced fully or partly because their function is either completely gone or is partly affected, or there are certain cases where there is a genetic disorder in the patient because a certain kind of protein is not able to be produced by that individual. In the case of X-linked recessive disorder, say haemophilia, a particular type of protein is not produced in an individual. In those cases regenerative medicine perhaps helps to take care of the patients with the help of bone marrow derived *stem* cells"(Scientist, 1, *emphasis added*).

Further, he argued that stem cells have the ability to solve the problem of organ shortage, which is considered to be very crucial these days at a global level.

> "If you can create or make an artificial organ outside the body with the help of stem cells then the shortage problem will not come into the picture" (Scientist, 1).

The expectations of scientist 1, in terms of solving the problem of organ shortage using stem cells, could be seen as an effort to mobilise resources, since there is an on-going campaign about a crisis in the supply of organs for transplantation worldwide. For instance, in the US, reportedly 95,000 patients were on the waiting list in the year 2006 (Abouna, 2008). Similarly, in Europe, 10,000 people were on a transplant waiting list in 2008[16]. In the UK alone, 7,980 persons were on the active national waiting list in the year 2009-10 (Farrel et al., 2011). Campaigners highlight the number of deaths in the US and EU arising from this (Abouna, 2008).

The shortage of organs is also one of the reasons behind illegal global trafficking of human organs worldwide. India, amongst many countries, has emerged as one of the preferred places for illegal human organ trade (Scheper-Hughes, 2000), having a large number of poor and vulnerable people. In 2008, a report was published in Time magazine, which established the linkages between desperate foreign patients and black marketing of organs in India (Robinson, 2008).

Against this backdrop, expectations regarding the impact of stem cell research on the burgeoning organ shortage crisis help legitimize and generate resource/funding for this line of research. For stem cells, scientist 1 is creating an expectation on the same lines. On a similar line, scientist 2 also endeavours to set an agenda for raising funds by saying that:

[16]http://www.eppgroup.eu/press/showpr.asp?prcontroldoctypeid=1&prcontrolid=7317&prcontentid=12766&prcontentlg=en [Accessed June 12, 2012].

> "[His] research might help to understand the ways embryonic stem cell combats stress. Embryonic stem cell seems to be better than other cell types in understanding the stress. The embryonic stem cells synthesize a fair amount of serotonin and some of our research suggests that it helps a cell to survive stress ... not clinically might be any immediate help but as if we understand better ... might be some options" (Scientist, 2).

He can 'understand better' only when there would be a favourable environment for basic research in the form of better laboratory facilities and other necessary resources for conducting state-of-the-art research. Increasing budgets for the development of biotechnology and stem cells in particular in recent years suggest that expectations of their future impact on the treatment of debilitating diseases are playing a key role.

However, it is often the case that, "many expectations are widely optimistic and over-estimate the speed and extent of the impact of biotechnology" (Nightingale and Martin, 2004: 546). For example, the US Federal Drug Administration (2004) White Paper states that:

> "Today's revolution in biomedical science has raised new hope for the prevention, treatment, and cure of serious illnesses. However, there is growing concern that many of the new basic science discoveries that have been made in recent years may not quickly yield more effective, more affordable and safe

> medical products for patients. This is because the current medical product development path is becoming increasingly challenging, inefficient, and costly. During the last several years, the number of new drug and biologic applications submitted to FDA has declined significantly; the number of innovative medical device applications has also decreased. The costs of product development have soared over the last decade (FDA, 2004: i)".

Thus, there appears to be a mismatch between expectations of the capacity of biotechnology to revolutionise health care on the one hand, and the impacts of biomedical research in clinical practice on the other. This pattern seems to be reproduced in India in the case of stem cells.

However, by contrast with the sentiments expressed in the FDA White Paper, a representative of firm in India suggests that their basic research will help in bringing down the cost of stem cell based treatments and in the long term enable them to provide affordable products and services to common people in India. He argues that:

> "A normal man in India can't afford it, even if you look at the high middle class person, he also can't afford the treatment because it is beyond his reach and it does not come under the insurance and all. So I want to make this entire procedure very affordable. Now there are two ways to go, one is to make

> official products, which basically people can use, and the other is services" (Firm's representative, 7).

In this context, the representative of firm is invoking the spectre of unaffordability of high-tech medicine for the majority of the population in India to suggest that stem cell work can go some way towards addressing current levels of health inequality. Stem cells are portrayed as the great equalizer, a mechanism for bringing biomedical progress to the masses and, in turn, social justice. However, it is instructive that this future is envisioned by a firm representative, as it implies that the state is not capable of transforming the social relations of the technology in a way that would be possible in a market-based system. The representative of firm here is trying to create a future where, through his 'particular' basic research, it would be possible to provide affordable stem cell based products or services. In India, it is estimated that day by day the costs of medical facilities are increasing. In a recent survey, conducted by the Indian Institutes of Populations Sciences and WHO in six states of India, it was observed that Indians spend 70% of their income to access basic health care facilities and medicine (Zee News, 2011). Increasing health care expenditures are viewed as one of the reasons for poverty in India (Reddy et al., 2011). It appears that, against this backdrop, a firm representative in India makes an effort to justify his basic research and create a scenario where his 'high-tech' research can provide affordable medical services.

Similar to the stem cell scientists and the representative of firm, policymakers in India, as highlighted earlier, who are associated with stem cell development, believe that stem cell research is a promising area and it has many applications. An official of the DBT stated that:

> "It is promising area ... has different applications ... for basic research there is a lot of things that can be done ... can use these stem cells for drug development, for *in-vitro* studies with upcoming nanotechnology; I think that stem cell and nanotechnology have good prospects. Gene therapy always has an issue with viral vectors to carry the gene; I think stem cell can replace those" (Policymaker, 2).

The narrative of the policymaker reflects a largely peculiar feature of biotechnology where there is a tendency of changing expectations over time (Brown and Michael, 2003). It appears that, if a particular expectation fails to achieve desired results, then another expectation is created to sustain a particular area of science and technology. For instance, gene therapy was once heralded as a potential cure for various disease conditions and there were high expectations of gene therapy in the 1990s. However, it failed to achieve those futures which were once created and now focus is turned to emerging areas such as stem cells and nanotechnology (Brown and Michael, 2003; Selin, 2007; Wilson, 2009). Similarly, many proponents of xenotransplantation are now shifting their attentions to stem cells (Brown and Michael, 2003). The shifting focus from gene therapy to stem cells at

government level in India is very interesting in the sense that a nation-state is largely playing a leading role in the creation and maintenance of expectations over time. This is the reason the Indian state is often highlighted as "India Inc." in the Indian press (Sunder Rajan, 2006).

These kinds of expectations coupled with high levels of support from the government have helped in the construction of a favourable environment for the basic research in stem cells. In India, almost every leading government agency, i.e. the Department of Biotechnology (DBT), the Department of Science and Technology (DST), the Indian Council of Medical Research (ICMR) and the Council of Scientific and Industrial Research (CSIR), are supporting various stem cell programmes in different institutes. The government of India has invested US $500 million for stem cell R& D during the period 2004-2007. The private players have also made significant investments (Dey, 2007). As highlighted in the previous chapter, the DBT is supporting around 55 programmes in stem cells. Similarly, the ICMR has also funded around 40 extramural research projects in different areas of stem cell research.

The expectations of scientists and firms in India of stem cells and consequently the greater support from the different agencies could be seen as a step to exploit basic research. Here the assumption is to diffuse or translate knowledge from basic research to the clinic, which is similar to the US and the UK (MRC, 2007; Wainwright et al., 2006b). The development of a translation focus for stem cell research in India is close to what Martin et al. (2008a) have observed in the case of haematopoietic stem cells development

in the West. They argued that "great emphasis is now placed on the exploitation of basic research and creating new policies and institutions to ensure that scientific findings can be applied in the clinic" (Martin et al., 2008a: 29).

On similar lines, recently, inStem has been established in India with the mandate to exploit basic research for clinical applications as highlighted in the previous chapter. Some of the research institutes/medical colleges in India have now started research fellowships for graduate students for conducting research in the different areas of stem cells. It is clear that expectations of stem cells in India have been able to generate resources at various levels, whether at the level of establishing new institutes or starting new programmes for stem cells.

In a study conducted by Alan Cribb and his colleagues, it was observed that the stem cell scientists in the US and the UK are not yet advocating a move from the lab to the clinic on the grounds that more rigorous research is required before doing so (Cribb et al., 2008). Likewise, some of the Indian stem cell scientists' interviews reveal that at the moment their hope with stem cells is confined within the boundary of the laboratory, which is similar to the scientists of Western countries such as the US and the UK. A scientist in India argued that:

> "I would think that in the normal case scenario, you would go step by step...where it is that you figure out the basic questions, try to figure out some answers...go into animal

models...and say from animal to primates and many more"

(Scientist, 2).

The narration of this scientist infers that only after addressing certain questions through basic research should one go to the clinical stage.

The analysis of expectations of stem cell basic research informs that key players such as scientists and a policymaker including a representative of firms believe that stem cells hold great promises for health care and they have potential to treat various degenerative diseases and can restore damaged cells, tissues and organs. The interviewed scientists create a promising future of stem cell basic research on the basis that it can provide a solution to on-going organ shortage problems and it will help in understanding stress. In addition, one of the representative of firms creates expectations for his particular basic research by highlighting that his basic research will help in bringing down the costs of various treatments so that stem cell based therapy can be affordable to common people in India.

The discussion also highlighted the role of the state in creating and sustaining expectations as a policymaker in India portrayed that stem cells can have applications in drug developments and also argued that they have potential to replace shortcomings of gene therapy. It shows the active role of the Indian state in maintaining the expectations of the overall field of biomedical research in the country.

It can be argued that these kinds of expectations over the years have helped in the proliferation of stem cell basic research in India. However,

simultaneously various hospitals, clinics and some firms came up with a claim to treat various chronic diseases using stem cells. It would be interesting to know how these players are creating expectations of stem cell clinical applications in India.

5.2.2 Expectations of stem cell clinical applications

Most of the clinicians interviewed in India are expecting stem cells to cure various chronic diseases for which there are no existing treatment options available or, more specifically, where all treatment options for a particular disease have been exhausted. The clinicians in India are creating a vision of a future where all debilitating diseases can be cured using stem cells. For instance, a clinician in India argued that:

> "I think the stem cell research and therapy has huge potentials; from my own study in embryonic stem cells as well as my role as head of medical services and clinical research here...I have seen patients were improving and benefitting from this therapy basically for disorders on which doctors have given up, there is no treatment available and the patient is deteriorating; we have seen improvement in the quality of life of these patients and there have been considerable benefits to these patients so I think the potential is large if used properly" (Clinician, 3).

This interview material reflected that the clinician is using embryonic stem cells as a treatment modality. However, the website of the hospital shows that only adult stem cells are being used to treat patients. It is pertinent to highlight that, though the clinician has no clinical experience of embryonic stem cells, she is creating a future for embryonic stem cells by saying that they have a 'huge potential'. The key words 'huge potential' and 'potential' have been used in the field of science and technology, more specifically in the emerging area of biotechnologies, to mobilise resources (Brown and Michael, 2003; Kitzinger and Williams, 2005).

In a somewhat similar way, another clinician argues for the use of stem cells as a main line therapy as it has regenerating powers. He recalls that:

> "The treatment for these muscular dystrophies is not present worldwide anywhere so whatever relief we are giving through stem cells that is going to be our achievement only because in spite of the best result in Duchenne muscular dystrophy the child dies by the age of 19 or 20 years and all over the world people are using only cortisol for it as its treatment and everyone knows that cortisol has his own side-effects: water retention, osteoporosis and so many other complications. So if you don't use the cortisol and instead of that you use mesenchymal stem cells, it has regenerative powers and it regenerates the tissue, so why should it not be used – that is

> my question. It should be promoted as main line therapy" (Clinician, 1).

The clinician emphasises that there are no treatment options available for muscular dystrophy and on this basis he advocates that stem cell should be use as a main line therapy. However, in India as per the guidelines for stem cell research and therapy (2007), stem cell based therapies are considered as experimental, except for some haematological conditions. Section 13.1 of the guidelines clearly emphasises that "As of date, there is no approved indication for stem cell therapy as part of routine medical practice, other than Bone Marrow Transplantation (BMT). Accordingly all other than BMT (for accepted indications) shall be treated as experimental" (DBT-ICMR, 2007: 11).

Other clinicians are also creating a future for stem cells, based on their past 'experience':

> "We have seen a lot of improvements in the case of muscular dystrophy...we had moderate improvement in spinal cord injury, multiple sclerosis, stroke. All these patients, for many years, were in very bad clinical conditions; now they are improving, they are better" (Clinician, 2).

Here, the clinician provides particular 'evidences' that he has already treated so many patients with stem cells for various incurable disease conditions such as spinal cord injury, multiple sclerosis, stroke etc. and, he further claims that stem cell will be an important tool to tackle various disease conditions in coming decades:

> "In my opinion, it is going to be the therapy of the next era. I expect that, after 10-15 years, for every intractable problem, this is going to be the solution" (Clinician, 2).

These hopes, promises and expectations of stem cells by the Indian clinicians have framed a bright future in terms of treating various incurable diseases, and it seems that, in the next few years, most of the problems with debilitating diseases will be solved. However, previous studies have shown that these kinds of early expectations rarely materialise and mostly result in disappointment (Brown, 2003; Martin, 2006).

The case of stem cells is also similar to most of the other previous biotechnological 'revolutions'. Stem cell science is still at an early stage of its development and mostly confined at the level of laboratories. The translation of stem cells is long and arduous. There are many obstacles to bring stem cells from laboratory to clinic, in terms of quality control, efficacy and patients' safety (Crystal, 2009; Levine, 2010). However, various clinics in India are offering stem cell therapies to patients in the anticipation of curing all the debilitating diseases for which there are no existing treatments. The narration of clinicians in India and their expectations justify the previous arguments in this domain, where it was argued that "the goals of clinical work are structured around therapy i.e. around curing or benefiting patients" (Cribb et al., 2008: 353).

The stem cell firms in India, another key player in the stem cell arena, have more or less similar expectations of stem cells to clinicians. Firms in India are

mostly engaged in private cord blood banking as discussed in the previous chapter. Only a few firms are conducting research in adult and embryonic stem cells. The thrust is more on adult stem cells compared to embryonic stem cells. Stem cell firms in India are basically involved in stem cell transplantation with their research focusing on the development of stem cell based products for a wide range of disease conditions. They also provide stem cell isolation services to various hospitals and clinicians, which are being used by some medical practitioners as discussed above in the treatment of patients (Pandya, 2008).

Firms in India are also creating a positive future for stem cells in the country. Indian firms promote the idea that the stem cell has an ability to cure various degenerative diseases, as a firm's representative illustrated that:

> "There are several clinical disorders for which traditional medicine does not offer any cure. There is only a certain amount of palliative care for the degenerative diseases. Regenerative medicine is evolving as the new branch of therapy to address this spectrum of disorders and a better understanding of regenerative medicine will pave the path for several newer therapies in the future" (Firm's representative, 4).

On the basis of 'regenerative capacity' of stem cells, firms in India are creating a 'hope' amongst patients:

> "The stem cell based treatment is in a unique space because many of the diseases which we look at, or diseases which have no treatments what so ever right now...we are trying to use stem cells to improve the outcome of that disease, so in that sense we are in the unique space...we are trying to treat disease where these patients and doctors have lost hope for doing anything of this sort" (Firm's representative, 5).

Firms are also promoting the similar idea like clinicians, that stem cells have capacity to treat those diseases for which all traditional treatment options have been exhausted.

The statement of firm's representative 4 reflects the same tone:

> "Today people are going through normal standard therapy. OK...there are still...standard therapies are not able to cure many diseases...they address the system, not the root cause of disease; so in stem cell we are aware that the main purpose of the stem cell is the root cause of the disease, for example in diabetes...can we recreate the insulin generating cell...pancreatic cells...so it is hope for the patient...yes there is possibility, they can hope for getting their disease cure so we put regenerating hope...these patients whether for spinal cord injury or whether it is diabetes or it is liver cirrhosis, so

> for those people the current standard of treatment gives some hope but still with a lot of restrictions...lots of patients not getting a cure...so for those patients I think stem cells can be a bigger hope, it can cure those patients " (Firm's representative, 4).

The stem cell as a future hope is created on the grounds that existing therapies are unable to serve a large number of patients since conventional therapies have many restrictions. The representatives of firms argued that many patients who are afflicted with diabetes, spinal cord injury and liver cirrhosis are unable to get benefit from standard therapy. And for those patients stem cells can be a great hope. It would be worth highlighting here that in India more than 50% of all deaths occur due to chronic diseases and there are millions of the population affected with chronic illnesses such as diabetes, cardiovascular diseases and cancers in the country (Patel et al., 2011). For example, India has around 50 million type 2 diabetes patients (Diamond, 2011). It can be argued therefore that some firms' representatives are taking 'advantage' of having large numbers of patients affected with chronic diseases and portraying stem cells as a potential solution for the same.

It appears that these kinds of hope help in mobilising patients towards experimental stem cell therapy. Patients in India, which include both domestic as well as foreign, are being charged around US $3,000-US $50,000 for a stem cell experimental treatment (Chatterjee, 2011; The Times of India, 2010). It seems that in India also 'hope' became the basis of 'trade' and 'capitalization'

of an unproven therapy (Martin et al., 2008b). This 'hope' in India has put patients at health and financial risks. It has been a matter of national and international criticisms at different platforms. The reasons for these criticisms are: a) there is no animal data for any stem cell therapeutic applications; b) there are no properly phased, blind and controlled clinical trials; c) there is a lack of systematic data regarding clinical procedures; c) there is no follow-up of a patient after the stem cell intervention; and d) moreover, some clinics combine a stem cell transplantation procedure with traditional medicines like Ayurveda and Acupuncture (Murdoch and Scott, 2010; Sipp, 2011). The combination of biomedicine with traditional medicines or alternative medicines is not entirely a new approach, and which is being provided with stem cells in India. It is recognised by many medical systems even in Western countries to use a combination of modern medicines with traditional medicines. For instance, the alternative medicines such as acupuncture, hypnotherapy, aromatherapy, Reiki, and spiritual healing are being used with biomedicine in the UK through some National Health Service (NHS) hospitals and NHS affiliated hospices to treat cancer patients. However, the concern in the Indian case is that still there are no scientific evidences regarding the efficacy and safety of stem cells and there is a suspicion as to whether clinicians in India are using authentic 'stem cells' for treatments (Broom and Tovey, 2007; Sipp, 2011).

Similar to some firms and clinicians, some of the policymakers in India also feel that India can lead in the clinical applications of stem cells. An ex-official

of the ICMR who has been involved in the policy-making process of biomedicine in India for many years, stated that:

> "When we had discussion [in 2002] of course everyone agreed to one thing, that stem cell has a lot of promises and so India should not shy away from stem cell research. India should actively participate in the different types of stem cell research...the reason is of course that we have able scientists in this country who can take up this challenge and do something and also we have a lot of needy patients who will be there so, once the research gets translated into practical applications, many will benefit; and we have also clinicians who are very capable of doing clinical trials and clinical research and so India should take a lead role in this and we should support and promote stem cell research" (Ex-policymaker).

Here again the argument is that India has lots of needy or desperate patients that can benefit from stem cell clinical applications. However, the above narration reflects that, at the moment at government level, India is not advocating direct use of stem cells in clinics. No doubt there is an aim to use stem cells for therapeutic applications but only after going through a step by step process, i.e. from basic research to clinical trials.

The expectations of stem cell regarding its therapeutic applications are being created on the basis that India has lots of needy or desperate patients who are

afflicted with various chronic diseases, and the existing therapies are unable to cure those patients. Clinicians and firms in India are playing a leading role in this direction. It appears that clinicians are comparatively more excited compared to firms since they argued to use stem cells as a main line therapy. In contrast, policymakers believe that only after having rigorous basic research stem cell should be used for various therapeutic purposes.

In India, in addition to stem cell basic research and clinical use of stem cells, the excitement towards stem cell cord blood banking has escalated over the years, given the mushrooming of cord blood banks in recent years. Similar to therapeutic applications of stem cells, cord blood banking, especially those being private in nature, raised legitimate concerns. Firms in India have made several efforts to attract expectant parents to store their child's cord blood. The next section discusses how and on what basis various firms are creating expectations of cord blood banking in India.

5.2.3 Expectations of cord blood banking

Cord blood banking is one of the important constituents of stem cell research and therapy. Umbilical cord blood is viewed as one of the good sources of stem cells. In recent years, various cord blood banking firms have been established with the concept of preserving cord blood. The idea behind it is that, from preserved cord blood, stem cell can be retrieved whenever a patient needs stem cell intervention. There are basically two types of cord blood banking: a) public cord blood banking, which can be used by anyone,

i.e. analogous, and there are no storage fees; and b) private cord blood banking where the purpose of banking is only for the self, i.e. autologous, though it can also be used by siblings or other family members, and for this service banking firms charge expectant parents to preserve their child's cord blood. The various studies in the West have critically examined the role of expectations in cord blood banking (Brown and Kraft, 2006; Martin et al., 2008b). These studies have shown the importance of cord blood banking in the construction of stem cell expectations over the years.

Since most of the leading firms in India are multinational, their strategies are more or less similar to what they adopt to create positive expectations in the West. These firms advertised directly their banking services to the expectant parents through various workshops, seminars or via clinicians and the internet[17]. Expectant parents are being encouraged to 'invest' their money for a 'healthy and happy future' of their child in the name of 'biological insurance'. The advertisement leaflets of companies are making big promises of the benefits of stored cord blood such as "your child and families can [have] access to potential treatments for over 75 serious ailments such as leukaemia, thalassemia, brain injury, juvenile diabetes and many more" (Srinivasan, 2010). Not only firms but the government of India also seems to be very positive towards cord blood banking, given the high birth rate per year in India. An ex-policymaker argued that:

[17] http://www.lifecellinternational.com/expertise-tips-on-pregnancy.aspx [Accessed Feb 12, 2011].

> "That was the time [in 2002] having the slow development of cord blood banks in India and it is also suggested that, yes, cord blood stem cell is a good source, and a country like India where you produce combined Australia and New Zealand every year...OK...that's our annual population is 25 million which is more than the combined population of Australia and New Zealand...Australia is 22 million, New Zealand is 2 million...24 million but we produced more than 25 million per year...so we have enough source material and if we effectively use it probably we can do lot of wonders" (Ex-policymaker).

However, compared to firms, the government of India appears to be more aligned towards public cord blood banking. An official of the ICMR illustrated that:

> "I belong to the lobby that nobody should store their cord blood for future use...unless family, where siblings are suffering or can be used for those siblings...but otherwise it is very important to have public banking" (Policymaker 2).

Despite having criticism of private banking and limited use for the self, private cord blood banking firms have been able to collect a significant sample of cord blood units over the years. The representative of a leading banking firm during a field work visit informed that:

> "Today we have more than 25,000 clients; we have their child's cord blood stored with us" (Firm's representative, 1).

The cord blood banking firms in India are creating expectations on the basis that, if parents can afford it, then they should preserve their child's cord blood, and also some of the banking firms stressed that people themselves want to go for private cord blood banking. A firm's representative illustrated that:

> "There is a lot of hope and hype in the cord blood banking business; there is something which is good about it...there are people who have money who say why not...my child is precious I want to save it; whether it is 100% proven or not there is some justification in saving a child's cord blood and I can afford it, then why shouldn't I do it...people want it...they come up to us and say I want to store it" (Firm's representative, 5).

Over the years, cord blood banking firms have been able to influence expectant parents through their claims to treat large numbers of ailments and have created a 'demand' amongst expectant parents, where affordable parents do not even question the legitimacy of private cord blood banking. They also take 'advantage' of the largely joint family system in India while putting their claims in favour of private cord blood banking. As a firm's representative argued:

> "If there is an indication in the family it is a very good option...it is a very good option...you never know when it might come in handy" (Firm's representative, 4).

It is also reflected from the above statement that not only 'certain future' but 'uncertain future' can also have the capacity to mobilise individuals in a particular direction. *'You never know when it might come in handy'* is somewhat speaking about a 'speculative future'. The representative of firm argues that, at the moment, there might be no benefit from cord blood banking but in future we can take advantage from it. However, the firm's representative is not sure about the future prospects of private cord blood banking.

The other private cord blood banking firms argue that cord blood stem cells have potential to replace bone marrow transplantation and on this basis they are attracting expectant parents. A firms' representative of cord blood banking opined that:

> "We are of the opinion that cord blood banking is useful in terms of regenerative medicine...there is a lot of debate as to how useful cord blood banking is...whether it is worth spending that money for saving your child's cord blood...the opinion we have is that, if you can use these cells for a particular use...cord blood banking originally started as a replacement for bone marrow transplantation...it's very difficult to get bone marrow and to store bone marrow and to source bone marrow is difficult because we need donors...cord blood itself could be a useful alternative for bone marrow" (Firm's representative, 5).

The idea here is similar to what I discussed in the previous section, that stem cells are viewed as a novel form of therapy having the capability to replace those existing therapies which are unable to tackle various debilitating disease conditions. In sum, the expectations around private cord blood banking are created on two key ways. First, if there is an indication in any members of the family of any untreatable disease than cord blood is useful and second it can be used as a replacement for bone marrow.

In these preceding contexts, where there are great expectations associated with stem cells in terms of their potential use in basic research, clinical applications and cord blood banking, India is portrayed as a global player in the stem cell sector.

5.2.4 Expecting India as a global player

The narration of policymakers resonate the fact that the proliferation of stem cells will be able to firmly place India in the global stem cell arena. One of the officials of the ICMR, who is involved in the policy-making process of stem cells over the years, believes that India is not far behind other developed countries, such as the US and the UK, and in the next few years, India will be able to produce some significant results in stem cells:

> "Definitely we are moving at same pace with other developed countries, probably now with Obama saying yes for stem cell research, probably may increase funding in the US but we are

at a par with them and definitely India at least has some results in the next few years" (Policymaker, 1).

It is clear from the overall narration of different key players of stem cells that in India there are positive expectations of stem cell in terms of its capability in basic and translational research as well as in cord blood banking. In spite of the absence of any legitimate products or services, the stem cell sector in India has raised a significant amount of funds and attracted many patients, not only from India but from different parts of the world as well. Drawing from the notion of Biocapital (Sunder Rajan, 2006), I would argue that, at least in the case of stem cell, India is more close to commercial capitalism rather than commodity capitalism. It could be seen as a departure from its initial mode of commodity capitalism, which was highlighted in the case of drug development in India by Sunder Rajan (2006). It appears that the Indian stem cell sector is now embracing the corporate culture of Western economy such as the US where vision, hope, hype etc. dominate the bio-economy rather than tangible products and services (Sunder Rajan, 2006). The narration of a policymaker regarding the potential of cord blood banking in India elucidates that India is on the path of speculative capitalism. It can be argued that post-liberal (1991) India has cast off its largely socialist character and now endorses the corporate culture of the West, especially after it became the signatory of the TRIPS patent regime in 2005. For instance, India has recently introduced, the "Protection and Utilization of Public Funded Intellectual Property (PUPFIP) Bill, 2008", similar to the Bayh-Dole Act 1980 of

the US. This bill allows universities and autonomous research institutions to patent publicly-funded research. This exercise of the Indian state reflects that now India has also flexed its arms to commercialise its research. There is an apprehension that the Indian version of the Bayh-Dole Act will have a drastic effect in the health sector of India, leading to denial of basic health care to millions by increasing the cost of medicine (Prakash and Abraham, 2009).

However, it would be premature to draw a conclusion that India has started to fully imitate the corporate culture of US science since, in the same year i.e. in 2008, India adopted the Open Source Drug Discovery (OSDD) model, which discourages the property rights for neglected tropical diseases. The motto of OSDD is to make a balance between health as a right and health as a business and to provide "affordable health care for all".

The PUPFIP and OSDD approach together elucidates that currently India is at the crossroads of bio-politics, which embraces both contrasting and opposite natures of bio-economy together and hence it can be inferred that India has geared up for a strong market-centric approach to capture the global market of knowledge-based economy with strong social backing.

Though at government level India is projected as a global player, some of the key players believe that it is too early to expect India as a global player.

5.3 Negative expectations of stem cells

Though, the majority of key players have a very positive attitude towards stem cells as per their institutional settings, some of the key players, such as scientists, believe that, it is very early to move from lab to clinic. A scientist argues that:

> "[I think] we are giving hope too soon; maybe it is going to be good but I think we need to watch and be little more cautious...we don't know if there are going to be any other side-effects so I think, unless it is going to be followed with first of all experiments on animals then translate to human beings then followed in human beings for at least 4 to 5 years to ensure that there are no side-effects, only then we should really be offering it as treatment in my opinion" (Scientist, 3).

Another scientist expressed his concerns during an interview about the possible side-effects of stem cell intervention in human beings:

> "In my opinion, because it is a case of human subject and you are intervening in the normal system by putting some cells...there is a possibility that those cells may behave abnormally on another side; or in other words there is the possibility of some tumour formation" (Scientist, 1).

The side-effects of stem cells are already reported in some cases at the international level, which questions the legitimacy of high expectations in this area (MacReady, 2009).

Against the policy makers (section 5.2), some scientists in India argue that there is only hype of stem cells, and they do not believe that India is as strong as the West:

> "I don't think we are that strong. There is lot of hype associated with this. I think we are starting okay. We got some people and some good ideas and fortunately we are getting better funding so it looks like we'll do well in future. At this point, if you see how we are in terms of other countries, that we are at the forefront of research, I don't agree with that" (Scientist, 1).

Another scientist stated that:

> "I find this a very hyped statement; nobody can say that India will not be a global player in anything, whether it be car manufacture or information technology or stem cells, but realistically speaking in terms of how much stem cell research is going on in the country, while there are some pockets where there is very good research, which is world-class going on, by and large we still have not reached the stage in many areas where we can say that we are going to be a global player" (Scientist, 2).

It can be argued with the help of the above interview materials, that in India, as far as the future of stem cell clinical applications is concerned, it is highly contested. However, in terms of application of stem cell in understanding basic biology and to enrich their basic knowledge, scientists in India feel that stem cell can be a good source. The narration of Indian scientists, which is similar to the scientists of the US and the UK, at least in the case of stem cell science, reflects the normative structure of scientists across the world where the main aim is to enrich 'basic' or 'fundamental' knowledge (Cribb et al., 2008).

The narration of key players in the Indian stem cell sector shows that the 'future depiction' of stem cell in India is similar amongst different stakeholders in terms of its promises. However, there is a difference of opinion on how to achieve that 'future'. The difference of opinion is more explicit between scientists and clinicians. While clinicians are ready to use stem cell as a main line therapy, in contrast scientists feel that more rigorous research is required before offering stem cell based treatments to patients.

5.4 Creating expectations through media and internet

In addition to key players associated with stem cell development, the media are playing a major role in the creation of high expectations of stem cell amongst the general public in India. In the area of science communication the role of the media has been given foremost importance. It was observed that

the media act as a broker between science and the public and play a fundamental role in shaping the public views for a particular scientific endeavour (Caulfield, 2004; Nelkin, 2001). The science news coverage in the media largely influences the attitudes of the public towards science, which helps in setting the agenda for public policy (Nelkin, 2001). In addition, it creates high expectations amongst the general public of emerging new research areas, which not only help marshal resources for an early investment but also assist in building public trust. It was believed that public trust is very crucial for controversial technologies such as human genetics and stem cell research (Caulfield, 2005). However, at the same time, the growing body of literature in this domain has criticised the role of the media in raising 'unrealistic expectations' of genetics and stem cell research, which have several social, ethical and commercial implications (Caulfield, 2004; Wilson, 2009). In addition to media coverage, especially in the case of stem cell, the direct-to-consumer advertisement via the internet has played a vital role in generating expectations regarding its 'potential' in treating various incurable diseases (Lau et al., 2008).

In the case of India, the expectations of stem cell have been maintained since 2001 through various media coverage, internet and public statements from different stakeholders over the years. Some of the policymakers also portrayed positive expectations through publications in peer-reviewed journals as well (Sharma, 2006, 2009). In the year 2001, when India's two research laboratories drew attention at global level by getting NIH funds for

their existing embryonic stem cell lines, the daily *Washington Post* highlighted India's achievement with the headline *'India Plans to Fill Void in Stem Cell Research'* (Laxmi, 2001). Subsequent years have witnessed a wide range of cover stories and case studies in various national and international newspapers, which portrayed India as an emerging global player in stem cells, not only in basic research but also in clinical applications. From journalistic points of view these news items attempted to balance the story by highlighting various concerns of safety and social issues. However, catchy headlines and a few quoted statements largely draw the attention of common people towards stem cells. For instance, one of the leading news agencies in India under the headline *'Stem cells: a new hope for diabetic patients'* depicted that "India's stem cell research can change the way health care is practiced" (United News of India, 2009). Similarly, recently a story was published in *The Hindu* with the headline, *'Delhi doctors save Pak boy with stem cell transplant'* (The Hindu, 2010).

Furthermore, various news items published the statements of leading policymakers full of hope, such as "Once we achieve success, around 58 million cardiovascular disease patients and 10 million cancer patients, among others, can benefit from it" (Indo-Asia News Service, 2006). Some of the leading Indian science magazines in their coverage represented stem cells as 'miracle cells', where it was highlighted that stem cells not only have the capacity to treat large numbers of incurable diseases but also they can offer possibilities of endless life (Dey, 2007). It appears that 'strategically' there is a

projection of various disease burden and simultaneously stem cells as a possible 'miracle' to tackle these diseases through the media in order to mobilise patients towards stem cell intervention.

Not only the Indian media but also the international media either directly or indirectly are also engaged in creating high expectations of stem cells in India. *The Global Post*, an online US news agency, recently published a story about the controversial clinician Dr Geeta Shroff, based in New Delhi with the captivating headline, '*Unfettered by regulation, India pulls ahead on stem cell treatments*' (Khullar, 2009). This story was based on interview materials with different experts. The quote of a US-based physician, who visited Dr Shroff's clinic in 2007, illustrated that "India is at the forefront of emerging stem-cell treatments in many ways." Further he argued that "convinced of their superiority, American scientists hate the notion that the hottest breakthroughs may be happening in other parts of the world and vociferously denigrate them" (Khullar, 2009).

However, it is not often the case that the news coverage portrayed only positive stories; it also highlighted concerns and warnings of stem cell policymakers about the possible harm and potential risks with headlines such as '*Patients beware: Stem cells won't cure it all*' (Vora, 2011), '*Misuse of miracle cure feared*' (Perappadan, 2005), '*Fortis uses stem cell shot, medical body calls it "illegal, unethical"* (Chatterjee, 2011).

Despite concerns, it seems that patients are highly influenced by the largely positive coverage of the media, given the fact that thousands of patients have

received stem cell interventions over the years at different hospitals and clinics in India (Harachand and Brahiwal, 2011). Similarly, the expectant parents are luring towards private cord blood banking. It was estimated that on average, per year 30,000 Indians opt for cord blood banking (Vora, 2011). In addition to the media, the websites of various stem cell hospitals, clinics and firms, which are heavily loaded with promises of stem cells and various claims to treat/cure patients, are creating expectations of stem cell based treatments. These websites are also using patients' testimonials and stem cell related promotional videos to support their claims[18][19][20].

Generally, the media coverage on biotechnology is seen as an exercise to draw attention towards research activities of a particular institute, which helps in attracting funds and in raising the research profile of that particular institution. These efforts are basically confined in the developed countries where research is largely viewed as a commercial enterprise. However, it was argued that 'hype' through the media might generate unrealistic expectations about the potential benefits of a technological intervention and consequently there is apprehension that, if the given expectations are somehow unable to materialise, then it will not only erode the public trust but also the credibility of a particular research stream will be mooted (Caulfield, 2004). The discussion of media coverage and advertisement through the internet about

[18] http://www.chaitanyastemcell.com [Accessed Dec 17, 2011].

[19] http://drrajput.co.in [Accessed Sept 14, 2011].

[20] http://www.lifecellinternational.com [Accessed Dec 13, 2010].

the potential benefits of stem cells in India shows that now the developing world has also begun to imitate the research culture of the developed world at least in the area of stem cell.

5.5 Summary and discussion

This chapter has discussed the real-time current expectations of stem cells in India under the theoretical framework offered by the sociology of expectations. The previous studies in this domain, which were largely confined in Western settings, have highlighted that high expectations of a particular technology are used as an effective tool for mobilising resources and to establish various socio-technical networks. My discussion in this chapter also reflects a similar occurrence in a non-Western setting. Over the years the great expectations of stem cells have been able to mobilise substantial investments for both the public and the private sector in India and also established a close network of different key players. While analysing the expectations of different players, it was observed that clinicians are more excited about the therapeutic applications of stem cells in comparison to other players such as scientists, firms and policymakers since they advocate using stem cells as a main line therapy. If we compare the narration of scientists and clinicians in India, it can be argued that the professional norms across the world are the same, at least in the case of stem cells, i.e. scientists are more interested in basic research while clinicians are more interested in clinical applications (Cribb et al., 2008).

The analysis in this Chapter depicts that in India expectations of stem cells are being created mainly on the basis that stem cells have the capacity to understand the many problems of basic research and to address various intractable diseases including the problem of organ shortage. In addition, it was portrayed that India have many desperate patients and expectant parents and for them stem cell is necessitate. It was also stressed that stem cells can provide affordable medical services to a large number of poor people in India. To attract expectant parents for the private cord blood banking, it is emphasised that it is not only useful for the self but also for the other family members and it has the capacity to replace bone marrow blood cells.

Furthermore, there is a projection that India will be able to establish herself at the international level by the promotion of stem cell in the area of science and technology. This could be one of the reasons behind the major government support and funding for various stem cell research programmes in the country and the involvement of government in the creation of hope for the potential benefits of stem cells.

The government of India is now also interested in capitalising on its research investment. The introduction of the PUPFIP bill could be seen as an effort in this direction. However, the presence of the OSDD model simultaneously informs that India is still not ready to fully shed its socialist character. Nevertheless, the expectations of stem cells reverberate that, at least in this emerging area, India is preparing herself to adopt the corporate culture of the

West, especially of the US. It can be argued that, under the current environment of the TRIPS regime, India is gradually adopting the corporate culture of the US, at least in the kind of technological development where there is a competition for intellectual property rights. To sustain the current global regime, a country needs substantial investments in R&D programmes and it can only be possible under a favourable and acceptable environment within a particular national regime. The support of a wider section of society thus becomes necessary to justify investment in an emerging area of research and it can only be achieved when a particular research area promises to solve many existing problems. The articulation of vision, hope and hype with respect to a particular technology is viewed as an effective tool to attract public support and consequently investment. However, expectation studies and other related discourse in this domain argued that, if given expectations were unable to materialise or more specifically the expectations were unmet, this might result in damaging the public trust and hence the proliferation of technology. The case of gene therapy is widely cited to support this claim (Wilson, 2009).

Though expectation studies speak about the possible damage of a particular technology because of unrealistic or high expectations, they do not explicitly pay attention to the ethical implications of high expectations, especially in the area of biomedical research where technologies such as gene therapy and stem cells potentially have several risks. In the past, it was argued the high expectations of gene therapy led to the death of an 18-year-old, Jesse

Gelsinger, during a clinical trial (Wilson, 2009) and recently, it was allegedly reported that an Israeli boy has developed a tumour after several stem cell interventions in a clinic based in Moscow (Amariglio et al., 2009).

In the Indian scenario high expectations of stem cells have been able to attract many native as well as foreign patients towards unproven stem cell services which raise legitimate ethical and governance concerns.

It was argued that the convergence of hype, hope and promises of medical potential creates the demand for stem cell treatments for which the science of stem cells is not mature enough (Murdoch and Scott, 2010). The immature stem cell treatments have put patients at health and financial risk (Pandya, 2008). The high expectations of stem cells in India help in creating a favourable environment for its proliferation, more specifically in a range of clinical applications. These unproven stem cell applications raise the issues of patient safety and efficacy. Previous studies have highlighted that many patients are also not fully informed about the pros and cons of the various stem cell interventions (Pandya, 2008).

The next chapter of the thesis has analysed the ethical issues in the background of high expectations including the ethical perception of key players and how are these player draw ethical boundaries as a way of legitimising their stem cell activities.

Chapter 6: The Ethics of Stem Cell Research and Therapy in India

6.1 Introduction

The previous chapter has analysed the expectations of stem cells in India. I argued that high expectations pinned on the therapeutic applications of stem cells as well as an underlying desire of the Indian state to capture the global market of stem cells have raised several ethical and consequently governance issues. In this chapter, I will discuss those ethical issues which have been associated with the proliferation of stem cells in India over the years.

If we closely analyse the debates in the area of stem cells, it can be argued that, the use of human embryo in stem cell research emerged as the main ethical issue in the West (Gottweis et al., 2009). In contrast, in Asian countries such as China, India and Singapore, the use of stem cells in clinics has raised more controversies than the source of stem cells (Bharadwaj and Glasner, 2009; Cohen and Cohen, 2010; Gottweis, 2009; Patra and Sleeboom-Faulkner, 2010; Sleeboom-Faulkner, 2011).

In this chapter, an attempt is made to discuss the various ethical issues which have emerged with the proliferation of stem cells in India. This chapter is closer to empirical bioethics (Borry et al., 2005; Petersen, 2011). Over the past few years, the empirical studies of bioethics have attracted great attention amongst the social science scholarship. The scholarship in this domain claims that the social and cultural factors are largely ignored by the traditional

philosophical bioethics while assessing the ethics of new technologies (DeVries, 2003; Hedgecoe, 2004; Petersen, 2011). It was argued that normative principles of bioethics such as autonomy, beneficence, non-malfeasance and justice do not account for social and cultural factors and they are highly universal and mechanical in its approach (Petersen, 2011). Therefore, there is a need to take into account various social and cultural factors as well, while ensuring normative bioethics. For instance, in normative bioethics principles there is a great emphasis on informant consent procedure which is highly contentious in different social and cultural environments (Zwart, 2008). Although this chapter discusses raised ethical issues against the framework provided by the principles of normative ethics, it also highlights the limitations of such principles in different cross-cultural settings.

The aim of this chapter is to analyse various ethical issues associated with the high expectation created around stem cells in India. It examines the issues related to: a) the use of human embryos in stem cells; b) unproven therapies; and c) the proliferation of cord blood banking. Furthermore, it analyses the extent to which procedures of informed consent are capable of handling some of these problems in India. It also aims to examine how different key players legitimate or, alternatively, challenge various activities of stem cells, i.e. the construction of ethics by various key players. Specifically it draws from the notion of 'ethical boundary-work' (Frith et al., 2011; Hobson-West, 2012; Wainwright et al., 2006a) to examine how the boundaries between legitimate

and illegitimate (or ethical and unethical) activity are drawn by the actors themselves.

In doing so, this chapter focuses on the debates in India regarding the use of human embryo in research and clinical applications of stem cells in section 6.2. Section 6.3 explores the tension amongst key players with respect to stem cell based treatments. The stem cell treatment is widely conceptualised as a 'business' rather than a therapy, so this aspect is discussed in section 6.4 with respect to the India stem cell sector. In addition to stem cell treatments, cord blood banking also emerged as a potential area of 'business', which raises a legitimate ethical concern. The ethical aspect of cord blood banking is examined in section 6.5. In biomedicine informed consent is seen as an important procedure to safeguard human research subjects and patients during a clinical setting by various national and international bodies. In terms of stem cell treatments in India, section 6.6 explores the functioning of informed consent. The final section deals with the summary and discussion.

6.2 The use of human embryo

The use of human embryo in biomedical research has been a controversial issue for a long time, especially, following the use of *in vitro* Fertilization (IVF) techniques in the late 1970s (Hauskeller, 2004; Walters, 2004). However, their use in stem cell research comparatively generated more heat and raised intense debates on ethical grounds worldwide in the late 1990s, following the

creation of human embryonic stem cells in 1998, since it requires killing of an embryo to harvest stem cells (Hauskeller, 2004; McMahan, 2007). The ethical issues in Human Embryonic Stem Cell (hESC) basically surround two points: the sanctity of human life at the stage of embryo versus the promises of human embryonic stem cells in the alleviation of suffering and to cure diseases (Reichhardt et al., 2004). However, in addition, other issues were highlighted which provoked intense ethical debates (Gottweis et al., 2009), for instance: a) the source of human embryo, i.e. aborted, IVF supernumerary, non-IVF donated, cloned; b) embryo creation date; c) embryo age; d) hESC line origin; e) hESC line creation date; and f) hESC line research purpose.

In the West, it has been observed that the ethical debates are mainly restricted to the use of human embryo in research and therapy, more specifically to the moral status of human embryo and its acceptability (Gottweis et al., 2009; Haimes et al., 2008). However, within the West itself there are different approaches for human embryo, which results in a different regulatory framework in terms of using human embryo in stem cells. For example, Germany, Italy and Ireland do not allow the derivation of hESC lines from surplus IVF embryos, while the policy of the UK and Denmark is that it is permissible to derive hESC lines from these embryos (Caulfield et al., 2009; Gottweis et al., 2009). It was argued that, "embryos are not fixed, universal biological entities but are defined by, and acted upon relation to, their social context" (Haimes et al., 2008: 124). It can be inferred, therefore, that there are different ethical approaches on the same issues across different countries,

and accordingly policies are made to regulate stem cell research and therapy. It was observed that, "policies range from the complete prohibition of hESC research (as in Ireland, Austria, Lithuania, Poland and Slovakia) through an array of regulatory configurations that allow certain kinds of research to policies that permit the creation of embryos for research and therapeutic cloning (as in Belgium, India, Israel, Sweden, China, Singapore, South Korea, and the United Kingdom)" (Gottweis et al., 2009: 5). The variations across different nation-states provide the opportunity to negotiate ethical and legal regimes in the global market of stem cells and it also sets the level and direction of research in particular nation-states (Bharadwaj and Glasner, 2009).

In the case of India, it was observed that both the regulatory and cultural environments are favourable for stem cells since the Indian government is highly supportive and India does not carry the same kind of 'ethical baggage' compared to most Western countries, especially with respect to eggs and embryos (Bharadwaj and Glasner, 2009; Gottweis et al., 2009). However, the proliferation of stem cells in India is perceived as a departure from 'an imagined normative global order' (in principle, Euro-American order) in terms of 'ethical and moral standards' (Bharadwaj and Glasner, 2009). This departure results in a phenomenon, termed 'bio-crossing'. A 'bio-crossing' is visualised as a passage across geo-political, ethical and moral borders which is not always governed. This passage can exist independently of local and global

normative principles and is characterised by competing and contested ethical and moral frames (Bharadwaj and Glasner, 2009).

These competing and contested ethical frames could be seen while comparing the ethical discourses within India with respect to the West. It was illustrated that the human embryo does not accord that kind of significance in India, as in the West (Bharadwaj and Glasner, 2009; Gupta, 2011); for example, during a public consultation meeting in India, which was organised by the ICMR, it was observed that, there was more concern about the clinical applications of stem cells rather than using human embryo in research and therapy. The organiser of the public consultation stated that:

> "We know ethical issues in stem cell research revolved around embryonic stem cell so we thought, because there is such a huge diversity in India plus we are having different religions in the country, we thought let us have consensus of all religious bodies...Only in one of the public consultations did they raise the issue about embryo, that was probably representing the Christian community' so it's quite natural they are against killing embryo...they say that embryo has life" (Policymaker, 1).

The provisional data of India's census 2011 shows that Christians belong to only 2.3% population of India. The majority of India's population are Hindus (80.5%) followed by Muslims (13.4%) and other religions such as Sikhs (1.9%),

Buddhists (0.8%), and Jains (0.4%)[21]. It can be, therefore, argued that there is a small voice against the killing of an embryo in India at the moment. However, Hinduism, which is the dominant religion in India, has pluralities of views regarding the moral status and killing of an embryo. The killing of an embryo is seen as an evil act. Artificial insemination, test tube babies and abortion are not acceptable and considered as sinful acts (Lakshmi, 2001). In the epic, The Mahabharata, it is stated that life begins at conception, as Mishra pointed that:

> "The ancient system of Indian medicine known as Ayurveda assumes that fetuses are alive and conscious when it prescribes a particular mental and spiritual regimen to pregnant women. This same assumption is implicit in the Mahabharata, the Hindu epic about a fratricidal war apparently fought in the first millennium BC. In one of its famous stories, the warrior Arjuna describes to his pregnant wife a seven-stage military strategy. His yet-to-be-born son Abhimanyu is listening, too. But as Arjuna describes the seventh and last stage, his wife falls asleep, presumably out of boredom. Years later, while fighting his father's cousins, the hundred Kaurava brothers, Abhimanyu uses well the military

[21] http://censusindia.gov.in/Ad_Campaign/drop_in_articles/04-Distribution_by_Religion.pdf [Accessed Jan 04, 2012].

> training he had learned in his mother's womb, until the seventh stage, where he falters and is killed" (Mishra, 2005).

It was argued that in Hinduism there is more support for 'the personhood of an embryo' than in Christianity (Mishra, 2005). However, in contrast, in the same epic another narration reflected different views, which indirectly support the use embryo in stem cell research.

There is a story about the birth of the hundred Kaurava brothers in the beginning of The Mahabharata epic where "It is mentioned that after two years of pregnancy their [Kaurava's] mother had produced a mass of flesh and then a sage divided the flesh into 100 parts, which were treated with herbs and ghee, and kept in pots for two years – from which the Kaurava brothers emerged" (Mishra, 2005). By highlighting this piece of story, the proponents of stem cell research in India argued that this is an early evidence of human cloning through stem cells (Mishra, 2005) and stated that stem cell technology was in fact one of the lost sciences of India (Thambisetty, 2003).

In Hinduism, therefore, it can be argued that on the one hand there is respect for human embryo, while on the other hand the killing of a human embryo is permissible under certain circumstances. Hinduism is perceived as less monolithic and more diverse than any other religion such as Christianity and Islam (Mishra, 2005). The Hindu tradition has flexibility to accommodate pluralities of views and it allows a more pragmatic approach to achieving the desired goal and in doing so morality is devalued sometimes (Varma, 2006). Lannoy (1971) illustrated that, "Hindu ethics has its public face – Dharma, or

normative, rules – and its private wisdom, or pragmatic rules, to distinguish between the principles men espouse and the tactics they adopt" (quoted in Varma, 2006: 28). Although in India, it is believed that life begins at conception, the destruction of an embryo is justified in extraordinary unavoidable circumstances and when it is done for a greater cause (Reichhardt et al., 2004). For instance, abortion is permitted, if there is a direct threat to the life of the mother (Walters, 2004).

Islam, the second major religion in India, also does not have any opposition for embryonic stem cell research since they do not respect early embryo as a human being (Reichhardt et al., 2004).

In Buddhism, there is no ethical problem with the therapeutic application of adult stem cells. However, they are against the intentional destruction of human embryo. Their views on conception are similar to Hindu traditions as the followers of Buddhism believe in the beginning of life at the time of conception (Keown, 2004).

In India, there is no consensus on the moral status of the human embryo. It is often argued that, "different philosophical, religious and ideological persuasions define and debate life in an eclectic and open-ended way" (Bharadwaj, 2009: 246).

In India, it seems that there is a common voice in the favour of embryonic stem cell research, if it is for therapeutic purposes, as a scientist expressed in his opinion:

> "If they [researchers] will use for therapeutic application and not for any other purpose then I don't think there should be any problem of ethical clearance" (Scientist, 1).

The opinion of this scientist echoes the earlier discussion of Hinduism's views where ethical issues are diluted for a greater cause in terms of curing disease and alleviating suffering. This view is also adopted in the Indian guidelines for stem cell research and therapy (2007), where therapeutic cloning is permitted, which is similar to some of the Western countries such as the UK, Belgium and Sweden (Gottweis et al., 2009).

The development of embryonic stem cells in India is closely linked with IVF clinics. It is illustrated that, the proliferation of various IVF clinics in India largely weakened the issue of the moral status of a human embryo (Bharadwaj and Glasner, 2009; Gupta, 2011).

6.2.1 Stem cell and IVF clinics

IVF clinics in India are seen as the potential suppliers of raw materials (e.g. ova and embryos) for stem cell research (Gupta, 2011). In India, where infertility is stigmatised, couples are offered free IVF in return for donating embryos for [stem cell] research (Salter and Waldby, 2007; Bharadwaj and Glasner, 2009; Bharadwaj, 2003). As a result, private IVF clinics have flourished without any stringent oversight (Gupta, 2011; Widge, 2002) as highlighted in Chapter 1.

In India, there are only guidelines for IVF clinics and hence any violation cannot be punished in the absence of a law. In a recent study, Bharadwaj and Glasner (2009) observed that IVF clinics in India, in general, generate more than a dozen embryos in a cycle and, even after three or four cycles of embryo transfer, IVF clinics are still able to keep half of the spare embryos for stem cell research. In exchange for free IVF, the expectant parents do not generally have any concerns about the future 'exploitation' of their 'left over' embryos (Bharadwaj and Glasner, 2009) and the procedure of informed consent also becomes a ritual exercise in order to avail 'free IVF treatments'.

It appears that, against this backdrop, there is a general acceptance of using 'spare embryos' in stem cell research in India. A stem cell research scientist in India believes that:

> "To my mind there is no ethical problem in using spare embryo because I think that in any case ART clinics are generating these embryos and, if the donors have no problem with it, to my mind this is not an issue. I think those are a good source for human embryonic stem cells because, to me, they don't represent an independent life form, they are a dependent life form, so I think this is the perfectly good source for embryonic stem cells" (Scientist, 3).

The representative of a firm also expressed his opinion in favour of 'spare embryos' by citing the DBT-ICMR guidelines, 2007:

> "I think there are well-defined guidelines by the ICMR. We can take an embryo from IVF with the consent of the donors and it should be a spare embryo" (Firm's representative, 4).

As per the DBT-ICMR guidelines, 2007, the use of spare, surplus and supernumerary eggs in stem cell is permitted after informed consent (Gupta, 2011).

In the preceding context, it can be argued that, in India, both cultural and regulatory environments undermine the larger philosophical issues of the moral status of a human embryo. The use of spare embryos is seen as permissible. There is no stringent law to limit the generation of numbers of embryos in a cycle. In exchange for the free IVF facility the morality attached with embryos is diluted. As a result, the use of embryos in research and therapeutic applications of stem cells has proliferated over the years (Bharadwaj and Glasner, 2009; Gupta, 2011). However, the larger issue in India is the use of stem cells in clinics, since it is still in an experimental stage and largely unproven. However, some of the clinicians in India are offering it as a standard therapy for a large number of incurable diseases. This has raised several ethical issues in terms of efficacy of the treatments and safety of the patients.

6.3 Experimental vs. standard therapy

The clinical applications of stem cells is a rapidly emerging field in India (Sleebom-Faulkner and Patra, 2011), given the mushrooming of hospitals/clinics across the country. Both public and private sector hospitals are offering therapies for a wide range of untreatable diseases, such as spinal cord injury, muscular dystrophy, myocardial infarction, Alzheimer's disease and many more, using mainly adult stem cells (Patra and Sleeboom-Faulkner, 2010; Sleeboom-Faulkner and Patra, 2011). The majority of clinicians are using autologous stem cells for treatments, except a few, who are using embryonic stem cells (Bharadwaj and Glasner, 2009; Patra and Sleeboom-Faulkner, 2011). India has become one of the favourable destinations of stem cell based therapies, both for domestic as well as for foreign patients (Cohen and Cohen, 2010). However, the clinical development of stem cells in India is not validated by a wider medical and scientific community in the absence of scientific evidence in terms of basic research and clinical trials (Blakely, 2009; Patra and Sleeboom-Faulkner, 2010).

A scientist in India expressed his concern regarding the unproven stem cell clinical development by saying that:

> "There are lots of clinics in India, I mean doctors in India who offered treatments which is not clear. I mean they are not clear about the process, the procedures and they also charge patients so it's gone from being an experimental therapy to almost a standard therapy. I think it is wrong" (Scientist, 2).

He further argues that:

> "I don't think they have been doing it...if you have not done proper trials...it is not clearly established as a therapy...this should not be done" (Scientist, 2).

Another clinician of a public hospital stated that:

> "So far as practically proving the utility of a stem cell is concerned, the only situation where it has been proved to be useful and it can be recommended in haematological disorders...certain haematological disorders. Other than that everywhere else it is experimental and should do as a part of clinical trial. There is no justification for offering routine treatment with stem cell based therapies" (Clinician, 4).

The clinician believes that stem cells should be used only in certain blood-related disorders, and in other conditions it should only be offered as a clinical trial and not as a standard form of therapy. The recently constituted NAC-SCRT emphasises that "given the current state of knowledge and evidence, only hematopoietic stem cell transplants for blood diseases and limbal stem cell transplants for corneal diseases can be performed as standard therapy outside of clinical trials in India. All other forms of stem cell transplants, including those with blood or marrow derived stem cell, cord blood stem cells, mesenchymal stem cells and any embryonic stem cell

derived tissue should only be used within an appropriately reviewed and monitored clinical trial"[22]

As discussed in Chapter 4, only by 2009 did the regulatory authority of India approve the first true stem cell clinical trials in the country (Jayaraman, 2009). However, before that, several cases were reported to treat/cure a significant number of patients from different parts of the world as well as patients from India, using stem cells. It infers that all of these patients, before 2009, had received stem cell intervention without having clinical trials. It is a matter of concern that India's premier research intensive public hospital, the All India Institute of Medical Science (AIIMS), New Delhi had already conducted clinical trials on 750 patients during the period 2003-2006 for diseases including myocardial infarction, cardiomyopathy, muscular dystrophy, cerebral palsy, diabetes, retinal pigmentosa, and spinal cord injury (Patra and Sleeboom-Faulkner, 2010). In 2005, there was a report published in national newspapers claiming the 'success' of AIIMS to treat cardiac disease using stem cells. However, there were no publications found in terms of basic research, or Phases 1 or 2 clinical trials prior to use of this stem cell based treatment. The ICMR officially raised concerns over AIIMS' work since it had not taken prior approval from a regulatory authority (Pandya, 2008; Singh, 2005).

During field work, it was found that those who are involved in clinical applications of stem cells in India are not following the mandate of existing guidelines, as a scientist comments:

[22] http://www.icmr.nic.in/icmrnews/NAC.htm [Accessed Oct 18, 2012].

> "Research people take permission no problem but question is...Permission is most important for those who use those cells in clinic that is most important but the idea is to make their hand tied but actually they are not going to ethical committee or other apex committee to prove or to accept their proposals...They don't bother...They keep on using that" (Scientist, 1).

The narration of scientists in India not only raises ethical issues but also draws a clear line between 'bench' and 'bedside' and reflects the tension between basic and translation research. Salter and Qui (2009: 47) perhaps correctly argued that, "for novel fields of biomedicine, the knowledge production process from the basic science, through clinical experimentation and trials, to the therapeutic product is long, arduous and uncertain." Drawing on ideas of boundary work, it can be argued that clinicians in India are unable to understand the scientific underpinning of laboratory research particularly in the case of stem cell translation (Wainwright et al., 2006a). However, the proponents of 'bedside' claim that scientists lack the ability to understand the problems of research on human subjects (Wainwright et al., 2006a). It can be argued therefore that there is a tension between 'two cultures' in India similar to that which has been observed in the West.

Though, the tension is clearly visible here, the narration of clinician 4 who is working in a research-intensive public hospital and involved in various stem cell projects, suggests that it would be hard to draw any clear conclusion that,

at a professional level, scientists and clinicians are on different poles. The clinician illustrated that:

> "There are a number of people who are offering stem cell...so-called stem cell therapy out in the local market which is completely unproven (Clinician, 4).

Another clinician of a corporate private hospital who is conducting stem cell clinical research argued that:

> "Stem cell therapy as of now is research-based therapy and used in modalities or in situations in which treatment is advised...there is no way we could allow a clinical practice of therapy which is not yet approved" (Clinician, 11).

The statements of clinicians indicate that not only scientists but also some clinicians, whether they are practising in private hospitals or public hospitals, have concerns over experimental stem cell based treatments. It can be argued therefore that the boundary between scientists and clinicians is blurred in the case of stem cell science in India, at least on the issue of its clinical applications.

In addition to concern over unproven therapy, it was highlighted that, no record is maintained in terms of safety and efficacy of the stem cell interventions, by the stem clinicians, and hence, the evaluation of their work done becomes a daunting task. An ex-policymaker of the ICMR asserted that:

> "They [clinicians] continue to do this therapy and people are going to them for therapy but we have no documented proof of how well they are doing the proper clinical trial or maintaining records where you can systemically evaluate the work done and see the outcome but we don't have...but they [clinicians] claim and these all are claims and we don't accept them as a standard treatment at the moment" (Ex-policymaker).

It was also highlighted in various academic studies as well as in the media that Indian clinicians are unable to provide the treatment procedures and protocol of their study (Blakely, 2009; Cohen and Cohen, 2010). The ex-official of the ICMR, who is very critical about the overall stem cell clinical development in India, again stated that:

> "The hype is more, and the hope is definitely there but at the moment proof is still not there...because of hype patients are willing to go to any extent to spend money to get the treatment done...naturally...they are suffering' they want some cure so they are willing to go...but we don't have any proof to say that, yes, it is really working...it is going to take some more time" (Ex-policymaker).

In the absence of any proof and documentation, it is very hard to know, what, exactly, stem cell clinicians are using for the treatments. Furthermore, it was argued that most of the clinicians in India do not even know about stem cell;

instead they are using it for different treatment modalities. The representative of a firm stated that:

> "They [clinicians] don't know really what they are using...I know of instances where a doctor claims that I am using stem cells and where I have seen that actually it is not stem cells to begin it...it is something...it is something which he has been told that this is the stem cells, you use this and this is going to help" (Firm's representative, 5).

In general, biomedical research is subject to peer review to ensure scientific rationale and transparency, amongst other things (Hyun et al., 2008). However, in the case of stem cell in India it appears that both peer review and transparency are not ensured. For instance, the controversial clinician Dr Shroff always refused to publish her work or allow the inspection of her clinic (Sinha, 2008).

In spite of all these above highlighted concerns, those clinicians who are offering unproven stem cell therapy have their own justifications for their stem cell treatments. Some of the clinicians in India are trying to defend their act by citing the Helsinki Declaration. A clinician of a public hospital in India expressed his opinion in the favour of an unproven therapy and questions the criteria of a proven treatment:

> "See there is a very clear-cut international guideline for research on human subjects, called the Helsinki Declaration. The Helsinki Declaration, I think paragraph some 31 or 33

> clearly states that the condition for which there is no cure or for which all treatment options have been exhausted, a physician has a right to use unproven therapy...our ethical guidelines are very clear we only treat those patients, we found there is no other hope and we are getting good improvement...what is proven treatment?...what is the criteria of proven treatment?...when does something become proven?...so that itself is a question mark...and then a physician has a right to use an unproven therapy. There are enough publications now...clinical papers which are showing improvements" (Clinician, 2).

The main argument made by clinicians is that, if all treatment options have been exhausted for a particular disease, then a physician has a right to use an unproven therapy. The Helsinki Declaration (1964 amended in 2008) in its article 32 stated that "the benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances: a) the use of placebo, or, no treatment, is acceptable in studies where no current proven intervention exists." Further, article 35 of the Helsinki Declaration illustrated that, "in the treatment of a patient, where proven interventions do not exist or have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-

establishing health or alleviating suffering. Where possible, this intervention should be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information should be recorded and, where appropriate, made publicly available."

The Helsinki Declaration does allow using experimental therapy. It is subject to informed consent and transparency, however. In the Indian case it can be argued that stem cell clinicians are following the mandate partly, not holistically. The clinician 4 has argued against the way, the Helsinki Declaration is being used to justify unproven stem cell therapy in India:

> "I don't think those people really fully understand what the Helsinki Declaration is all about and it is very unfair to invoke the Helsinki Declaration in doing all these kind of things because then there is no end to justifying whatever they want to do; this is all I can say, they have their points of view. I don't think, the Helsinki Declaration says that you can go and do whatever you want to do. It's not like all these so-called therapies are completely harmless. They have potential for causing definite harm to patients, so looking at the Helsinki Declaration here is actually very misleading"(Clinician, 4).

The above contrasting narration of clinicians reflects that the use of experimental therapy for terminally ill patients is highly complex since at international level also there is no clear cut framework to address this issue as highlighted in Chapter 2. This is the reason for several campaigns from

patients worldwide in the past and most recently, *Abigail Alliance Vs Von Eschenbach*, for the right to access experimental drugs/therapy (Falit and Gross, 2008). It is argued that it is unfair to wait for long in the case of life threatening conditions (King, 1995). In this situation the act of some clinicians in India could be justified that they are providing treatments to terminally ill patients. At international level in many countries there are mechanisms in place dealing with access to experimental drugs/therapy under 'compassionate use' with certain safeguards and prior approval from regulatory bodies. However, these mechanisms are not uniform and across the countries it is highly varied as discussed in Chapter 2.

In Indian conditions as per information provided by a clinician, there is no policy document with respect to 'compassionate use'. This means that the Indian clinicians are using stem cell intervention in the name of helping terminally ill patients without any safeguards. These therapies are being offered directly to the patients without having any pre-clinical studies and clinical trials, as was reflected by the statement of a clinician:

> "There is a new thought among clinicians and groups which are currently involved in autologous, that is something known as practice-based evidence; till now we were thinking only in terms of evidence-based medicine for which clinical trials are required. Here clinical trials, I would say one thing would be practically or realistically for follow-up of 10 years or 15 years is not feasible as of now, when we know that it is safe. See

> what we are doing is not a clinical trial or a randomised control, what we are doing is a clinical study" (Clinician, 3).

This 'clinical study' is against the national and international norms (DBT-ICMR, 2007; ISSCR, 2008). These guidelines in principle advocate that the stem cell based treatments should be conducted only under clinical trials except for certain conditions such as bone marrow transplantation, and they should proceed through rigorous pre-clinical and clinical studies before administration in humans (DBT-ICMR, 2007; ISSCR, 2008). The international Society for Stem Cell Research (ISSCR) in its guidelines, "condemn[s] the administration and unproven use of stem cells or their direct derivatives outside of a clinical trial" (ISSCR, 2008: 4-5, quoted in Murdoch and Scott, 2010).

During field work, it was also found that most of the clinicians in India believe that they are using adult stem cells, which are safe and therefore there is no need to go through a pre-clinical study on an animal model or clinical trials on human beings. Clinician 2 who is very active in stem cell translation expressed his opinion that:

> "We don't have any problem; we are using autologous bone marrow derived stem cells. The autologous stem cells have been going for many years for treating blood disorders and everything so it is a safe treatment. We got no side effect whatsoever with stem cells per se...so I think there is no safety issue at all" (Clinician, 2).

Apart from invoking the 'Helsinki Declaration' and 'adult stem cells' to justify the clinical activities, the 'desperation of patients' is also being quoted to legitimatise the use of stem cells in clinics. The representative of a firm who provides stem cell isolation services to various hospitals and clinicians in the support of stem cell therapy quoted the argument made by a patient:

> "If you say whatever you are doing is only for research, do you think I have to live my life like all this until death? Can't you try whatever you know is possible?" (Firm's representative, 2).

Drawing on the notion of ethical boundary-work, the above opinions of different clinicians reflect that the 'Helsinki Declaration', 'adult stem cells' and the 'desperation of patients' are used to justify the therapies based on stem cells. In doing so, the Helsinki Declaration is being used as a justification for experimental therapy, and adult stem cells are often portrayed as safe therapy to address the safety concerns. In addition, it is argued that the patients are desperate to go for stem cell based therapies since existing therapies are unable to address their particular disease conditions. As far as the use of adult stem cells is concerned, some other key players suggest that there is a need for follow-up for many years to ensure that the adult stem cells are safe. The representative of a public cord blood banking firm opined that:

> "As of now, we know that adult stem cells are safe but we don't know if there are going to be any other side effects, so I think unless it is going to be followed with first of all

> experiment on animals then translate to human beings then followed in human beings for at least 4 to 5 years to ensure that there are no side effects, only then we should really be offering as treatment in my opinion" (Firm's representative, 1).

Some of the clinicians, who are working in public hospitals, believe that it is very early for various Indian centres to use stem cells in clinics:

> "It is true that we have to go for phase 1 study for another 2-3-4 years for all the stem cell applications then only you can utilise them for proper clinical studies...It is very premature for Indian institutes to utilise stem cells" (Clinician, 6).

A scientist of a public research laboratory claims that there is a possibility of tumour formation, even in the case of autologous stem cell intervention. Further, he advocated for all possible tests before moving to translational level:

> "In my opinion, because it is a case of human subjects and you are intervening in the normal system by putting in some cells, those cells are patient-derived such as autologous, there is the possibility that those cells may behave abnormally on the other side or in other words there is the possibility of some tumour formation OK...so for me all possible testing should be done before it goes to phase 1 clinical trial" (Scientist, 1).

The adverse outcome of an unproven adult stem cell is already reported in the Feb 17, 2009 issue of PLoS Medicine, where an Israeli boy had developed a tumour after getting an adult stem cell treatment in a clinic in Russia (MacReady, 2009).

The above discussion depicts that the majority of the clinicians in India are offering various stem cell interventions as a main line therapy, though both the scientific community and regulators in India, including a few clinicians and the representative of a firm, believe that it is still an experimental therapy and it should not be used as a standard therapy. There is need to follow up stem cell therapies for some years to ensure safety.

However, clinicians who are offering stem cell therapy in India legitimatise their activities by citing the Helsinki Declaration. In doing so, they also insist that using adult stem cells is safe, despite them having no evidence in the form of clinical trials. In addition, they invoke that patients themselves want to go for stem cell based treatments.

The willingness of patients has a direct link with the expectation rhetoric, as policymakers are of the view that, because of hype, patients are attracted towards unproven therapy. It can be argued that in India patients are being used as one of the necessary resources for the development of stem cell science (see Chapter 5), which paves the way for the application of an unproven therapy.

The use of experimental stem cell therapy has raised safety issues for the patients as there is evidence of tumour formation by using adult stem cells. In

addition, one of the main worries, apart from safety issues, is that patients are being charged a hefty amount for risky treatments. In the Indian case the high expectations attached to stem cells not only poses possible health risks for patients but also financial risks.

6.4 Therapy or 'business'

The International Society for Stem Cell Research (ISSCR) Guidelines for the Clinical Translation of Stem Cells condemns the charging of patients for an unproven use of stem cells, and argued that, these activities are against the norms of professional ethics (ISSCR, 2008). It is observed that patients in India are paying a hefty price for an unproven therapy (Blakely, 2009). An official of the ICMR is clearly against this money-making endeavour, as she illustrated:

> "For all these unproven therapies you are not supposed to charge them. These are in the form of clinical trials. These are not a therapy" (Policymaker, 2).

Some of the clinicians also support the view of ICMR's official, as a clinician argued that:

> "Basically it is a money-making endeavour for all these people who are doing it, so obviously there are lot of ethical issues in this situation"(Clinician, 5).

However, the other clinicians in India have their own justification for charging the patients. A clinician of a leading corporate hospital, who was recently in a

controversy for the same (Chatterjee, 2011), made a statement in the favour of charging the patients.

> "Nowhere in the guidelines, is it mentioned that money would not be charged. Especially, what we are doing with these stem cells which we retrieved from the bone marrow, there are centrifuge and now that equipment is costing something, that is FDA approved equipment, nobody will provide you free of cost so who will bear the cost?"(Clinician, 10).

The above clinician justifies charging patients by highlighting that DBT-ICMR guidelines do not prevent this happening. However, he ignores the key point that stem cell should not be used as a standard form of therapy. Similar to the Helsinki Declaration, the national guidelines are also being cited to justify the 'business' of stem cell. In addition to stem cell treatment 'business', the cord blood banking 'business' is also growing in India, which raises various concerns similar to stem cell transplantation as described in the following section.

6.5 The ethics of private cord blood banking

In addition to therapeutic application of stem cells, in recent years the mushrooming of private cord blood banking firms could be seen in India. Chapter 4 has described in detail the overview of the stem cell sector in India, which depicts that the majority of firms are engaged in the 'business' of cord blood banking. They are mostly of foreign origin and private in nature. The

various studies, in both the science and social science domains, have shown that it is rarely used for the self and is basically based on 'future promises' and 'capitalising hope' (Kaimal et al., 2009; Martin et al., 2008b). The chances that a particular child will develop a condition requiring cord blood transplantation are very slim. It has been observed that 0.04% (1/2,500) of cord blood units stored would ever be used for autologous transplantation. The reason is that the occurrence of diseases currently treated with cord blood is small, and many patients would not be eligible for autologous cord blood, including those with genetic disorders and leukaemia (Kaimal et al., 2009).

The data from the interviews in India have shown that the mushrooming of private cord blood banking potentially exploited expecting parents. The representative of a hybrid (both public and private in nature) cord blood banking firm in India clearly stated that:

> "Private banking is rarely used for the self. It is very often ... this is something that people are being kind of promoting ... saying ... it can be used for the child from whom it is collected and this is rarely the case at all because, if the child has got the genetic problem and it has not been known at birth, the stem cells collected from the child would also be affected with the same problem and, unless you get involved in some sort of manipulation of those stem cells and then try to introduce them, only then will it be useful to the child from whom it has

been taken. The only instance when it can be used for the child from whom it's taken is if it is an acquired illness of some kind or something which is not genetic, in those instances yes ... when you talk about private banking it is more likely to be used only by somebody else in the family ... maybe an older sibling or maybe somebody else" (Firm's representative, 1).

A scientist who is involved in research using cord blood stem cells opined that it is more useful in the case of allogenic transplantation (i.e. a patient receives stem cells from his own blood) in contrast to autologous transplantation (i.e. a patient receives stem cells from a donor).

"The cord blood cells if at all, it can be used in an allogenic set up, it will be wonderful cells but for somebody used for autologous and the boy will be or kid will be grown and then he or she will have some problem and then the cell will be transplanted in that way it has no impact...impact will be less than .0001%, but if it is allogenic it will have tremendous potential" (Scientist, 1).

In spite of, the rare chance of self-use, cord blood banking firms in India are attracting patients in the name of 'biological insurance' (Mascarenhas, 2009), i.e. "an insurance for their child's future wellbeing" (Sullivan et al., 2005). However, a scientist feels that it is a kind of insurance where one will not get anything and it is only a money-making endeavour:

> "This is a short- time business strategy that some people have decided...I don't want to sound too harsh but in some way I really feel that this is a yuppie phenomenon okay...somebody has one lakhs (~US $2,000) to spend and they decide that wow! nothing is too good for my child so I am going to spend the lakhs, essentially on liquid nitrogen charges for preserving something. It sounds like a good idea but actually speaking there is not that much benefit to cord blood banking. It's like an insurance policy except in the case of an insurance you are going to use it at some point of time...whereas in cord blood...you know after the age of 21 you can give an autologus bone marrow transplant, why you need to have cord blood" (Scientist, 3).

The main criticism here is that private cord blood banking has a very limited use for the self. It is already documented through various studies that there are very low chances that a child will need his/her cord blood in the future (Hollands and McCauley, 2009). Furthermore, cord blood banking firms at the moment only preserve cord blood till the age of 21; then the question arises, what would happen if a child needed any transplantation after that age? The scientist argued that there is not much clinical benefit of preserving cord blood. Patients are being charged for only preserving materials such as liquid nitrogen. It does not deliver what it promises in the name of 'biological insurance'. Similar opinion has been also expressed by some other study in

the West, as Nelson argued that "insurance provides a certain benefit for an uncertain future"; however, in the case of stem cell banking, there is "an uncertain benefit combined with uncertain future" (Nelson, 2008b: March 13).

The scientist 3 is of the view that the cord blood banking is more beneficial for firms themselves rather than the child of expectant parents. She stated that:

> "To charge people for a low probability event sounds more like a business plan than a necessity" (Scientist, 3).

The private cord blood banking is even criticised by the representative of a firm, who, himself engaged in the 'cord blood banking business'. He expressed his opinion against the preservation of cord blood, if a child is affected by any genetic disease:

> "The problem is that you can't use your own cord blood if you have a genetic disease. If you have a blood disorder later in life then you can't use your own cord blood because the stem cells in the cord blood may also have the same genetic disease or the same problem which you have now, so that really makes life difficult for cord blood banking companies because how do you justify this?" (Firm's representative, 5).

The European Commission's Group on Ethics in Science and New Technologies' (EGE) report on the ethics of private cord blood banking also questions the legitimacy of private cord blood banks for self-use. This report

argues that, "they [private cord blood banks] promise more than they can deliver" (Puigdomench-Rosell and Virt, 2004:20). The representative of a hybrid cord blood banking firm argues along the same lines:

> "They do give a lot of false claims. There is a long list of 70 diseases that everybody keeps counting...I think, there needs to be more serious studies that go on before one can actually say it can be used for late year illness...their tall claims really frightened me...if you go to the website you feel that every disease under the sun can be cured" (Firm's representative, 1).

It is argued that, the cord blood banking firms are playing with the emotion of parents. An ICMR official stated that:

> "Private banking, I find playing with the emotions of people who are donating or storing their cord blood...after 18...21 years its maintaining them for so long is of no use...I don't think so...Unless and until in family you need somebody requires then definitely one should store that"(Policymaker, 2).

The statement of the policymaker echoes the similar observation highlighted by Brown and Kraft whilst studying the role of expectations in the proliferation of cord blood banking in the UK where emotion plays an important role. It was reflected by this study that, at the time of birth, mothers are more emotional

and also quite vulnerable and they can be easily influenced by any promises if it is for the future of their child (Brown and Kraft, 2006).

The other main ethical concern is that most of the firms in India do not possess enough scientific expertise to retrieve the stored cord blood. A stem cell clinician raised this issue during the field visit:

> "My experience with one of the cord blood banking was, they have saved it but they don't know how to retrieve it. They don't know a standardised way to remove [that] preservative and in a patient who had an autologous cord blood store we could not use her stem cell because the company did not know how to use it" (Clinician, 3).

In recent years, apart from umbilical cord blood banking, firms in India have started offering storage of other 'potentials sources' of stem cells; for instance, umbilical cord blood tissues, menstrual blood, milk teeth and dental pulp, similar to other banking firms in the Western countries (Dasgupta, 2010; Nelson, 2008b). The representative of a leading cord blood bank in India provided the following information during the field visit:

> "The last couple of years we have set up research operations where we have launched the umbilical cord tissue bank that's a complimentary service to the cord blood banking service; now expecting parents have the opportunity of having the children's cord blood and tissue stem cell stored at birth. We also now license the technology from CryoCell, i.e. menstrual

> blood service...we are planning to roll out in the next few months in India" (Firm's representative, 3).

However, the representative of another firm argues that, it is practically impossible to retrieve stem cells from frozen cord tissue.

> "Some companies are saying okay...you pay us a small amount more and we will save the tissue for you. We will take the umbilical cord tissue and we will save it for you; whenever you need cells, we will remove it and we will derive cells from it and we will give it to you, which is hoggish because if you see the umbilical cord it is the complex tissue, it is thick sometimes and the thickness makes it difficult to freeze it ... if you take cord tissue and just freeze it you will kill all the cells which are there in the cord; you can't derive any cell from it later on but it is a marketing gimmick" (Firm's representative, 5).

It is clear from the above discussion that private cord blood banking firms in India are primarily a business venture. This business is based on promises rather than any tangible products or services. Expectant parents are being mobilised on 'emotional grounds'. The notion of 'biological insurance' is also playing a major role in attracting expectant parents. However, there are very slim chances that a child would ever use her/his preserved cord blood in the future. Furthermore, some firms claim to treat various genetic disorders by using a child's own cord blood, which is again not valid since stem cells in the

cord blood may contain same genetic defects. It was argued by some of the informants that firms do not even know how to retrieve stem cells from the preserved cord blood, which raises concerns in terms of the legitimacy of banking firms.

The development of private cord blood banking in India, which is similar to the development in the West, reflects the universal nature of bio-economies which "depend on a promissory future economic value and potential rather than present use" (Martin et al., 2008b: 128).

It is argued that, in a medical condition where the main motive is to make money, it becomes very difficult to obtain informed consent and, moreover, when clinicians do not disclose their treatment procedures for an untested therapy (Cohen and Cohen 2010). In India, the informed consent procedure, in general, always has been a debatable issue given medical paternalism and the problem of patients without basic literacy (Kalantri, 2004; Rajkumar et al., 2007). The stem cell research and its clinical application can be seen as a further addition into this.

6.6 Stem cell translation and informed consent

Informed consent is seen as one of the key aspects in biomedical research and therapy for the safety and autonomy of patients. It is recognised as the main bioethical principle "to protect the individual patient or healthy volunteer subject from possible exploitation and harm" (Corrigan, 2003: 771). There is a

great emphasis on informed consent all over the world, at least on paper, through various national and international guidelines (Kalantri, 2004). As per the Helsinki Declaration, 'informed consent' refers to:

> "In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing the non-written consent must be formally documented and witnessed" (World Medical Association Declaration of Helsinki, 2008).

However, various studies have shown that 'consent' is hardly 'informed' in most of the cases (Doyal, 2004). The international universal procedure of informed consent, more specifically the principle of autonomy, largely ignores the importance of culture, language and levels of education (Corrigan, 2003; Hoeyer, 2009; McCabe et al., 2005; Schenker et al., 2007). For example, in India, where most of the decisions are taken collectively at the level of family

(Bharadwaj and Glasner, 2009), it is very hard to adhere to the principle of autonomy. Furthermore, the content of the consent form is usually written in English and it is much harder for the majority of the illiterate population to fully understand the informed consent documents. An attempt has been made to translate these documents in vernacular languages. However, exact translation of English words and phrases often leads to confusion (Padhy et al., 2011). It is also observed that, "consent forms in most hospitals *in India* are either too brief or sketchy or full of incomprehensible medical and legal jargon (emphasis added)" (Kalantri, 2000).

In the case of stem cell intervention in India, it was documented that the patients undergoing stem cell treatments are not fully informed about the possible side-effects of an experimental therapy (Cohen and Cohen, 2010; Pandya, 2008; Patra and Sleeboom- Faulkner, 2010). A clinician in India argued that patients are not informed that these treatments are unproven:

> "There are many desperate patients who have no hope practically with conventional therapy and are not told that these treatments are unproven" (Clinician, 4).

The regulatory bodies in India through various mechanisms try to ensure that the ethical guidelines should be followed. The procedure of informed consent, however, is diluted in the Indian condition, since patients have great trust in clinicians and they regard them as next to God (Sanwal et al., 1996), and generally patients do not question the mode of treatments/procedures offered by clinicians. The representative of a firm argues that:

> "He [patient] just relies on the doctors basically and it is normal practice in India...whatever doctors say, you go for that" (Firm's representative, 7).

Trust is often viewed as a defining element in the patient-clinician relationship, especially for patients since they generally encounter clinicians at a vulnerable stage and at that time patients highly depend on clinicians (Goold, 2001). In general, patients have placed a high level of trust in the medical system not only in India but more or less in every part of the world (Rowe and Calnan, 2006). Trust is especially important for health care, as it allows patients to reveal personal information and to follow various treatment procedures. However, increasingly in the corporate nature of medical care, particularly in India where more than 80% of health care services are being provided by the private sector, the trust relationship between patients and clinicians could be vulnerable. Clinicians might take unfair advantage of this trust. Various studies and media reports in the stem cell domain have already highlighted that, in desperation to cure, significant numbers of patients are spending large sums of money without questioning the largely unproven treatment procedures (Chatterjee, 2011; The Times of India, 2010; Zarzeczny et al., 2010).

Furthermore, it is argued that patients are incapable of making their own choice as they are not strong enough intellectually as well as psychologically (Kallivayalil and Chadda, 2011; Ravindra, 1994), as a stem cell scientist pointed out:

> "Very often people who are terminally ill, they are not in a position to give informed consent" (Scientist, 3).

In addition, particularly in the case of stem cell, Indian scientists believe that those who offer therapy, are not fully informed themselves of the pros and cons of stem cell therapeutic applications. As a scientist 3 argues:

> "I don't think that these people are really giving a full picture because very frankly people who are offering don't have the full picture because...If you look at the websites of people who are offering this kind of therapy and in some of the cases we came to know about...for example, a doctor is giving autologous bone marrow cells to a patient...say...who has muscular dystrophy; now muscular dystrophy is a genetic disease, so there is no point in giving autologous cells, as they still have the same genetic defect so what would be the point?"(Scientist, 3).

The above discussion revealed that the patients in India who are undergoing stem cell therapy are not only receiving untested therapy, but far worse they are not fully informed about the possible side-effects of stem cells. The universal informed consent procedure in the Indian state of affairs is largely diluted, given the different cultural and socio-economic conditions.

In the whole process we cannot ignore the influence of high expectations on the functioning of informed consent. The previous chapter has discussed in great detail the role of high expectations in the proliferation of stem cell

research and therapy. The high expectations put pressure on both researchers/clinicians and patients for 'breakthroughs' and the desire to cure, respectively, and this leads to the dilution of informed consent (Churchill et al., 1998). Even policymakers/regulators in India are very excited for a 'breakthrough' in order to emerge as a global player, as discussed in a previous chapter. The statement of an ex-policymaker indirectly reflects how the procedure of informed consent can be ignored or compromised in the background of high expectations. She illustrated that:

> "Because of the hype, patients are willing to go to any extent...when you have patients suffering from a particular illness, the family is willing to go to any extent to get them treated and people do come and get treatment" (Ex-policymaker 1).

Against this backdrop, it can be argued that the procedure of informed consent is not only subject to various socio-cultural conditions but also to high expectations associated with a new 'revolutionary medical advancement'. However, in various ethical documents such as the Helsinki Declaration or CIOMS guidelines, there is no provision to address this important issue, as discussed in Chapter 2.

6.7 Summary and discussion

The proliferation of stem cells has raised intense debates worldwide with respect to the use of human embryo in research and the applications of stem cells in curing a wide range of debilitating diseases. In the West, the debates are mainly concentrated around the use of human embryo as a raw material in research. However, in India, the main ethical issues surround the clinical applications of stem cells, which are largely unproven. The human embryo in India does not raise those kinds of ethical issues as in the West. One of the reasons might be that the dominant religion of Hinduism in India is less monolithic than Christianity. In addition, there is no consensus on the moral status of human embryo in Hinduism. Hindus' ethics are flexible and they vary as per 'demand' of a particular situation. There are no stringent rules and regulations in terms of using human embryo in biomedical research. Both the cultural and regulatory environments, therefore, have diluted the issue of human embryo in stem cell research in India.

However, the therapeutic applications of stem cell have raised several ethical issues, such as the safety of patients and efficacy of the treatments and, furthermore, the financial exploitation of the patients. The narrations of key players in stem cells, i.e. scientists, firms' representatives and policymakers have expressed their concern over the unethical clinical development of stem cells. Among clinicians, differences in opinion could be observed. Some of the clinicians are in favour of unproven treatment in a condition when all treatment options for a particular disease have been exhausted. However,

other clinicians are against the applications of unproven stem cells in clinical settings. During field work, it was observed that the clinicians who are working in private hospitals are mostly engaged in unproven stem cell treatments. However, in some cases, it was also found that some of the clinicians of public hospitals are also offering questionable stem cell therapy. It can be argued, therefore, that the professional norms in India, more specifically in the case of clinicians, vary from person to person and they are independent of their institutional affiliations.

The national and international guidelines, particularly the DBT-ICMR guidelines and the Helsinki Declaration, were cited to justify the questionable clinical activities of stem cells by the clinicians. In addition it is argued that no safety issues are attached with adult stem cells and, moreover, it is also stressed that there are significant numbers of needy patients who are desperate for the stem cell intervention.

In sum, if we see these justifications in the background of ethical boundary-work (Frith et al., 2011; Hobson-West, 2012; Wainwright et al., 2006a), it clearly reflects that there are three key ways to legitimatise the application of stem cells at clinical level. First, the Helsinki Declaration allows it to happen; second, desperate patients; and the third, the use of adult stem cells is safe.

India started its stem cell programmes in the very beginning of the last decade with the support of both public and private research institutes. Later, several public and private hospitals and clinics started offering various treatments using stem cells. However, none of the treatments has gone

through clinical trials and in the absence of any documented evidence of various stem cells clinical interventions it is very hard to examine the treatment modality. Furthermore, patients are being charged for these unproven therapies. The proliferation of stem cell in India is seen as a money-making business rather than to alleviate suffering of the so- called 'desperate' patients.

The 'mushrooming' of private blood banking has also emerged as another money-making endeavour. It is argued by the different key players such as scientists, clinicians, policymakers and a few representatives of firms that, in the name 'biological insurance', expectant parents are being exploited since there is a rare chance for a child to use its own cord blood in the future.

In the whole process, key issues such as informed consent procedures are largely ignored. Generally, patients go for stem cell intervention when they are at the terminal stage. They have exhausted all existing treatment options when they encounter stem cell clinicians. It was observed that, at this stage, patients are incapable of giving informed consent, as reflected by the narration of some of the key players. It appears that terminally-ill patients will continue to be the subject of exploitation given that various international guidelines do not effectively address the issue of terminally-ill patients. In addition, the role of high expectations in the functioning of informed consent has also not been given attention.

Though this chapter investigated the significant ethical issues and the way these are framed by key players to justify research and clinical activities, the

larger question remains as to why some of the clinicians continue to offer a treatment which is perceived as unethical? The interesting thing is that these therapies continue to flourish, despite concerns expressed by the policymakers. It suggests that either India has no stringent mechanisms in place to govern stem cells or there are well-developed mechanisms for the same but the implementation of these established mechanisms is poor. The next chapter of the thesis therefore examines the existing governance framework related to stem cells.

Chapter 7: Governance of Stem Cell Research and Therapy in India

7.1 Introduction

The previous data chapters have discussed the proliferation of stem cell research and therapy and raised ethical issues in the backdrop of high expectations and promises to solve various problems of basic research and to cure a wide range of debilitating diseases.

The prominent ethical issue in the Indian stem cell sector is the clinical applications of stem cells, given that it is still considered as an experimental therapy. Despite concerns expressed at the regulatory level from time to time, some clinicians continue to offer treatments that could be described as unethical, given that they have not been subject to a process of testing and are not offered as part of a regime of a clinical trial. Regulatory agencies appear to be helpless to restrain unproven stem cell clinical development and this raises the fundamental questions – 'what are the formal mechanisms that govern stem cell research and therapy in the country?' and 'how do these mechanisms work in practice?'

In recent years the Indian regulatory authorities have introduced several changes in response to concerns about lack of oversight in this area. For example, the much awaited National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) has been constituted. The mandate of this

committee is to examine the scientific, technical, ethical, legal and social issues in the area of stem cell based research and therapy. Regulatory agencies have also taken a step to provide a legal backup to the existing guidelines, with the Indian Council for Medical Research (ICMR) introducing a public consultation in different parts of the country. In addition, since the use of stem cells in clinics is linked with general medical practices, the government has also introduced some changes to strengthen the governance of medical practice in the country. This chapter analyses these changes in more detail and aims to investigate why they seem to be not effective in practice.

Against this backdrop, this chapter aims to understand the governance mechanisms dealing with biomedical research and therapy in general and stem cells in particular. The chapter is informed by the conceptual framework provided by Pierre and Peters (2000) (see Chapter 2) to understand the different modes of governance i.e. governance as hierarchy, governance as networks, governance as community and governance as market. In doing so, Section 7.2 explores the role of different agencies in biomedical research governance as a whole. Section 7.3 investigates the governance of medical practices and highlights the recent changes in this governance system, which has been prompted by concerns raised about clinical practices including the use of stem cells in clinics. Section 7.4 draws on interview data to explore the existing stem cell governance framework in India. Section 7.5 examines the motives behind the 2011 public consultation on stem cells held in different

Indian cities by the ICMR and investigates its contribution towards the goal of strengthening stem cell governance.

7.2 Biomedical research governance: Governance by hierarchy

The institutionalisation of biomedical research in post-independent India can be traced back to 1949 when the Indian Research Fund Association (IRFA) was re-designed into the Indian Council of Medical Research (ICMR). The IRFA was constituted by the British government in 1911 in response to the plague epidemic of the late 19th and early 20th century in India. The ICMR acts as the apex body for planning, promoting and co-ordinating biomedical research in the country (Muthuswamy, 2010), under the Ministry of Health & Family Welfare. Over the years, ICMR has developed its institutional network by establishing permanent institutes and regional centres in the different parts of the country focusing on specific diseases (ICMR website). Since 2007, ICMR has been supervised by the newly constituted Department of Health Research under the same ministry. Apart from ICMR, other government agencies, i.e. Department of Biotechnology, Department of Science & Technology and Council of Scientific & Industrial Research, are also involved in the promotion of biomedical research through various research and development programmes.

7.2.1 Department of Health Research

The Department of Health Research (DHR) was launched on 5th October, 2007, though it officially started functioning in November 2008. The DHR is headed by a secretary who is also the director-general of the Indian Council of Medical Research (ICMR). The DHR is constituted to promote and co-ordinate basic, applied and clinical research as well as clinical trials and operational research in areas related to medicine and health. It is also assigned to promote and provide guidance on research governance and ethical issues in medical and health research. The supervision of the DHR and the ICMR by the same person suggests that the DHR is just a new name for the ICMR on paper and it is very hard to accept in this situation that the DHR will entirely act as a new agency with fresh ideas to govern biomedical research in India. Moreover, as per the information provided at the DHR website, the ICMR will now be supervised by the DHR. Since both departments are working under the same leadership, it can be argued that the constitution of the DHR does not make any sense.

7.2.2 Indian Council of Medical Research

The Indian Council of Medical Research promotes biomedical research through intramural as well as extramural research. "Intramural research is conducted through the Council's 30 Research Institutes/Centres/Units. These include (a) nineteen mission-oriented national institutes located in different parts of India that address themselves to research on specific areas such as

tuberculosis, leprosy, cholera and diarrhoeal diseases, viral diseases including AIDS, malaria, kala-azar, vector control, nutrition, reproduction, immunohaematology, oncology, medical statistics, etc; (b) six Regional Medical Research Centres that address regional health problems, and also aim to strengthen or generate research capabilities in different geographic areas of the country; and (c) five Unit/Centres dealing with food & drug toxicology, viral diseases, handling microorganisms of a highly infectious nature, prenatal diagnosis for neonatal retardation etc, and supply of various animal models and feeds for experimental purposes" (ICMR website)[23].

Similarly, "extramural research is promoted by ICMR through (a) setting up Centres for Advanced Research in different research areas around existing expertise and infrastructure in selected departments of medical colleges, universities and other non-ICMR Research Institutes; (b) task force studies which emphasise a time-bound, goal-oriented approach with clearly-defined targets, specific time frames, standardised and uniform methodologies, and often a multi-centric structure; and (c) open-ended research on the basis of applications for grants-in-aid received from scientists in non-ICMR research institutes, medical colleges, universities etc located in the different parts of the country" (ICMR website)[24].

One of the major roles of ICMR is to advise government on various ethical issues raised by biomedical developments. The ICMR acts as an apex advisory

[23]http://www.icmr.in [Accessed Sept 20, 2011].

[24] http://www.icmr.in [Accessed Sept 20, 2011].

body by formulating ethical guidelines for studies involving human and animal subjects. A policy document on ethical issues involving research on human subjects was first released by ICMR in 1980; later, with the new advances in biomedical science, it was revised in 2000 as "Ethical Guidelines for Biomedical Research Involving Human Subjects"; again, in 2006, keeping pace with the development of stem cell science, bio-banking and growing worldwide interest in clinical trials in India, these guidelines are revised as "Ethical Guidelines for Biomedical Research on Human Participants". These guidelines can be viewed as a fundamental document in terms of biomedical research ethics in India, though it is not directly legally binding. However, the amendment of the Drugs and Cosmetics Act of 2002 and the Medical Council of India Act of 2002, the compliance to ICMR ethical guidelines was made mandatory for clinical trials and research by clinicians (Muthuswamy, 2010). These guidelines lay emphasis on the constitution of an Institutional Ethics Committee (IEC) at institute level, which is equivalent to Institutional Review Boards, the Ethics Review Board and Research Ethics Boards of other countries. It is expected that every research proposal involving human participants should have approval from IEC. Ethical guidelines highlighted that, "it is mandatory that all proposals on biomedical research involving human participants should be clear by an appropriately constituted Institutional Ethics Committee." In addition to IEC, in India, there is also a provision of an Independent Ethics Committee which is not a part of any institution and, as its name indicates, it works independently. This ethics

committee works for those researchers who are not affiliated to any institution or institution where there is no ethics committee. Independent Ethics Committees have been functioning at places like Delhi, Mumbai, Bangalore, Hyderabad, Ahmedabad etc. (Dent and Krishan, 2007).

Although the ICMR ethical guidelines place significant emphasis on the need for independent ethics committees, various reports have questioned the extent to which this objective is achieved in practice. In various institutions, either there is no ethics committee or, where one exists, the extent to which it functions in practice or might be considered independent is questionable. In a report published in 2008 in the *Bulletin of the World Health Organisation*, it was mentioned that "Fewer than 40 ethics committees in India are properly constituted and functioning" (Chatterjee, 2008). To investigate this problem further, the ICMR conducted a survey in 71 institutions where ICMR-funded research projects were going on. Only 36 institutions responded to the ICMR, out of which only 23 had standard procedures for ethical review and only 14 had trained members in research bioethics (Jesani, 2009; Kumar, 2006). It was alleged that the members of various ECs are not well trained (Bhan, 2012). In addition, there is concern over the conflict of interest in ECs since, in some cases, members of ECs are themselves involved in conducting clinical trials (Sreelata, 2012).

The Drug Controller General of India (DCGI) who approves and monitors clinical trials is entirely dependent on ECs for maintaining ethical standards, though it has no linkages of any kind with ECs. More specifically, the DCGI has

no control over the functioning and supervision of ECs. It is entirely up to the institutions how they manage ECs, where the trials are being conducted (Jesani, 2009). It therefore can be argued that, in maintaining ethical standards in biomedical research in India, the role of ECs is questionable.

Efforts are underway to legalise ICMR ethical guidelines and there is a proposal to establish a Biomedical Research Authority. In the proposed Bill, every IEC should register with this authority. The authority would evaluate and monitor functioning of the IECs. There is also a proposal to rename the Central Ethics Committee on Human Research (CECHR) as the National Ethics Committee in the proposed Bill. The CECHR was set up by the ICMR in 1996 to monitor clinical research in the country. This committee examines various proposals related to biomedical research as well as ethical issues which are brought to its notice (Muthuswamy, 2010).

7.2.3 Department of Biotechnology

The Department of Biotechnology (DBT) under the Ministry of Science and Technology is playing a major role in the promotion of various programmes in the area of medical research. It is basically a funding agency which was set up in 1986 to support research programmes in agriculture and health sectors. India's 6th five-year plan (1980-85) was viewed as a first policy document which initiated the development of biotechnology in the country. In 1982, an apex official agency, *viz.* the National Biotechnology Board (NBTB), was established to initiate and promote R&D in various areas of biotechnology.

The NBTB formulated the "Long-term Plan for Biotechnology in India" in 1983. This plan identified priority areas for the development of biotechnology in view of national needs. Later, in 1986, NBTB was re-designated to a fully-fledged government body called the Department of Biotechnology. Since its inception, DBT is playing a major role in the development of biotechnology (Salter et al., 2007). From the 8th five-year plan (1992-97) to the 11th five-year plan (2007-12), the DBT budget has increased by 16 times. In the year 2008, DBT in partnership with the Wellcome Trust (UK) launched the Biomedical Research Fellowship Programme, worth US $130 million. The major thrust of the Wellcome Trust/DBT India Alliance is to capacity build the Indian scientific community. In the area of stem cells, DBT has constituted a separate task force to promote stem cell R&D in the country. It is also involved in formulating stem cell guidelines with the ICMR.

7.2.4 Department of Science and Technology

The Department of Science and Technology (DST) was established in 1971, with the mandate to promote new areas of Science & Technology (S&T) and to play the role of a nodal department for organising, coordinating and promoting S&T activities in the country. It involves formulation of policies relating to S&T, co-ordination of areas of S&T in which a number of institutions and departments have interests and capabilities, and to support basic and applied research in national institutions. DST is supporting various programmes in stem cells as well (Padma Srivastava, 2009).

7.2.5 Council of Scientific and Industrial Research

The Council of Scientific and Industrial Research (CSIR), an autonomous but government-funded body registered under the Societies Registration Act 1860, was established in 1942. It is viewed as India's largest Research and Development (R&D) organisation, with 39 laboratories and 50 extension centres (CSIR website). Over the years since its establishment CSIR has been able to provide affordable health care for the common man by the development of cheap life-saving drugs. The CSIR website claims that "eleven out of the fourteen new drugs developed in India are from CSIR."

7.2.6 Central Drugs Standard Control Organization (Drugs Controller General of India)

The Central Drugs Standard Control Organization, i.e. the Drugs Controller General of India (DCGI) has the responsibility to lay down the standards of drugs, cosmetics, diagnostics and devices and to approve licences to manufacture certain categories of drugs as the Central License Approving Authority. It regulates market authorisation of drugs and clinical research/trials in the country. In sum, it is similar to the US Food and Drug Administration.

In the previous chapter, one of the main concerns raised by some of the informants was that stem cell treatments are being offered without having clinical trials. However, in India the procedure of clinical trials itself raises serious concern. The DCGI is supposed to monitor clinical trials in the country;

however, over the years several studies and media reports reflect that the DCGI is unable to curb unethical clinical trials (Jayaraman, 2012; The Indian Express, 2012; Yee, 2012). There are allegations that large numbers of poor and vulnerable people have developed serious adverse side-effects during clinical trials in India. The death of several research participants is also reported (The Hindu, 2011). Recently, the procedures of clinical trials in a public hospital in Indore inform us about the growing violations of ethics and problems with the biomedical research governance in India (Yee, 2012). It was alleged that, in Indore, "a total of 81 patients, including 18 children, had serious adverse effects and even death during clinical trials" (Yee, 2012: 397). However, the matter is still under investigation. There are also allegations that clinicians have received millions of dollars from pharmaceutical companies to conduct these trials (Yee, 2012). Furthermore, it was also reported that the survivors of the Bhopal gas disaster have been used as 'guinea pigs' without informed consent. The clinical trials on gas victims also question the validity of clinical trials data since the long-term exposure to leaked mythyl isocyanate (MIC) is yet to be documented. There is no idea about the physiological conditions of those gas victims and this might have an effect on the results of clinical trials (Ghosh, 2011; Lakhani, 2011).

7.2.7 Summarising biomedical research governance

The above description shows that there are multiple agencies in place to govern biomedical research in India. These agencies are promoting

biomedical research through funding and also providing guidance to researchers to conduct research in an ethical manner, especially for contentious areas such as genomics and stem cells. Some of the agencies act as a monitoring and licensing authority with respect to clinical research and biological products. All these agencies work under different ministries, for instance the DBT functions under the Ministry of Science and Technology and the ICMR is under the Ministry of Health and Family Welfare, which is seen as problematic in a governance mechanism with respect to co-ordination while dealing with the same area such as stem cells (Bharadwaj and Glasner, 2009; Salter et al., 2007). However, the ICMR is the main agency for preparing policy documents. Over the years it has played a leading role in the formulation of various policies, guidelines and preparing bills. Basically, ICMR sets the direction of biomedical research in the country. The Indian FDA, i.e. the DCGI, also makes decisions based on ICMR guidelines.

It appears that, in India, there are well-developed state-led mechanisms (what Pierre and Peters (2000) call governance as hierarchy) in place for the governance of biomedical research. However, serious questions have been raised over the functioning and independence of ECs, and the legitimacy of clinical trials suggests that this governance framework is weak and ineffective in practice. This suggests that the system for governing stem cells as an area of research is likely to be found wanting. Before discussing stem cell governance in more detail, it is important to put it in the context of the governance of medical practices in India since the intervention of stem cells in

clinics emerged as a main ethical issue, and the governance framework in dealing with clinicians has a profound impact on the clinical practices of stem cells.

7.3 Governance of medical practices

As described in Chapter 2, there are multiple systems of medicine in India. Ayurveda is recognised as the principal system of medicine. Siddha, Unani, Homoepathy and folk medicines are also considered as a part of the Indian System of Medicine (ISM). In the first half of the 20th century biomedicine began to interact with traditional medicine (Khan, 2006).

After independence, with government support, biomedicine has become a well-established system of medicine in India. It is accessible through both public and private players. This section aims to explore the different modes of governance with respect to medical practices in India. It also analyses to what extent different modes of governance are effective in practice. As far as governance of medical practices is concerned, it basically governs through various legislative measures as well as through a state-sanctioned self-regulatory body. In addition, governance in the form of the association of medical professionals and civil society are also visible. But, how they work in practice is a different matter.

7.3.1 Statutory governance: Governance by hierarchy

The quality and structure of health care delivery systems in India has always been a matter of concern. And, in response to various concerns, the government of India has taken several initiatives over the years. India has formulated nearly 41 Acts which directly or indirectly regulate the hospitals and clinicians (Phadke, 2010). Health is a state subject, and different states are free to formulate different laws according to their needs. This is the reason for so many laws in the country. It is pertinent to highlight here that the Indian Constitution does allow central government to make any laws on state subjects with the consent of state legislative assembly.

Recently, the government of India has passed the Clinical Establishments (Registration and Regulation) Bill, 2010. The statement of this Act highlighted the dismal state of the health care sector. It is stated in this Act that:

> "At present the supervision and regulation of the quality of services provided by the health care delivery system to the people by both public and private sectors has largely remained a contentious and, therefore, unresolved issue. The current structure of the health care delivery system does not provide enough incentives for improvement in efficiency. The private health care delivery system in India has remained largely unregulated and uncontrolled. Problems range from inadequate and inappropriate treatment, excessive use of higher technologies and wasting of scarce resources to serious

problems of medical malpractice and negligence" (Phadke, 2010: 232).

It is believed that this Act will be able to streamline the medical facilities in India. Before going on to analyse the main features of this Act, it would be pertinent to highlight some other important Acts which directly or indirectly govern biomedicine in India (multi-layered structure of governance).

7.3.1.1 Indian Medical Council Act of 1956

The Indian Medical Council Act was enacted in 1933 and, according to the mandate of this Act, a Medical Council of India was established in 1934. After independence, this Act was repealed and a new one enacted in 1956 with the main functions of establishing and maintaining uniform standards of medical education and recognition of medical qualifications through a state-sanctioned self-regulatory body named the Medical Council of India (MCI). This Act also aimed to regulate the practice of medicine by introducing an ethical code of conduct for registered medical practitioners in 2002.

7.3.1.2 Drugs and Cosmetics Act 1940

This Act regulates the import, manufacture, distribution and sales of drugs (and cosmetics). It also oversees the clinical trials in the country. In terms of clinical trials, this Act is perceived as very weak since, in the case of any transgression, the violator cannot be punished as there is no provision for this. Under this Act, the DCGI can only suspend or stop the trial. The Ministry

of Health and Family Welfare intends to amend this Act to make violation of medical ethics a punishable crime. At present, medical ethics violations are dealt with indirectly under various sections of the Indian Penal Code (Dhar, 2010).

7.3.1.3 Indian Penal Code

The Indian Penal Code is meant to define criminal acts and related punishments. In the case of medicine in India, Section 304-A deals with complaints against medical practitioners for alleged medical negligence (Nayak, 2004). The violation of medical ethics in India is treated as a medical negligence (Dhar, 2010). However, to prove a doctor has been negligent is complicated given that, according to a recent order of the Indian Supreme Court, an opinion of an expert or panel of doctors is necessary to begin a case of negligence against alleged clinicians (Kamath, 2010). Furthermore, the law related to medical negligence has been subject to judicial interpretation. It is alleged that the Supreme Court in India has provided protection to medical practitioners through its own interpretation of the law. During a hearing a case of medical negligence the apex court stated that, "... it is the bounden duty of civil society to ensure that the medical professionals are not unnecessarily harassed by complainants who use the criminal process as a tool for pressurising the medical professionals and hospitals for extracting uncalled for compensation. It would not be conducive to the efficiency of the medical profession, if a doctor is to administer medicine with a halter around

his neck" (Menon, 2010: 96). The analysis here reflects that the success of a statutory mode of governance is subject to other modes of governance as well, at least in the case of Indian medical governance.

7.3.1.4 Indian Contract Act of 1872

This is basically the Law of Contract and provides legal protection to the agreements between the parties. However, it has hardly been used for health issues in India (Peters and Murleedharan, 2008).

7.3.1.5 Law of Torts

This law is viewed as a most important law in terms of governing the medical malpractices in India. It applies to all health professionals, whether in the public or the private sector. This law can be useful in a circumstance when a clinician treats a patient without informed consent (Nandimath, 2009). Tort is a civil law and under which an aggrieved party can claim for compensation to another party in the case of any wrong act.

The Indian Penal Code, Indian Contract Act of 1872 and Law of Torts appear to be competent enough to govern medical practices in India. However, they are subject to judicial interpretation and, furthermore, the delay in disposal of court cases poses limitations on the real benefit of these laws. Till 2010, more than 30 million cases were pending in various courts of India and there is estimation that, within the existing judiciary system, it will take 320 years to clear all cases (The Times of India, 2010). Moreover, a large section of the

population in India struggles for basic necessities such as food and water, and they do not have enough money and other resources to fight for several years for justice. Legal services in India are not only lengthy but also expensive. Given the situation, it is hard for an aggrieved patient to go court against any clinician. It appears that, to address these concerns, medical services were incorporated into a new piece of legislation discussed below.

7.3.1.6 Consumer Protection Act 1986

The Consumer Protection Act was enacted in 1986 to protect the interests of consumers from poor products/services. The intention was to provide speedy disposal of consumers' disputes. The medical services were included in this Act by the year 1995 after a Supreme Court ruling. The Supreme Court ruled that "patients aggrieved by deficiencies in medical services rendered for payment can claim damages under the Act. The court said, however, that the Act would not cover doctors and hospitals providing free services to all their patients" (Mudur, 1995: 1385). It means that this Act governs only private medical practitioners. There is provision to set up a commission at the district, state and national level in this Act; collectively they are called the Consumer Forum. The Consumer Forum is a quasi-judicial body. The mandate of this Act is basically to provide inexpensive and speedy legal services to consumers. However, the organisational structure of the Consumer Forum has been always a matter of criticism (Peters and Muraleedharan, 2008). It is viewed that a heavy workload coupled with an insufficient work force and poorly

developed infrastructure leads to the ineffectiveness of the Consumer Forum. Furthermore, in terms of medical practices, the requirement of expert advice from other doctors to begin a case of alleged malpractice against a doctor makes it less effective. It is argued that "almost all cases of medical negligence under the Consumer Protection Act fail because it is impossible to get a doctor to testify against another doctor. They fear being ostracised" (Joshi, 2011).

7.3.1.7 Right to Information Act 2005

The mandate of this Act is to "provide for setting out the practical regime of right to information for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority, the constitution of a Central Information Commission and State Information Commissions and for matters connected therewith or incidental thereto" (Right to Information Act, 2005). Over the years this Act has been used to seek information regarding the functioning of clinical trials by various activists and it has exposed several unethical trials in the public domain (Paliwal, 2011). However, mere exposure does not guarantee that the alleged will get stringent punishment. In one of the poor states, Madhya Pradesh, through clinical trials government doctors made millions of dollars of money; in contrast the concerned authority fined alleged doctors a mere US $100 for their violations (Yee, 2012). Furthermore, this Act is only applicable to public authorities; therefore it poses a limitation

on the capacity to obtain information from private bodies such as private hospitals and private clinicians in the case of medical services. It is pertinent to highlight here that the private sector contributes nearly 80% of health care services in India.

7.3.1.8 The Clinical Establishments Act 2010

This Act is seen as a comprehensive Act to streamline the functioning of all the systems of medicine in India, which covers a wide range of public and private health facilities (Phadke, 2010). There is a provision to constitute a National Council to determine the standards and regulation of the clinical establishments. The National Council shall consist of the Director-General of Health Services, Ministry of Health and Family Welfare, the representatives of the Medical Council of India, Dental Council of India, Nursing Council of India, and Pharmacy Council of India, including other representatives from different systems of medicine. At state level, the State Council will monitor the activities of clinical establishments and their registration process.

However, the Indian Medical Association (IMA) expressed their concern over the composition of the National Council, especially the inclusion of the members of different systems of medicine (i.e. Siddha, Unani etc.) and persons from pharmacy and nursing in the Council. The IMA feels that these persons are not competent enough to oversee the practices of biomedicine (Phadke, 2010). Since this Act made it mandatory to have a minimum infrastructure for a hospital or nursing home in order to operate, the IMA

believes that it will unnecessarily raise the cost of health care services. The IMA alleged that this Act basically serves the purpose of corporate hospitals (Sinha, 2012). In addition, there is concern that this Act will be an added bureaucratic exercise to control the medical practitioners in India, which are already regulated by a significant numbers of legislations (Phadke, 2010). There is an apprehension that this Act will only promote 'inspector raj' (The Times of India, 2011). In India, bureaucratic organisations were seen as a stumbling block rather than being effective and efficient in the progress of science (Bagla, 2003); that is why 'red tape' is often used for Indian bureaucracy (SciDevNet, 2006). Whether this Act will streamline the health care delivery system or work as 'red tape' is still uncertain since, even after two years, only a few states ratify this Act (The Hindu, 2012). Recently, the Minister for State for Health in India has held responsible 'red-tapism' for the delay in the implementation of various projects (DNA, 2010).

The above analysis highlights that India has both civil and criminal laws in place to regulate medical practices. However, these laws are subject to certain limitations and hence their effectiveness is questionable. In this situation, therefore, one can ask about other modes of governance.

7.3.2 State-sanctioned self-regulation and professional governance: Governance by networks

The Medical Council of India (MCI) is a state-sanctioned self-regulatory body to govern biomedicine in the country holistically, as it oversees both medical

education and clinical practices (cf. Salter, 1999). Through the Indian Medical Council Act, as highlighted in Section 7.3.1.1, government has provided statutory power to the MCI. The board of governors of the MCI consists of India's leading medical professionals and its main objectives are: a) maintenance of uniform standards of medical education, both undergraduate and postgraduate; b) recommendation for recognition/de-recognition of medical qualifications of medical institutions of India or foreign countries; c) permanent registration/provisional registration of doctors with recognised medical qualifications; and d) reciprocity with foreign countries in the matter of mutual recognition of medical qualifications[25].

One of the main roles of the MCI is to register medical practitioners to ensure a proper standard of medical practices. The MCI acts at central level, while at state level there is a provision of State Councils. All medical practitioners have to register through State Medical Councils. To ensure ethical conduct of clinicians, the MCI has put forward *Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002*. However, its various provisions have been violated over the years by some of the clinicians. For instance, Indian clinicians and corporate hospitals advertise their medical services either through media interviews or hoardings at public places. Advertising is considered as an unethical act as per the medical code of ethics. However, the principles of this code are often violated by some of the medical professionals and also been challenged in the background of a highly market-

[25] http://www.mciindia.org/AboutMCI/Introduction.aspx [Accessed Nov 12, 2011]

driven health care sector (Balasubramanian, 2008). The MCI, at both central and state levels, is perceived ineffective in ensuring ethical conduct of medical professionals. It was observed that "they have not bothered to exercise the powers given to check unethical medical practice" (Pandya, 2007: 2). The MCI and its counterpart the State Medical Council have been plagued with corruption charges over the years (Pandya, 2007; The Times of India, 2010). It is not surprising, therefore, that there is a lack of proper implementation of existing oversight mechanisms dealing with medical practices. It was argued by some of the medical practitioners in India that "it is important to have ethical guidelines. But the profession should enforce them. We need to develop mechanisms so that a variety of transgressions are regulated and penalised" (Jain, 2010).

In addition to state-sanctioned self-regulation, there is the presence of another network in the form of medical professionals, i.e. the Indian Medical Association (IMA). The main objectives of the IMA are: a) promotion and advancement of medical and allied sciences in all other different branches; b) the improvement of public health and medical education in India; and c) the maintenance of honour and dignity of the medical profession. The official website of the IMA highlighted that "[IMA] looks after the interest of doctors as well as the well-being of the community at large."[26] However, critiques argued that the IMA works more as an interest group for doctors rather than working for the society. The opposition of the Clinical Establishment Act 2010

[26] http://www.ima-india.org/IMA.html [Accessed Sept 24, 2011].

by the IMA reflects that the medical professionals are basically concerned about themselves rather than society at large. Moreover, it is alleged that, unlike in the West where similar medical associations play a vital role in shaping health policies of a nation-state, the IMA never made any contribution in the medical policy of India (Thomas, 2011).

In addition to statutory and professional governance, it would be interesting to analyse whether in India there is any contribution from the public in governance of biomedicine.

7.3.3 Civil society: Governance by community

India has witnessed several civil society movements after independence related to the environment (Chipko movement in the 1970s), development (Narmada Bachao Andolan in the 1980s), agriculture (anti-GM movement in the late 1990s) and, more recently, the anti-nuclear power movement (Bhattacharya et al., 2008; Scoones, 2008; Srikant, 2009; The Economist, 2010). These movements have made a contribution to some extent in the governance of respective sectors. For instance, recently, protest against Bt Brinjal, a genetically modified crop, forced the Indian government to postpone the approval of commercial release of this technology. If we analyse the nature of various mass movements in India, it reflects that the issues such as livelihood and displacement were more prominent in these movements. The anti-GM crop movement revolves around the issue of livelihood, unlike in

the West where health issues are more prominent than livelihood (Srikanth, 2009; Swaminathan, 2000).

By contrast, the health sector in India has hardly witnessed any public debate or civil society movements in terms of the role of biotechnology or pharmaceuticals. The exploitation of poor people during clinical trials and surrogacy or issues related to organ trade, human tissues, body parts and placenta do not seem to attract ordinary people (Bhattacharya et al., 2008). Though various health issues do not attract a mass movement, there have been some individual efforts in the form of campaigns or petitions to raise legitimate health issues, which has forced the government to act. For instance, the proper implementation of The Pre-conception and Pre-natal Diagnostic Techniques (PCPNDT) Act, 1994 is made possible because of the petition filed by some of the non-government organisations and activists in the Supreme Court in 2000. The Supreme Court then gave direction to state governments for the proper implementation of the PCPNDT Act (Kurup, 2011). However, its implementation is still questionable (Ghosal, 2012). Recently, on the issue of unethical clinical trials, gradually common people in India have now started lobbying (Rajalakshmi, 2012; Shukla and Phadke, 1999). For example, in Feb 2011, a protest movement was organised against the unethical clinical trials on Bhopal gas victims. This movement compelled the government of India to take action against the clinicians who were involved in the clinical trials. However, various health activists are not satisfied with the government action (Rajalaksmi, 2012) as the penalty

imposed on alleged doctors was a token (Yee, 2012). It can be argued therefore that, although, the public are getting sensitised with health-related issues, their contribution in the governance framework is not adequate.

According to Pierre and Peters' (2000) framework of governance, in India three modes of governance in the form of hierarchies, networks and community are visible. As far as the market mode of governance is concerned, even though there is a growing market of stem cells in India, it is seen as exploitative rather than empowering for patients as reflected from the analysis in previous chapters. Therefore, the market mode of governance can be ruled out. The discussion in this chapter suggests that medical practices in India are governed through multiple actors ranging from the government, a state-sanctioned self-regulatory body, medical professionals and individual health activists. The legal framework appears to be a more dominant mode of governance compared to others. It appears that there are well-developed legislative measures in place and also, in response to various concerns, the government of India from time to time either revised the existing laws or came up with new measures. However, the system in place is unable to check the growing numbers of violations. Despite enormous power vested in the MCI, it rarely takes action against those clinicians who violated the code of medical ethics (Vashishtha, 2010). Similarly the DCGI is unable to prevent transgression during clinical trials.

Various legislations which are in place to govern clinicians appear to be very strong on paper but not in practice. The Clinical Establishments Act 2010,

which is supposed to standardise the health care delivery system in the country, is still waiting ratification from the majority of the states. This Act is not binding on states, given that health is a state subject. Furthermore, medical professionals are also opposing this Act on various grounds. The State Medical Associations of some states have already requested to their respective state government not to ratify the centrally imposed legislation (Sinha, 2012). In this situation, the implementation of this Act across the country is questionable.

The governance through the medical community also seems to be weak as medical professionals are not involved in any policy-making process and, furthermore, there are allegations that the medical associations work more for their own interest rather than for society. Some individuals have now started questioning the medical authority using the Right to Information Act. However, these individuals' efforts are unable to take shape of a mass movement at the moment.

Against this backdrop, it can be argued that, in India, statutory measures are a dominant mode of governance. However, these have failed to prevent various transgressions, and serious doubts remain over their capacity to govern in practice. It appears that there are significant difficulties in ensuring implementation of statutes in the health sector, and existing monitoring mechanisms are weak. Stem cell work in India has proliferated in this context, directly or indirectly governed by the various government agencies and medical Acts discussed in preceding sections. The next section analyses the

governance of stem cells, which is directly governed by the DBT-ICMR guidelines.

7.4 Stem cell governance

The main document to govern stem cell research and therapy in India is the DBT-ICMR 'Guidelines for Stem Cell Research and Therapy' 2007. This policy document was jointly prepared by the DBT and the ICMR in 2007. Because of the involvement of the DBT and the ICMR in preparing this policy document, it was assumed that these two agencies are regulating stem cells in the country. However, for any clinical trials and pharmaceutical products based on stem cells and umbilical cord blood banks, the monitoring and licensing authority is the DCGI. Nevertheless, India has always been accused of having various agencies to govern stem cell development (Bharadwaj and Glasner, 2009; Salter et al., 2007).

7.4.1 Multiple agencies

The formulation of 'Guidelines for Stem Cell Research and Therapy' 2007 jointly by the DBT and ICMR shows that, in India, these are the two main agencies which regulate stem cell science in the country (Bharadwaj and Glasner, 2009; Salter et al., 2007). However, the DBT-ICMR guidelines clearly establish that the DCGI is the main regulatory agency to approve stem cell

marketable products and to provide licences to cord blood banking firms. A firm representative stated that:

> "DBT is a funding agency. ICMR is an advisory body; the only regulatory agency is DCGI" (Firm's representative, 5).

However, the DCGI has no expertise in the area of stem cells; more specifically they have no experts to internally evaluate the stem cell proposals. An ex-policymaker argued that:

> "At present we have an expert committee on stem cell research both in the DBT and in the ICMR ... at the moment DCGI has no such expertise" (Ex- policymaker).

The DCGI is perceived as equivalent to the US FDA; however it is argued that it is not competent enough to deal with biological materials such as stem cells. A policymaker argued that:

> "Actually DCGI does not have their framework to evaluate these [stem cells] proposals. Initially, DCGI thought that stem cell does not fall as a biological entity so they say that it does not come under their purview so they started forwarding, I mean all these applications to ICMR but later on they realise that it is part of schedule Y, it comes under biological cell or vaccine or recombinant; everything comes under biological and on the basis of that probably they now started building up

framework, they are also stabilising committee" (Policymaker, 1).

At the moment it seems that the ICMR is working as an Indian FDA, though as per the mandate it is a funding-cum-advisory body to the health ministry. The actual Indian FDA, i.e. the DCGI, might therefore be seen as just a licensing authority for 'rubber-stamping' drugs and clinical research, since it makes its decisions solely on the recommendation of the ICMR, at least in the case of stem cells. In addition, all the policy documents relating to biomedical research in India are formulated by the ICMR, and the so-called Indian FDA has little influence over the policy-making process relating to biomedical research and therapy in India. A policymaker in India stated that:

> "ICMR is not a regulatory body, actually it is a funding agency and being an advisory to the health ministry as you know our FDA is not that strong. It is still building up so Indian FDA requested ICMR to help them with ... so all the policy documents ICMR is involved with ethical guidelines for biomedical research ... Guidelines for AR ... Guidelines for foods derived from GM crops so these all were made by ICMR" (Policymaker 2).

The active role played by the ICMR reflects that it is a regulatory agency for biomedical research and therapy in India and this also creates confusion amongst other stakeholders such as clinicians. For instance, a clinician, on the issue of multiple agencies in India to govern stem cell science, argued that:

> "The Ministry of Health appointed ICMR as a regulatory body so they are the apex body. All stem cell work has to go with ICMR. DBT has no regulatory role at all. DBT only gets funding, DST gets funding but all the regulations are done by ICMR, that is very clear. In India, the Ministry of Health clearly puts stem cell in the area of ICMR" (Clinician, 2).

The narration of a clinician who believed that the ICMR is the regulatory authority for stem cells instead of the DCGI clearly elucidated the weakness of the 'Indian FDA and also reflects confusion over jurisdiction. The involvement of different agencies in the governance of stem cells has been a major issue in India, and there have been institutional and bureaucratic disputes in the past between the DBT and the ICMR to ascertain their own guidelines before a final agreement on a combined set of guidelines in 2007 (Bharadwaj and Glasner, 2009; Salter et al., 2007). The involvement of the DBT in the formulation of guidelines also raises a fundamental issue about its role in the governance of stem cell science in India. Though, the DBT is a part of stem cell policy in India, it does not monitor those stem cell activities which are not funded by the DBT. A DBT official stated that:

> "Unless it is funded by the DBT we are not concerned at all because we are not the controlling body as such for the therapy. It is DCGI, Ministry of Health and Family Welfare. So DBT is basically an agency to promote stem cell research R&D, pre-clinical and clinical" (Policymaker, 2).

The DBT only monitors those stem cell research activities which are financially supported by its various R&D programmes. The DBT has a separate stem cell task force for the same and different committees to oversee stem cell research. However, for marketable stem cell products and clinical trials the approval of the DCGI is required.

Apart from the ICMR, the DBT and the DCGI, who are involved in the governance of stem cells, the government of India has recently constituted a long-awaited National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT), which was proposed in the DBT-ICMR guidelines 2007. The NAC-SCRT will oversee and monitor the activities in the field of stem cell research and therapy. However, the NAC-SCRT has no statutory power, as a member of NAC-SCRT on the issue of legislative power stated:

> "This is something we talked about in the last two meetings. NAC-SCRT does not want a policeman role but it is mandatory for the institutions to follow NAC-SCRT otherwise the licence of the institution will be cancelled. Our members can't go from one institute to other" (a member of NAC-SCRT).

Though the member of the NAC-SCRT stresses that the violation of the mandate of NAC-SCRT will lead to the cancellation of licences, it is not clear who will be the designing authority to cancel the licence since NAC-SCRT still has no statutory power to cancel any licence. In the past, the DCGI has warned the New Delhi-based clinician Dr Geeta Shroff for offering unproven

embryonic stem cell treatments. Nevertheless she still continues with her work (Pandeya, 2010).

After the constitution of NAC-SCRT, the question was raised as to how it will co-ordinate with the Indian FDA. At the moment this important aspect appears to be not clear. A firm representative argued that:

> "Once the NAC formed, we need to get more clarity in terms of the roles and responsibilities of NAC, whether NAC will only focus on basic research and will focus on the clinical side which we need to get clarity and how NAC will internally interact with DCGI, so also we need to have some more clarity from ICMR" (Firm's representative, 4).

The concern over co-ordination between the NAC-SCRT and the DCGI is largely diluted, if we closely analyse the composition of NAC-SCRT. The policymakers who are in charge of the stem cell division in the ICMR and the DBT are also members of NAC-SCRT. A member of NAC-SCRT stated that:

> "The NAC-SCRT is body which is created jointly by the ICMR and the DBT. Geeta Jotwani from ICMR and Alka Sharma from DBT are also members of NAC-SCRT" (a member of NAC-SCRT).

Though the long awaited NAC-SCRT is now in place, the question remains, as to whether the NAC-SCRT will be able to regulate unproven treatments with stem cells in India. A scientist who is also the member of the DBT stem cell

task force questioned the capacity of NAC-SCRT to regulate clinical activities of stem cells:

> "Once NAC-SCRT is in place it is going to be still difficult to regulate people who don't come to government for funding" (Scientist, 3).

The narration of different stakeholders clearly depicts that there are multiple agencies in the governance of stem cells in India. However, their jurisdiction is limited at the level of research, marketable products and banking services. Moreover, these agencies can only regulate that research which is being funded by public money as they do not have any jurisdiction over privately-funded research programmes. However, in the case of marketable products and banking services, the approval of the DCGI is essential for both, whether it is public or private.

The presence of various agencies has been a matter of criticism, since it often results in a lack of co-ordination (Bharadwaj and Glasner, 2009; Salter et al., 2007). However, if we closely analyse, it is the ICMR who is playing a leading role in stem cell governance at the moment. In the past there was a great thrust to have a NAC-SCRT. Now the NAC-SCRT is in place. The constitution of this committee is seen as a new step to oversee stem cells in the country but if we see the composition of NAC-SCRT, mostly the same 'elite persons' are members of this committee who are the programme officer of stem cells in the DBT and the ICMR. Moreover, there is no member from the so-called Indian FDA, i.e. the DCGI in the NAC-SCRT. It clearly depicts that the Indian

FDA has no expertise to oversee stem cells. Recently, the DCGI has constituted a special division for stem cells in response to criticisms of not having any internal evaluation mechanism (BioSpectrum, 2012). Now it looks as if the DCGI can deal with violations independently without the assistance of the ICMR. However, the appointment of Director General of ICMR as a chairman of this stem cell division reflects that the DCGI is still not competent to supervise the proliferation of stem cells.

These 'various agencies' basically govern the research part of stem cells. The larger question of how to regulate stem cell medical practices still remains. During my field work, I encountered different key players arguing for a stringent mechanism to be put in place and for more clear and efficient guidelines to prevent unethical stem cell intervention.

7.4.2 Guidelines and a law

The DBT-ICMR stem cell guidelines (2007) group research into three categories: a) prohibited; b) restrictive; and c) permissive. In this framework, although reproductive cloning is prohibited, therapeutic cloning and research on hESC and Chimera are encouraged. In various academic discourses, these guidelines are seen as permissive for the development of stem cells in India (Bharadwaj and Glasner, 2009). During field visit, it was observed that different key players express different opinions on the mandate of existing guidelines with respect to its capacity to regulate the stem cell clinical development.

A clinician opined that:

> "The guidelines are very progressive as compared to the world guidelines. They are very clear, they put things in three categories, prohibited, restricted and permissive, like cloning and other thing is prohibited...embryonic stem cell is restricted where as adult stem cell and umbilical cord cell is permissive. Only country in the world which is divided things among these lines. We divided stem cell work in different categories so I think we are very progressive" (Clinician, 2).

However, some other stakeholders such as scientists and some other clinicians including a few representative of firm feel that guidelines should be clearer and updated, in keeping with recent development of stem cells. A scientist, who is working in a government-funded research laboratory, expressed his opinion that:

> "The DBT-ICMR guidelines are pretty old...they are not yet modified...they are in the process of upgrading it but the guidelines are mostly forecast on how to use embryonic stem cells as such, but the question is that if I am a policeman and I say that you should not dacoit or steal anybody's items, that is perfectly fine...others are honest, you should not do that but if somebody does that, one had to act as police but there is no policing agent so far...they just make some policy...Now it has to pass through parliament as a rule and once it is made as a

rule then probably those malpractices will be stopped, otherwise it will not stop...I think UK, US and Europe it is not possible, nobody do that, the licence will be totally cancelled" (Scientist, 1).

Here, the scientist argues for a stringent punishment for those who violate the mandate of existing guidelines. In India, even after several concerns of unethical practices were expressed in some newspapers and magazines (Indian Express, 2011; Sachan, 2011), no clinician been punished. In contrast, in the UK, recently a doctor's licence to practise was struck off by the General Medical Council (GMC) for offering unproven stem cell treatments (BBC, 2010).

A private medical practitioner, who himself offers experimental stem cell therapy for muscular dystrophy, lamented on the policy of the government and argued that everyone is free in India to offer experimental stem cell therapy at the moment:

"[The] government of India has policies but I think they are sluggish...the legislation in India does not have any teeth on the stem cell therapy providers because they are still in the making of law and as I heard they don't come by the first quarter of the next year but till that time everyone is free, it is as good as any alternative medicine suppose you give Ayurvedic, Homeopathic nobody bothers you it is like same but definitely there should be some legal code for that

guidelines, if you don't follow the guidelines you should be penalised. There should be law and there should be punishment. Currently there is no law for that; just a guideline if you violated nobody is bothered. Even if you go to the Drug Controller of India he says, what can I do...when I don't have powers to crash you, even you don't follow the guidelines then why should I bother you?" (Clinician, 1).

The narration of this clinician informs us that the agencies who are involved in stem cell governance have no power to punish anyone who violates the existing guidelines and therefore everyone is free to use stem cells in clinics.

A representative of a cord blood banking firm stated the guidelines have been in place for many years, and there is a need to have a strict mechanism to deal with violations:

> "See there are only guidelines still after so many years of debate it has been starting in 2004. From 2004 to 2010 there are only guidelines still there is no policy that this is what has to be followed so unless it becomes a mandate and it becomes strict and enforcement everywhere across the country, you can't prevent this from happening" (Firm's representative, 1).

However, even if these guidelines become law, it will be hard to regulate stem cell clinicians with their existing mandate unless and until they cover the clinical part as well; at the moment they are essentially focused on basic

research, although they clearly mentioned that stem cell therapy is still experimental, except in bone marrow transplantation. In addition, although the Ethical Guidelines for Biomedical Research on Human Participants 2006 are legally binding through various Acts, they only deal with clinical trials and basic research. An ex-policymaker explains the problem within the existing governance framework, which allows clinicians to offer unproven stem cell therapies:

> "[The] Drugs and Cosmetics Act, which regulates all clinical trials...this was amended in 2002 and it says all clinical trials in this country, ICMR guidelines should be followed so according to that if anybody gets permission from the Drug Controller for doing a clinical trial they have to follow ICMR guidelines and if they don't follow them, under the Drugs and Cosmetics Act one can punish...similarly the other act is Medical Council of India Act which regulates doctors in this country...physicians...this was also amended in 2002 and it says that all the research being done by the doctors in this country, they have to follow the ICMR guidelines...so this also you can say indirectly mandate on the doctors whatever they do in the name of research they should follow the ICMR guidelines but the problem with the stem cell therapy is that those who are offering therapy don't consider it as research...OK...they think that it is therapeutic...patients are

given...it is a treatment who are giving treatment...any doctor has the right to give treatment...so they are doing their practice...it not comes under research...so there is no need for any permission and there is no need to follow any guidelines...you really can't punish them" (Ex-policymaker).

The above narration clearly suggests that there is a lacuna in the existing regulatory mechanism dealing with clinicians. Within the mandate of existing regulations, the regulatory authority can take action only in the case of research activities. However, if a clinician is offering a therapy, the regulatory authority cannot take any action. Therefore, the question arises as to how an unethical activity of a clinician can be regulated. The narration of an ex-policymaker reflects that various legislative measures described in Section 7.3.1 are ineffective. The ex-policymaker further clarifies that:

"For punishing you should have a strong mechanism so that you know...somebody has to complain...the complaint has to be seen by somebody and then you can take it to human rights or anything for the punishment...otherwise you can't do anything at the moment" (Ex-policymaker).

It is clear that there is no measure to control treatment procedures of the stem cell clinicians or clinicians in general, unless somebody specifically lodges a complaint against the said clinicians under various Acts described in Section 7.3.1. This oversight mechanism is not unique to India: in countries such as the UK, as per information provided on the GMC website, it appears

that GMC also takes action only after receiving a complaint, either from patients or from any aggrieved body. However, given that, especially in the health sector, as highlighted in Section 7.3.3, the public in India are not much empowered, so it is very hard to expect that they will lodge a complaint against any clinician.

Although in the Indian scenario there is a significant voice in the favour of a strong legislation, several studies have argued that a legislative measure alone is not sufficient to ensure ethical conduct (Brein, 1998; Montgomery and Oliver, 2009). The unethical practice of stem cell clinical application in India, I would argue, has nothing to do with specific legislation in this area; rather it is associated with the larger issue of medical malpractices in India. Medical practices in India are governed by nearly 41 Acts (Phadke, 2010). The compliance to ICMR ethical guidelines is mandatory through the Medical Council Act 2002 and the Drugs and Cosmetics Act 2002. In spite of this, from time to time several instances have been reported in the media where a patient was either misdiagnosed or mistreated, leading to further complications and even death (Indian Express, 2011, John, 2005).

In India the major problem is implementation of the existing laws and monitoring. An ex-policymaker argued that:

> "You may have guidelines...you may have a law...but implementation is a major problem...we already have so many laws in this country but the problem has been implementation and monitoring" (Ex-policymaker).

The problem of implementation and monitoring has been a longstanding problem in India. In the backdrop of the recent anti-graft movement, it has been argued that there is an age-old governance and ethical deficit in India (The Times of India, 2011). In these circumstances it is very hard to rely solely on legislative measures to regulate unethical behaviour. If we argue for a self-regulatory mechanism, then it also makes the situation more complex since the ethical behaviour of the medical profession in India is largely vulnerable against the backdrop of commercialisation of modern medicine (Bal, 2001; Pandya, 2007). In a recent study related to 'scientific research conduct' in the US context, it was observed that in the initial years 'scientific research' was governed largely by a normative mechanism when most of the research was supported by public funds. Later, especially after the 1970s, with the increasing research on human subjects; and consequently the exploitation of human subjects led to the formulation of guidelines and forced regulation. However, it was observed that the coercive pressure was only effective in federal government-funded research. It was ineffective to ensure ethical conduct in privately-funded research projects. Further, it was felt that both normative and coercive pressure requires scientific research to be conducted in an ethical manner (Montgomery and Oliver, 2009).

The decreasing child sex ratio (0-6 years) in India reflects that having a stringent law does not always guarantee a solution to the existing problems. The Pre- Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act is seen as one of the most stringent laws in India to prevent foeticide, which was

enacted in 1994. Despite this Act being in place, the child sex ratio in India has declined from 927 in 2001 to 914 in 2011 (Ghosal, 2012). The reason for this decline is partly due to poor implementation of this Act, and partly because of various socio-economic and cultural factors. It is argued that in general there is a strong preference for a son in India, which is one of the reasons for the declining child sex ratio (Singariya, 2012). In addition, it was observed that for some of the medical professional female foeticide is a lucrative business (Rahman, 2010). Against this back drop it can be argued that ethical behaviour is subject to various factors. For individuals or society to act ethically there is a need for holistic approach. Only having a law will not always ensure ethical conduct. In India, there are so many laws to regulate medical professionals. However, regulatory authority fails to curb various transgressions.

As far as stem cell governance in India is concerned, it is still in the development stage, as reflected from the interviews of different stakeholders. Various key players feel that the existing stem cell guidelines need to be updated. And there is a concern that it essentially addresses basic research and not clinical applications of stem cells. It appears that, in response to these concerns, the government of India has geared up to revise the existing guidelines and, in doing so under the leadership of the ICMR, the public consultations were conducted in different parts of India. The next section has attempted to evaluate the process of public consultations. It also tries to analyse the contribution of public consultations in developing the stem cell governance framework.

7.4.3 Public consultation

The initiative of public consultation could be viewed as a 'new' mode of [scientific] governance in India, especially in the stem cell sector (Irwin, 2006; Pierre and Peters, 2000). The ICMR has conducted four public consultations on stem cell research in different parts of the country. Though it was organised in only four places, in principle it has covered the entire country as it was based on the four regions. The first consultation for the western region was held in Mumbai on February 20, 2010 and the second one was held in Bangalore for the southern region on April 10, 2010, followed by a third at Dibrugarh for the north-east on May 14, 2010, and the last at New Delhi for northern regions on December 17, 2011. When I started my field work, three public consultations had been completed. Though the detailed outcome of the public consultation is still to be analysed, during the field work visit I got mixed opinions about the way the public consultation was conducted. It was seen as a good step by the ICMR. An ex-policymaker stated that:

> "The initiative of ICMR public consultation was very good. At some places the response was very good and at some places the response was slow...still people think that it is a highly scientific area and there is nothing for them to come in this debate...the common people representation was very limited...and mostly scientists are coming...ethics committee members do come...However in some places like Bombay and even in the north-east we had lot of patient representatives

> who were keen to know what the conditions were in which stem cells are applicable...what is the success rate...what is the hope that very soon this therapy will be available" (Ex-policymaker).

In the area of science and technology, especially after the 1980s, public consultation on controversial issues is viewed as essential in the decision-making process; in countries such as the US, the UK and across much of Western Europe and in the Asia-Pacific region, there is a great thrust on consulting the public on controversial issues such as GM crops, radioactive waste, stem cell research etc. (Irwin, 2001; Leroux et al., 1998; POST, 2002). However, there are concerns over the process of public consultations; for instance, questions arise over the representation of the wider public in a particular consultation process (Irwin, 2006). It was observed in the case of the stem cell public consultation in India that it was not able to take a wider public opinion. A clinician stated that:

> "See the public forum was expected more than what it actually did...it was supposed to be a public forum where people should be able to ask questions and debate over it but that did not occur" (Clinician, 3).

The public consultation was largely focused on the scientists, clinicians, and firms' representatives rather than on the public. A scientist-cum-member of the DBT stem cell task force illustrated that:

> "I think the notion of having a public consultation was a very good one but unfortunately the way it is played out that most of the people who come are either scientists or doctors who are already involved in these things and so the group who gathers essentially already know what's going on so you are preaching to the converted so there is no real debate as such" (Scientist, 3).

It is very hard to understand whether the way the public consultation was organised was for the public or for the scientists, clinicians, and firms' representatives who are already involved in stem cell development. One of the firms' representatives observed that, during the meeting, the public were not able to express their opinions or concerns:

> "In the two-hour meeting, one-and-a-half hours somebody was talking...some lectures; 15 minutes for the public, it is not adequate...see clinicians should not be the designing authority...basic scientists should not be the designing authority...the society for which we all are working, the society should take a consensus on any and every issue" (Firm's representative, 2).

Similarly, another scientist argued that:

> "It was good but it has not a good impact actually, the reason being because they have not really taken the public per se" (Scientist, 2).

In principle it is always acknowledged that public consultation should take account of as many different opinions as possible and it can only be achieved through the representation of a large section of the society; however, sometimes it becomes a daunting task to accommodate each and every opinion in the policy-making process. For instance, the UK government is still struggling to accommodate the output of public consultation on GM crops in decision making (Doward, 2011; POST, 2002). In one way public consultation can be seen as a more democratic approach, on other side the process of consulting the public and its credibility is often disputed, which questions its underlying democratic approach. It can be argued that consulting people on controversial issues is just a ritual exercise and it is difficult to solely make any decision on the basis of public consultation. The UK GM crops public consultation was criticised on two accounts: that it was too short, and it was poorly publicised. The consulting team acknowledge that it was difficult to get the public involved because of limited funding (BBC, 2003). It means, therefore, that it was not represented by the large section of the population. In contrast, supporters of GM crops question the public attitudes by arguing that it is basically based on 'emotion' rather than 'reason' and the public was accused of being 'anti-science' (Bingham, 2009; Gill, 2010). Furthermore, the 'pre-framing' of the consultation agenda and the issue of patronising the public often leads to the politicisation of public consultation (Durodie, 2003; Gill, 2010) and therefore the whole process of public consultation is questionable.

The stem cell public consultation in India was solely a government initiative; there were no issues or debates as such among the public. No civil society or any religious organisations raised any social or ethical issues related to stem cell basic research or its clinical applications. An official of the ICMR illustrated that:

> "There was not really a major issue for public consultation. Mostly I mean as we know ethical issues in stem cell research revolved around embryonic stem cell so we thought because such a huge diversity in India plus we are having different religions in the country we thought let us have a consensus of all religious bodies"(Policymaker, 1).

The narration of scientist 3 reflects there is no opposition of stem cells in India:

> "Unlike many other countries there is a very high acceptance of stem cell therapy so there are no philosophical and religious issues which people raise...saying that it is against Islam or it is against Hinduism...so those kinds of issues are not being raised in India...such a high public acceptance that there are...for example companies or hospitals where they are offering unproven stem cell treatment...people are not questioning...because they thought that this is a forefront science and going to be a miracle drug" (Scientist, 3).

Surprisingly, a country that once largely opposed biomedicine during the colonial period (Kapila, 2010), now seems to embrace it without any substantial resistance. Soon after independence, biomedicine proliferated under the patronage of "elite politicians and scientists" (Krishna, 2001), while at the same time ignoring the indigenous medical systems such as Ayurveda and even primary health care (Banerji, 2009). Biomedicine in India basically serves the urban elite and this concern was expressed in the National Health Policy of 1982. It was stated in this policy document that "the hospital based, disease and cure oriented approach towards the establishment of medical services has provided benefits to the upper crusts of society, specially those residing in the urban areas" (Banerji, 2009:806).

Stem cell, which flourishes in India under its ambitious biotechnology programme, largely attracts urban elites. These urban elites or more explicitly middle class are influenced by the promises of stem cells made by various scientists, clinicians, firms and policymakers at different platforms, though the safety concerns were also highlighted simultaneously (Basu, 2005; Mathew, 2011; Prasad, 2010; Somasekhar, 2006). It is largely perceived that stem cell is welcomed by the Indian middle class who can afford its services, though it is speculative and unproven (The Times of India, 2010). It is not unexpected; therefore, that stem cell is flourishing without any considerable opposition despite its potentially exploitative nature, at least in the Indian scenario.

It is not always the case that modern medicine has been accepted by Indian society. The protest against unethical trials suggests that now Indian society is

challenging the 'exploitative' nature of biomedicine. However, this protest is confined to the level of the poor and marginalised populations only, who are the victims. The urban and elite populations still have not shown any resistance towards modern medicine in India.

Against the backdrop of high acceptance of stem cells, it can be argued that the public consultation process has no relevance. However, at the same time, the whole exercise appears to be flawed as the representation of the wider public was questionable. In this scenario we cannot really draw any conclusion that stem cells are embraced by the wider population in India. The narration of the scientist 3 implies that the public consultation process was just a ritual exercise. She stated that:

> "I am not sure that it actually achieved the goals but procedurally you have to have this before because any guidelines go to law, you have to have public consultations on this type of issue so, on the one hand, you can say, you need it because you have to be procedural but you won't go beyond procedural is my point and is that where I think the consultations have not reached their goal" (Scientist, 3).

This statement of the scientist, who is also involved in policymaking process, suggests that the Indian government is interested to have a law in place, specifically for stem cells; that is why the public consultation was conducted. As per the above statement it can be inferred that the public consultation was conducted only because since procedurally it was essential for the law-making

process. In this situation it is quite obvious to have a low public participation. After the fourth public consultation the Indian regulators have revised the existing guidelines. The revised guidelines are available at the ICMR website as ICMR-DBT *Guidelines for Stem Cell Research 2012 (draft)*. The draft version of these guidelines informs us that the government of India is now more concerned about the unproven applications of stem cells in clinics. It emphasises in these guidelines that, "stem cell therapy (other than HSCT and epithelial –stem cell-based treatments for burns and corneal disorders) is considered/deemed to be experimental therapy as of now and should be conducted in the form of clinical trials. Those conducted outside clinical trial are unethical and hence not permissible" (ICMR-DBT, 2012: 23). The newly constituted NAC-SCRT also emphasised the same.

Though the procedure of public consultation was criticised by various key players, it has made some contributions in the governance mechanism, as revised guidelines are more clear about unethical stem cells practices. However, various concerns expressed by different key players during field work regarding legislation remain, and still India has only guidelines. The revised draft guidelines indirectly have exposed the confrontation between the DBT and the ICMR for the leadership. The guidelines of 2007 were entitled the *DBT-ICMR Guidelines for Stem Cell Research and Therapy*. The 2012 draft guidelines are entitled the *ICMR-DBT Guidelines for Stem Cell Research*. The name of the *ICMR* is now placed before the *DBT*, which suggest that these two

agencies are competing with each other for the leadership in the stem cell arena.

7.5 Summary and discussion

For the governance of biomedicine, there are multiple government agencies and legislations in place with different mandates. Some agencies are involved specifically in the promotion of basic research while some are engaged in the policy-making process as well. The analysis in this chapter shows that for the governance of stem cell research there are multiple agencies in place, namely the ICMR, the DBT and the DCGI. In addition, a committee, the NAC-SCRT is recently constituted with the mandate to govern stem cell in a more efficient way. Amongst these agencies, the DCGI acts as the main approval and licensing authority for stem cell clinical trials and products. The nature of the DCGI is equivalent to the US FDA. However, the DCGI does not take its decision independently as it has no internal evaluation mechanism for stem cell clinical trials and products. For this it is entirely dependent on the expertise of the ICMR. In the response to growing concerns, recently, the DCGI has constituted a stem cell division. This stem cell division will work under the leadership of the ICMR, which again reflects the co-dependency of the DCGI with the ICMR to make any decision on stem cells. It appears that despite having various agencies to govern stem cell, it is the ICMR, though mainly an advisory body works as a principal regulator. Furthermore, in the NAC-SCRT, the programme officer of stem cells of the ICMR and the DBT is appointed as a

member. This depicts that mostly the same persons are involved in the governance of stem cells in India under different agencies.

Although, the ICMR plays dominant role in the governance of biomedical research in the country, in the case of stem cells, it appears that there is a confrontation between the ICMR and the DBT on the issue of leadership in this emerging area. The conflict between these two agencies started in the very beginning in 2002 when India had taken the initial step to govern stem cells (Bharadwaj and Glasner, 2009; Jayaraman, 2005; Salter et al., 2007) and it appears that it is still continuing given the renaming of the revised draft stem cell guidelines 2012. This reflects the lack of co-ordination between the DBT and the ICMR and hence weakness in the governance framework, though the DBT has no major role on the policy front and the ICMR still dominates as a leading agency in the policymaking process.

All these agencies mainly govern the basic research and clinical trials, as informed by a policymaker. Though basic research does not raise any significant governance issues, the governance of clinical trials raises legitimate concerns given the ineffectiveness of ECs and the death of various research participants during clinical trials. Within the existing oversight mechanisms, the trials using stem cells, therefore, might be questionable.

In India, the use of stem cells in clinics has raised various concerns related to patient safety and their economic exploitation. To regulate medical practices in general, there are considerable numbers of legislative measures in place. The unregulated stem cell clinical activity, which is a part of general medical

practice, can be checked under the existing mechanisms. However, it appears that the state-led governance framework is not effective in practice.

Some of the legislations such as the Indian Penal Code, Indian Contract Act of 1872 and Law of Torts are very strong on paper. However, their effectiveness is subject to the judicial interpretations and the capacity of poor patients to use these laws against alleged clinicians. The expensive and time-consuming judicial services make the situation more complicated. Similarly, the Consumer Protection Act 1986 and the Right to Information Act 2005 appear to be only effective on paper. The Consumer Protection Act is largely perceived as meaningless, especially in the health sector since it is highly dependent on expert advice from other doctors to begin a case against an alleged doctor. The Right to Information Act no doubt has exposed several violations. However, the state-sanctioned self-regulatory body, the MCI, which acts as the licensing authority for clinicians, has enormous power to curb unethical clinical practices, and has never taken a strong step against alleged clinicians whose unethical activities have been exposed in the public domain.

As far as the effectiveness of other forms of governance is concerned, it appears to be not competent enough to govern medical practices. The IMA basically acts for the interests of clinicians rather than for patients, and civil society movements are also not strong enough to force regulators to take strong action against any violations. Therefore, overall different modes of the biomedical governance mechanism with respect to clinical practices are weak in India.

The clinical applications of stem cells flourish within this governance framework. Though majority of the key players in India including previous studies as highlighted in introductory chapter argue for a stringent mechanism to discourage the intervention of unproven therapy, I would argue that there is no need to have a law especially for stem cells. Within the existing framework stem cell transgression can be addressed. There is need to have a proper implementation mechanism of existing laws. Based on the analysis in this chapter, it can be argued that there is a need of proper co-ordination between different modes of governance. The state-led governance can only be effective if the MCI also takes action against the alleged clinicians. Simultaneously, different modes of governance need to be strong enough to have a contribution in developing a governance process. Pierre and Peters' (2000) model of governance argues that state-led governance is still a dominant mode of governance across nations and Chapter 2 also highlighted that, in the area of science and technology especially for stem cells, many countries have this mode of governance. However, the question rises as to whether this mode of governance is effective on grounds and whether for effective governance other forms of governance also need to be strong. My analysis has shown, at least in the case of stem cells in India, that governance in the form of hierarchy can only be effective if other modes of governance are also strong enough. Nevertheless, this needs further empirical analysis.

Chapter 8: Conclusions

8.1 Introduction

The overall aim of this study was to analyse the nature of stem cell activities in India, how key players from science, clinical practice, private firms and government justify or challenge the need for specific activities and frame the ethical issues they raise, and how arrangements to govern stem cell activities work in practice. To fulfil the overall aim, this study attempted to: map the current development of stem cells in India in terms of basic research, clinical activities and cord blood banking; analyse the configuration of expectations around stem cells by different key players; examine how key players construct boundaries between ethically legitimate/illegitimate activities and investigate the potential for different modes of governance around stem cell research and its clinical practice, and their capacity in implementing existing oversight mechanisms.

This chapter pulls together the empirical findings of the thesis and tries to establish a link between expectations, ethics and governance and highlights the policy implications of the study. It also highlights the strengths and weaknesses of the study including possible questions for future research. The summary of findings is as follows.

8.2 Stem cells in India

In India, there is considerable activity in the area of stem cells both in terms of research as well as at the translational level. In the area of basic research, major programmes are dominated by adult stem cells. Recently Indian scientists have succeeded in creating induced pluripotent stem cells (iPS). In media commentary, it is heralded as a country's growing research strength in the area of stem cells as few countries have been able to develop this technology. However, in contrast, research in embryonic stem cells has not yet gathered pace as shown in Chapter 4, possibly due to the failure to develop the 'state-of-the art' technical skills which are required. The embryonic stem cell lines, which were developed in 2001 by RLS and NCBS, and got NIH funding for further work, are still not available for researchers. However, recently JNASCR has developed a few stem cell lines which are available for conducting further research through UK stem cell banks. There are similarities here with the West; for example, Paul Martin and his colleagues in a survey of the regenerative medicine industry have observed that in the West most of the R&D focus is on adult stem cells (Martin et al., 2009). In India, most of the firms are focusing on cord blood banking, but adult stem cells are still the dominant aspect of R&D in the government-funded research laboratories and in the clinics.

At the translation level, hospitals in both the public and private sectors are offering stem cell therapy for a wide range of ailments. Therapies using stem cells have attracted a significant number of patients, not only from India but

from abroad as well: the so-called 'stem cell tourists'. Again, however, most are using adult stem cells derived from patients' own bone marrow. Treatments using embryonic stem cells do not appear to be widely replicated, with the exception of Nutech Mediworld. Some hospitals are also treating patients with cord blood stem cells. The interesting thing is that, especially with respect to stem cell based treatments in India, international commentary has paid more attention to embryonic stem cell therapy rather on adult stem cell therapy, despite its frequent ethically contested application in clinics.

In terms of investment by public and private sectors in stem cells, Chapter 4 showed that basic research in stem cells is extensively supported by the government of India as demonstrated by increasing public spending on various programmes over the years. From the 8^{th} five-year plan (1992-1997) to the 11^{th} five-year plan (2007-2012), the DBT's budget has been increased by 16 times, of which stem cells share more than $1/4^{th}$ of the total budget. In 2009 a new research institute, inStem, exclusively focusing on stem cells, has been established with government support. This is seen as a major boost for stem cell R&D in India (Sachitanand, 2011). One of the main aims of inStem is to bridge the gap between scientists and clinicians. For this, it has collaborated with Christian Medical College, Vellore.

In addition, private players are also making a significant contribution to the development of stem cells given the increasing presence of firms in this sector over the years. A few firms such as Stempeutics have invested millions of dollars in product development in this area.

Despite the formal separation between public and private sectors, a closer look indicates that there are in fact close linkages between government hospitals/laboratories, firms and clinicians. For instance, RLS has linkage with government hospitals such as AIIMS for clinical trials; similarly it has collaboration with NCCS, a public research laboratory. Arguably, firms are providing stem cell isolation services to clinicians as well. There appears to be a close linkage between firms and clinicians for unproven stem cell based treatments. The stem cell city cluster programmes initiated by the DBT aim to facilitate and establish links between publicly and privately-funded research. In addition, firms have developed strong collaboration with universities for knowledge production. Hence, boundaries between public and private are blurred at various levels.

The increasing activity of stem cells seems to be highly linked with visions of future market potential, which is estimated to be US $8 billion by 2015. In 2010, the market of stem cell-based treatments was projected to US $490 million. Presently, clinicians are charging patients US $3,000-US $30,000. Similarly, the estimated market of cord blood banking is worth millions of dollars, given the high birth rate (25 millions/year) in India, and firms currently charge US $1,500-US $2,000 to expectant parents to preserve their child's cord blood. It appears that the potential market of private cord blood banking has attracted many firms of foreign origin to India.

The growing market of different stem cell based services indicates that India can take the edge in this area similar to medical tourism. Affordable and

timely access to health care in India has attracted many patients from Europe, the UK and the US for routine medical services (Turner, 2007). The medical tourism industry in India was estimated to be US $2 billion by 2012 (Shetty, 2010). With comparatively greater restrictions on stem cells in the West and simultaneously growing stem cell activities in India, it is not surprising that stem cell tourism will also flourish similar to medical tourism. However, the use of stem cells in clinics and cord blood banking raises major ethical issues of patient safety as most of the treatment modalities lack enough scientific evidence and are largely categorised as experimental. Moreover, these patients are paying a large sum for the same procedure, raising further questions about economic exploitation. These ethical issues are directly linked to the governance framework since they raise a fundamental question as to why various clinical applications flourish in India despite being experimental. The blurring of boundaries between public and private players might have some influence on the governance regime.

Before analysing the ethical and governance issues in more detail, an attempt was made to investigate how it has become possible to attract various resources and actors towards an immature science. To address this question, both the role and the nature of expectations around stem cell futures were examined.

8.3 Expectations

Overall, future expectations constructed around stem cells in India are overwhelmingly positive, as is evident from the interview data and the media reports. It was observed that, in India, expectations of stem cells are being created by different groups, mainly on the basis that: a) stem cells will help in understanding the basic biology; b) they can solve the problem of organ shortage; c) there is a burden of incurable diseases such as diabetes, cardiovascular, cancer etc.; d) existing therapies have several limitations in dealing with these diseases; and e) there are many needy or desperate patients, and expectant parents in the case of cord blood banking. For private cord blood banking, expectations have been created that cord blood can be used in place of bone marrow cells and it was emphasised that it is not only useful for the self but also for the other family members.

As one might expect, different groups have different expectations as per their institutional and cultural setting. For instance, scientists are more excited about basic research whilst clinicians expect that stem cells have the potential to address a large number of incurable diseases. In contrast to the Anglo-American and European context, some of the informants emphasised that stem cells can provide affordable medical services to a large number of poor people in India. Furthermore, there is a projection that stem cell research will help India in establishing herself as a global leader in the area of science and technology since India has comparatively a more favourable environment than other developed countries. This seems to be one of the

reasons that the Indian state is playing an important role in the creation of hope for the potential benefits of stem cells, which resonates in the form of major government funding and support in various stem cell research programmes in the country.

These various visions in India are used as 'poles of attraction' (Stewart, 1999) for the alignment of various actors, resources and patients towards an experimental therapy, and helps in the creation of a 'community of promise' for transforming the health care sector in India in a way that might bridge the gap between the elite and the poor. The narratives of different groups reflect that the notion of desperate patients, global leadership and affordability for the poor all have the potential to legitimate the activity surrounding Indian stem cells. Affordability for the poor seems to be especially appealing given that millions of the population in India have very low incomes and they are unable to afford expensive medical services. In this context, Chapter 2 noted that a large number of health service providers are in the private sector and there is no insurance cover for the majority of the population in India. There is evidence that high medical bills are one of the reasons for poverty in India.

Along with widely-shared positive expectations of stem cells, there are fears as well, which are reflected by scientists' concerns over stem cell clinical applications on the basis that various therapeutic applications are not backed by enough scientific evidence. These scientists also questioned the ability of the Indian stem cell sector to be a global player in this area at the moment. The timeline of promises was the main issue for all scientists that were

interviewed; while they shared the views of other players as far as promises of stem cells are concerned, they felt that clinicians are giving hope too soon, especially with respect to the ability of stem cells to cure various disease conditions. The discrepancy between scientists and clinicians might be one of the reasons behind the establishment of inStem, as highlighted in Chapter 4. The mandate of inStem suggests that the Indian government is hopeful about the long-term promises of stem cells to address various incurable diseases. It can be argued that inStem has become the institutional embodiment of expectations.

The creation of expectations around stem cells in India is similar to what has been observed in the West where hopes, promises and visions are articulated to shape the development of a science and technological stream such as gene therapy, the human genome project, personalised medicine and stem cells. Comparing the nature of expectations of stem cells between India and the West, it was observed that in the West expectations' rhetoric mainly circulates around the *future* potential uses from embryonic (and adult) stem cell research (Kitzinger, 2008; Martin et al., 2009; Wainwright et al., 2006b; Wilson, 2009) and the storage of cord blood (Martin et al., 2008). While there are similarities in India, expectations are running ahead in the sense that they have been created around the potential of adult stem cell therapy *currently* offered in clinics.

Furthermore, a significant difference in the Indian case is the invocation of so-called 'needy' or 'desperate' patients – both from India and abroad – towards

various clinics as a way of mobilising expectations. In addition to patients, expectant parents are also influenced by the promises of private cord blood banking and, despite slim chances of the autologous use of cord blood stem cells, they are paying a hefty amount to preserve their child's cord blood in the name of biological insurance. This has raised profound implications for ethics as most of the treatment modalities have lacked enough scientific evidence.

The clinical development and use of unapproved stem cell therapies in India in the background of heightened expectations therefore informs us that there is a need to analyse the ethical implications of expectations. In the past, various studies in the sociology of expectations have paid little attention to this important aspect (Petersen, 2011). For instance, technologies such as gene therapy, personalised medicine, stem cells and private cord blood banking have not only attempted to capitalise on hope and influence the actions and policy decisions, they have also encouraged patients and families to go for unproven treatments. In the case of Indian stem cells, this has been profoundly observed and consequently put patients and families at health and financial risk. Arguably, the high expectations associated with gene therapy had even led to the death of a patient in the past (Wilson, 2009). Similarly, an Israeli boy was reported to have developed benign tumours after receiving stem cell treatment in a clinic based in Moscow (Ryan et al., 2010). Chapter 2 noted that, within social studies of expectations, most research has focused on how unrealistic expectations affected the financial, political and

public support for a given area of science and technology. These studies largely overlook the ethical implications of expectations (Martin, 2006; Wilson, 2009).

Furthermore, the involvement of the state in authoring expectations' rhetoric also needs to be analysed. Whilst developing the concept of 'sociotechnical imaginaries', Jasanoff and Kim (2009) argued that in STS research there is little attention paid to analysing the role of non-scientific actors and institutions in the promotion of science and technology. If one were to ask why a state supports and promotes a particular area of science and technology, the answer might vary across different nation-states which depend on widely shared societal visions which themselves vary across cultures. In the case of Indian stem cells it was observed that the state policymakers are highly influenced by the promises associated with stem cells. This finds expression in the high level of financial support from the state to various programmes in the country. In addition, to taking maximum advantage from the 'promise' of stem cells, the Indian government has established various networks of public and private players including scientists and clinicians, as highlighted in the previous chapter.

The notions of desperate patients, global leadership and affordability for poor people appear to pull heterogeneous actors together and help in the creation of a 'community of promise'. However, some negative expectations expressed by scientists problematise the concept of a 'community of promise'. It can be argued that the alignment of heterogeneous actors towards a particular

technology is subject to the nature of the technology in question and underlying promises attached with a particular technology will not always be helpful to pull different actors together and results in contested futures.

In sum, these findings inform us that the scholarship of sociology of expectations needs to consider the ethical implications of expectations and the role of the state in expectations discourse. These considerations will help in analysing the issues of ethics and governance which arise with the proliferation of a particular technology in the locale of heightened expectations.

8.4 Ethics

Comparing the nature of the ethical debate in the Western context with the Indian one, we see that, while, in the West, boundaries are mainly constructed around the use of different sources of human embryos (i.e. around ethically preferable sources of human embryo) (Wainwright et al., 2006a), in the Indian case these are being drawn around the use of stem cells in clinics (i.e. whether to use stem cells as a standard therapy to treat incurable diseases). This shows that there can be different forms of ethical boundary-work (Ehrich et al., 2006). Unlike in the West, the use of human embryos either in research or in clinics has not raised any major ethical issues in India. The reason might be that there are pluralities of views on issues related to eggs and the moral status of the human embryo and the dominant

religion Hinduism is less monolithic compared to other religions, hence allowing a flexible approach to accommodate different views. In contrast to controversies around embryonic research, the major questions around stem cell work in India are associated with the proliferation of unproven therapies. This is not surprising, given that expectations created around stem cells in terms of their therapeutic application are high, as highlighted in Chapter 5. How different stakeholders frame or respond to these ethical challenges was examined in depth in Chapter 6.

Therapeutic applications of stem cells have raised major ethical issues over the safety of patients in the absence of proven efficacy of the treatments, and the possible financial exploitation of patients given the significant costs of treatment. Most of the stem cell based treatments have not gone through clinical trials, nor have they been subject to prior approval by regulatory authorities, as was shown in Chapter 4. There is no documented evidence of any of these clinical interventions available in order to examine the treatment modality, i.e. whether it is beneficial or harmful to the patients. In this context, the proliferation of stem cell therapies in India might easily be described as a money-making business rather than an activity undertaken to alleviate the suffering of those desperate patients who are regularly invoked in the discourse of clinicians. The 'mushrooming' of private blood banking has also emerged as another money-making endeavour. The majority of my informants argued that, in the name of 'biological insurance', expectant parents are being exploited since there is a rare chance for a child to use its

own cord blood in the future. In the whole process, the informed consent procedures are largely ignored.

In the above context, Chapter 6 explored how key actors within the Indian stem cell community construct and justify ethical boundaries (Hobson-West, 2012; Wainwright et al., 2006a) around their work. It was observed that there is considerable variation in how different key players perceive the ethical issues around growing stem cell clinical activities. Whilst comparing the rhetoric of expectations and ethical framing of different key players, the chapter showed that, though expectations rhetoric is highly embedded in institutional settings, there are notable differences in how actors *within* a community construct their ethical arguments. For instance, not all clinicians are advocating the use of unproven stem cell therapies in clinics and charging patients for the same. Furthermore, many of them also consider the business of private cord blood banking to be unethical.

On the other hand, those who are offering stem cell interventions in clinics justify their practice as ethical in three key ways. First, they argue that adult stem cells are safe for use with patients without the need for clinical trials. Second, some employ international ethical guidelines to justify experimental therapy. Third, the figure of the desperate patient is invoked not only in the creation of expectations about stem cell futures (as we see in Chapter 5) but to make a case for stem cell intervention as necessary and desirable.

However, there is still considerable contestation over the interpretation of ethical guidelines, such as the Helsinki Declaration. Some clinicians argue that

this document allows them to use an experimental therapy if all other treatment options for an existing disease have been exhausted. Others assert that it is unethical to offer experimental stem cell intervention in the name of the Helsinki Declaration and they contend that stem cells should not be used as a standard therapy as there are still various unresolved and unknown safety issues. Scientists and policymakers were likewise critical. Representatives of firms expressed mixed opinions, in a way that is similar to clinicians, with some arguing that desperate patients are looking for some kind of help; therefore, they cannot spend time in doing research only.

The narratives of different actors suggest that the main contentious issue is whether to use experimental therapy in clinics and this is the reason some clinicians often invoked 'desperate patients' in their ethical boundary-work rhetoric. The issue of experimental therapy is highly complex given the ongoing campaign in different countries in the favour of right to access experimental drugs for terminally-ill patients outside of clinical trials, especially for certain incurable diseases for which existing standard treatments have been exhausted (CBC News, 2010; Okie, 2006; Vale, 2007-08). It is argued in some academic discourses that "technology assessment takes too long – it isn't fair to patients or physicians – scientists to have to wait in the face of life-threatening illness" (King, 1995: 8). Under this circumstance, the activity of clinicians in India might be legitimised on the grounds that they are providing some kind of treatment to terminally-ill patients. The US FDA also allows experimental drugs under 'expended access',

sometimes called 'compassionate use', on a case by case basis with certain safeguards such as prior approval from the FDA before doing so. However, in the Indian case, clinicians have not in fact gained or tried to gain this type of special-case exemption or approval from regulators; in this respect, therapies without any safeguards are being offered in the name of providing relief to desperate patients. This case suggests that the national/international biomedical governance community perhaps needs to develop a uniform mechanism and set of guidelines for 'compassionate use', interpretation of which is highly variable in different jurisdictions, as analysed in Chapter 2. As far as the situation in India is concerned, there are no policy documents related to 'compassionate use'.[27]

The analysis of discourse around the ethical challenges of stem cells in India informs us that 'ethical boundary-work' is flexible and subject to a particular social and cultural context. It illuminates that 'ethics' is framed and managed differently in different cross-cultural settings within the same area of science and it is highly linked with existing regulatory framework or policy documents. However, despite the differences in ethical controversy in India and the West, there is a significant similarity in rhetorical boundary-work in that both are centred on the health benefits of the research in question and on the capacity of the existing governance framework to legitimise the work, as Hobson-West (2012) and Wainwright et al. (2006a) have shown in other cases.

[27] As informed by a clinician in a personal communication.

The concept of ethical boundary-work can be very useful for guiding the developing governance framework as it provides an opportunity to analyse the views of key actors and accordingly a policy framework could be developed. For instance, in the Indian case, if a governance framework in the area of stem cells were sufficient to discourage experimental therapy (with appropriate safeguards) then it is possible that the various ethical issues could be addressed. However, the scholars, who used the concept of ethical boundary-work, have mainly concentrated on the construction of ethical boundaries, i.e. what is ethically preferable and what is not; how do certain actors ethically legitimise their work or manage the 'ethical' in their practice (Frith et al., 2011; Hobson-West, 2012; Wainwright et al., 2006a); and how is non-science in the form of 'ethics' used to justify the activities of science? This research has paid little attention to the policy implications of construction of various boundaries, a subject that was the focus of Chapter 7.

In sum, it is clear from the above discussion that the proliferation of stem cell activities in India could be easily described as unethical. In the Indian case, the interesting thing is that these therapies continue to flourish, despite concerns expressed by the policymakers. Chapter 7 examined the reasons behind this situation.

8.5 Governance

Informed by the governance model proposed by Pierre and Peters (2000), Chapter 7 analysed the biomedical governance (both research and clinical part) framework in India. This chapter investigated the extent to which a particular mode of governance was in place, i.e. a) governance as hierarchies, b) governance as markets, c) governance as networks, or d) governance as communities. The aim was to investigate the potential for different modes of governance around stem cell research and its clinical practice and their capacity in implementing existing oversight mechanisms.

For governance of biomedical research and therapy in India, there are a number of different government agencies and laws in place with different mandates. Various agencies are promoting biomedical research through funding and some agencies are involved in the policymaking process. For stem cells, there are multiple agencies to govern stem cell research such as the Indian Council of Medical Research (ICMR), the Department of Biotechnology (DBT) and the Drug Controller General of India (DCGI). In addition, the National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) is also in place for the same reason. Formally, therefore, it appears that there is fragmentation of governing capacity in the biomedical domain. The main approval and licensing authority for stem cells is the DCGI, which is the formal equivalent to the US FDA. However, this centralisation of authority amidst a fragmented governing structure does not translate into implementation

authority on the ground, as one of the policymakers also admitted that this 'Indian FDA' is not strong enough to actually deal with stem cell practices.

The governance structure as it works in practice is still more complicated since the DCGI takes its decisions with the help of the ICMR, as it has no internal evaluation mechanism for stem cell clinical trials and products as argued by various key players during field work. Recently, the DCGI created a stem cell division under the chairmanship of the ICMR, which again suggests a strong co-dependency on the ICMR to make any decision on stem cells. It can be argued that various agencies exist only on paper and it is the ICMR, though mainly an advisory body, indirectly working as an 'Indian FDA' rather than the formally authorised body, DCGI. Furthermore, in the NAC-SCRT, the programme officer of stem cells of the ICMR and the DBT is also appointed as a member. This shows that mostly the same persons are involved in the governance of stem cells under different agencies.

Although the ICMR plays a dominant role in the governance of biomedical research in the country, in the case of stem cells, it appears that there is a confrontation between the ICMR and the DBT on the issue of leadership in this emerging area, as highlighted in Chapter 7.

The analysis in this chapter suggests that, at one level, the form of governance of biomedical research in India appears to be primarily hierarchical or state-led to use the typology developed by Pierre and Peters (2000). However, in a significant departure from the governance-as-hierarchies approach, which strictly upholds the *public-private* distinction (Pierre and Peters, 2000),

biomedical research governance in India blurs the boundary between public and private through the City Cluster programme. The City Cluster programme is an initiative of the government of India for the development of biotechnology which involves private institutes/firms as well, along with publicly-funded research institutes. This indicates the transformation of the role of the state from a role based in hierarchy towards a role based in co-ordination and integration of public and private players (Pierre and Peters, 2000). This may be particularly relevant to the biomedical context; similar findings are reported by Burau and Vrangbaek (2008) in a comparative study of medical governance in the five European countries (Britain, Denmark, Germany, Italy and Norway). They observe that, though new medical governance is strongly dominated by hierarchical forms of governance, it is combined with other forms of governing. Further, they argue that in different countries the relative balance between forms of governance varies (Burau and Vrangbaek, 2008).

It is worth mentioning here that various agencies highlighted above only oversee basic research and clinical trials of biomedical research in general, including stem cells and not the clinical practice of stem cells as such. This was noted by a policymaker during field work, suggesting that the clinical use of stem cells remains relatively invisible within the existing governing structure for biomedical research – or out of their formal reach – despite its visibility in the media. In the absence of concerns over the use of embryos, basic research in stem cells does not appear to raise any significant governance issues. The

governance of clinical trials in general is considerably weak, given the ineffectiveness of Ethics Committees and the death of various research participants during clinical trials. In the previous chapter, we saw that some of the key players, especially scientists and policymakers, argued for the need to have clinical trials prior to the use of stem cell in clinics. However, when the procedure of clinical trials itself is flawed, the capacity of stem cell trials conducted within the existing biomedical governance framework to settle ethical concerns might be questionable.

If arrangements for governing biomedical research are ineffective in terms of their ability to manage the use of stem cells as therapy, the question remains: how are clinicians governed in India and what are the prospects for stem cell therapies to be regulated directly as clinical practice as opposed to research practice?

It was observed that there are various laws in India which directly or indirectly oversee clinical practices such as the Indian Penal Code, Indian Contract Act of 1872 and Law of Torts. These Acts are very strong on paper. Stem cell therapy is a part of this governance regime and any violation related to this practice can, in principle, be addressed by using these laws. However, it is beyond the capacity of poor patients to use these laws against alleged clinicians given the expensive and time-consuming legal process in India. In addition, the effectiveness of these laws is also subject to judicial interpretation. The Consumer Protection Act 1986 appears to be effective on paper, given that Consumer forums comparatively take less time to dispose of a case and are

also less expensive. The Right to Information Act 2005 is also an effective tool to expose various transgressions in the public domain. However, neither of these Acts, similar to other legislations, is efficient in practice. The Consumer Protection Act is largely perceived as meaningless since it requires expert advice from other clinicians to begin a case against an alleged clinician. The Right to Information Act no doubt has exposed several violations. However, this Act is unable to restrict unethical behaviour of clinicians given that the regulatory authority has never taken a rigorous step against alleged clinicians based on information revealed by using this Act.

In addition to these laws, India has a state-sanctioned self-regulatory body, i.e. the Medical Council of Indian or MCI (cf. Salter, 1999), which is equivalent to the General Medical Council (GMC) in the UK. The government of India has provided enough statutory power to regulate medical professionals in the country. This body acts as the licensing authority for clinicians, and has enormous power to curb unethical clinical practices. For instance, under the Code of Ethics Regulation 2002, the MCI has power to cancel the licence of any medical practitioners who violate the code of medical ethics. However, there are allegations that it has never taken a strong action against those clinicians who do not follow the existing code of medical ethics and is often itself plagued with corruption charges. In a popular television talk show *Satyamev Jayate* (Truth Alone Prevails), which aired on May 27, 2012, it was revealed that since 2008 not a single clinician's licence had been cancelled in India, despite various incidents of alleged medical malpractices. In contrast, in

the UK in 2010, the licences of 92 doctors had been cancelled by the GMC because their fitness to practice was in doubt.[28] This suggests that in India the self-regulatory mechanism does not work in practice.

A clinician stated that at the moment everyone is free to offer experimental therapy. An ex-official of the ICMR also admitted that India has problems with monitoring and implementation. Similarly, a scientist argues that these types of malpractices are not possible in the West given the strict measures for the same reason.

Chapter 7 has shown that both the hierarchical mode of governance of biomedical research and state-sanctioned self-regulatory structure for clinical practice including other legislations are ineffective in terms of controlling stem cell activity, despite their formal dominance in the existing governance framework.

Given the peculiar nature of stem cells and the difficulties noted above, the government of India has recently revised guidelines specifically oriented towards discouraging the use of stem cells for therapy. Indeed, most key players, even those who are allegedly involved in unethical practices, have argued for a stringent mechanism to check transgressions around stem cells. However, the new guidelines also appear to be ineffective as they do not have the legal teeth to punish any violations. The newly constituted NAC-SCRT has

[28] http://www.gmc-uk.org/news/10866.asp [Accessed Sept 12, 2012].

also no legal power to punish anyone in the case of violations, as informed by a member of the NAC-SCRT during field work.

If neither governance through command and control (hierarchy) nor governance through self-regulation is effective, what about other potential modes of governance? Pierre and Peters identify two other forms, i.e. governance through networks and governance through communities or civil society; but, again, neither possibility works in the Indian case. In principle, collaboration between the state and medical professionals, i.e. the Indian Medical Association (IMA) or a strong civil society voice might have been capable of exerting influence on the biomedical governance framework. However, the IMA arguably acts for the interest of clinicians rather than for patients, and civil society movements are not strong enough to force regulators to take strong action against any violations. The growing market of stem cell based therapies and cord blood banking, as described in Chapter 4, suggests that there is a strong market influence on the developing governance framework. Whether this empowers patients (citizens) is a separate question – so far, evidence suggests that various services provided by different players tend to be more exploitative rather than empowering for patients, as reflected in Chapter 6.

In sum, different modes of biomedical governance mechanism with respect to clinical practices are weak in India. The governance of stem cells is a part of this existing governance framework. It is not surprising, therefore, that

unproven therapies have flourished in India and clinicians are boldly justifying their activities on various grounds, as described in the previous chapter.

The analysis in Chapter 7 indicates that, in India, the dominant mode of governance in biomedical governance is hierarchical including state sanctioned policy network, i.e. professional self-regulation in the form of MCI. Neither government-professional networks nor civil society make a significant contribution to biomedical governance; rather, they are comparatively weak. This might be the reason behind the ineffectiveness of a hierarchical mode of governance in dealing with stem cell medical practices.

8.6 Policy implications

The findings of this study suggest that there is no particular need to have a law especially for stem cells. This is distinct from the argument made in previous studies and various key players during field work. Within the existing biomedical governance framework, stem cell transgression could potentially be addressed, but this would mean dealing with the major implementation gap that exists between the formulation of laws and their translation in practice on the ground.

Furthermore, there is a need to have more clarification with respect to using stem cells in clinics. The use of stem cells is often considered as a part of routine medical practices and, according to the MCI rules and regulations, it is the fundamental right of a clinician to do medical practice as per her/his

wisdom. It is not only the case in India; it appears that many countries in the West also acknowledge this right of clinicians (Cyranoski, 2012; GMC, 2012). In India, a clinician, who is accused of malpractices, can only be brought under legal proceedings if somebody makes a complaint against her/him. Because of the distinctive social and cultural factors such as lay deference to clinicians combined with lengthy and expensive legal procedures, lay people in India are generally reluctant to go against clinicians. India, therefore, needs to develop those kinds of mechanisms through which a clinician can be brought under legal proceedings directly by the regulators if it is observed that any clinician is using an unproven therapy as a standard therapy. In a recent decision, a US Court upheld the FDA claims that the use of adult stem cells should not be considered as routine medical practice and it should be categorised as an unapproved biological product as stem cells are manipulated before being injected into the patients (Cyranoski, 2012). However, the Indian government has neither taken a similar initiative nor developed any effective mechanism with respect to 'compassionate use', similar to the US FDA, and this is one of the reasons that various clinicians are offering stem cells in the name of helping terminally-ill patients, as highlighted in Chapter 5. In addition, a professional self-regulation mechanism also needs to be strong enough to deal with medical malpractices.

To summarise, the failure of the state (even during a state-led biomedical regime) to regulate the practice of medicine suggests that the Indian government is not very serious about curbing unethical practices of stem

cells. In addition, it has been unable to implement existing laws which are in place to oversee clinicians. Furthermore, state-sanctioned professional governance in the form of the Medical Council of India (MCI) is also not effective in enforcing professional norms such as ethical codes of conduct. This clearly indicates that both hierarchical and networks modes of governance fail to prevent transgression. An important reason might be that there are high expectations of stem cells at both state as well as clinical level, where there is a desire to be a global player as well as to cure various debilitating diseases.

Furthermore, there is a high potential market in India for both stem cell based therapies and cord blood banking. Against this backdrop, seemingly the Indian state and the state-sanctioned self-regulatory body, i.e. the MCI, allow the unproven stem cell treatments. On the similar line of medical tourism, there is great potential for stem cell tourism in India. It is not surprising, therefore, that neither the state nor the MCI implements existing regulatory standards forcefully. However, India has a long-standing problem with the implementation of various laws and social welfare schemes (Robinson, 2011). Chapter 7 highlighted the problems with the implementation of the Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act, 1994. The poor implementation of this Act is one of the reasons behind increasing female foeticide in India. Similarly, even after 10 years, India could not implement the mandate of the Biological Diversity Act, 2002 (Bhutani and Kohli, 2012). It was observed that, as a result, biodiversity has been declining

in India (Bhutani and Kohli, 2012). Furthermore, a gap was observed in the implementation of the public health policy related to HIV testing in some parts of India (Sheikh and Porter, 2010). It can be argued therefore that the stem cell sector is mirroring the wider problem of implementation in India.

But the larger question remains: what reform can be introduced in the current biomedical governance regime in order to prevent unethical clinical practices not only in stem cells but also in general medical practices? The analysis in Chapter 7 has shown that there is a difficulty in bringing a private litigation or implementation policy via courts due to a structural problem within the governance system. In this situation, this study suggests that there are two key ways that reformative measures can be introduced to strengthen the biomedical governance system. First, India can take a lesson from the UK GMC reforms which were introduced by the GMC in the 1980s and especially after the Bristol case[29] and the Shipman affair[30] (Stacey, 2000). One of the most notable reforms was the greater representation of lay members on its fitness-to-practice committee. This initiative has opened up the disciplinary proceedings against any doctors. At the moment, there are an equal number of medical and lay members in the GMC. This suggests that the public has an equally important role in regulating clinicians in the UK. In addition, recently the GMC has implemented a long-standing proposal of revalidation of

[29]The Bristol case was related to deaths of 29 babies and young children at the Bristol Royal Infirmary who had received complex cardiac surgery from 1985-1995.

[30]The conviction of GP Harold Shipman for murdering several of his patients in 2000.

licensed doctors[31]. Revalidation is the process by which practising doctors need to demonstrate their fitness to practise, usually every five years. During their annual appraisal and revalidation, doctors will have to provide feedback from patients as one of the supporting pieces of information, including other things. It can be argued that the GMC is more accountable to the general public and its proceedings are more transparent. In contrast, in the MCI there is no representation of lay members[32]. If the MCI introduced similar reforms on the line of the GMC, then the monopoly of doctors could be reduced and there could be a greater possibility of disciplinary actions against a clinician in the case of any violation. Chapter 7 has shown the poor record of MCI in taking action against any clinician. Second, there is a need to have a citizen health advocacy network. In India, there is no truly organised group to pursue the rights of patients (Shah and Garg, 2011). This type of network can pursue claims against medical malpractices and negligence through both the courts and the MCI. In the West there are some universities and groups who run health advocacy-related courses and programmes to train people in advocacy (Shah and Garg, 2011). A similar initiative could be taken in India. Finally, this study concluded that, by making decision-making more transparent, changing the balance of interests in the MCI, and empowering citizen advocates, some real progress can be made in the biomedical governance system of India, including stem cells.

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[31] http://www.gmc-uk.org/doctors/revalidation.asp [Accessed Dec 12, 2012].

[32] http://mciindia.org/AboutMCI/BoardofGovernors.aspx [Accessed Dec 5, 2012].

8.7 Strengths and weaknesses of the study

My study has analysed the stem cell sector in India and in doing so it mapped the different activities in basic research, clinical activities and cord blood banking. This has provided an opportunity to understand the current status of different areas of stem cell research and treatments in India which no previous studies has undertaken to date. By using the concepts of sociology of expectations, ethical boundary-work (Wainwright et al., 2006a) and Pierre and Peters' (2000) governance framework, my study has provided a more nuanced understanding of generation of expectations, framing of raised ethical issues and different modes of governance dealing with stem cell research and its clinical applications in India. Most importantly, my study takes account of key actors' perspectives and establishes a link between expectations, ethics and governance. Furthermore, the highlighting of adult stem cells and cord blood stem cells in India is noteworthy, given that many previous studies and international media had not paid due attention to the proliferation of adult stem cells and private cord blood banking. The use of adult stem cells in clinics and private cord blood banking also raised important ethical concerns, similar to embryonic stem cells, with respect to patients' safety and possible economic exploitation of patients and expectant parents in India. The analysis of expectations rhetoric helps to understand on what basis key players try to attract necessary resources, patients (both local and international) and expectant parents. Similarly, the findings of this study have shown how key players justify or challenge various stem cell activities. The

justification for using unproven stem cell clinical applications on terminally-ill patients in the name of the Helsinki Declaration is instructive, as it suggests that there is a need to have a robust framework for terminally-ill patients. Furthermore, unlike in previous studies, which focused on the inability of the DBT-ICMR guidelines in preventing unethical practices of stem cells, my study found that the ineffectiveness of different modes of medical governance is responsible for the unethical medical practices of stem cells. More specifically, the state-sanctioned body for self-regulation of the medical profession has never taken strict actions against those clinicians who are offering unproven stem cell therapy. Given this system, it is unlikely that abuses in the case of stem cells will be regulated any better.

For the data collection, I used a survey, documentary analysis and qualitative interviews. The survey was very useful for mapping the various stem cell-related activities which are being conducted at various public and private institutes, including identifying individuals to interview. The analysis of documents, including media analysis, was helpful for understanding the existing policy framework and the creation of expectations including ethical and governance issues. Qualitative interviews play a vital role in uncovering stakeholders' perspectives, which was not possible through survey and documentary analysis. Though I identified most of the individuals and locations for interview through carrying out a survey, I came to know about the newly-established inStem institute during an interview with one of my

informants. This suggests that combining various methods was really helpful for my study.

Although my research adds to and goes beyond sociological studies that have already been conducted around the proliferation of stem cell research and treatment in India, it has of course also certain limitations. A more systematic media analysis, especially the use of metaphors in press coverage and its ethical and social implications along the lines studies in the case of other areas of science and technology including stem cells (e.g., Hellsten and Nerlich, 2011; Nerlich and Jaspal, 2012; Musolff, 2009) might have been conducted. Similarly, the websites of various hospitals/individual clinics and firms could have been analysed in depth as various websites work as 'direct-to-consumer advertising' for stem cell treatments (Lau et al., 2008; Petersen, 2011). These websites are loaded with inflated promises and claims to cure a wide range of disease conditions which play an important role to attract both native as well as foreign patients. In addition, more in-depth qualitative analysis of interviews could have been carried out (Wainwright et al., 2006a). Research in this area might also benefit from the analysis of stem cells development within the context of different prevalent alternative medicine systems in India and socio-cultural differences such as the urban-rural divide, including interviews with patients who have either already received or are currently seeking stem cell treatments, as previous studies in this domain did. Had I started the research today, the subject of international stem cell

tourism might have also been a natural focus. These issues lay the foundation for future research that might build on my thesis work.

8.8 Future research

A research project specifically concentrating on the proliferation of private cord blood banking could be developed with the aim of analysing what drives expectant parents to try to preserve their child's cord blood despite its slim chances of self-use for the child and what are the different strategies being used by the private firms to attract expectant parents. The sociological study of stem cell tourism could be an another exciting project, given that a global form of governance for this emerging field is still at the nascent stage in the context of vastly different systems around the conduct of biomedical research and the regulation of stem cell science. The project could explore the relationship between domestic and international law, and the extent to which policymakers of a particular country can and should intervene to protect their citizens from perceived exploitation in another part of the world. In addition there is little known about the perception of patients who travel overseas for an unproven therapy. All these aspects and many more could be explored in the stem cell tourism project. A more in-depth analysis of the use of metaphors on stem cell-related websites and in news coverage is also warranted, and their ethical and governance implications could be explored.

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Appendix I: Contact letter

Dear XXX

I am writing to see if you might be able to help with a research project exploring the ethical principles governing the use of stem cells in India and how these are 'translated' into governance regimes at national and local level. The project aims to analyse the governance of research and clinical practice in relation to stem cell therapies and the main barriers facing the effective governance of the stem cell field. The findings will contribute in my PhD, funded by the Wellcome Trust (UK). I have enclosed an information sheet which provides further details.

I am conducting a series of interviews with leading scientists, clinicians, companies, and policy makers in India. I would greatly appreciate the opportunity to interview you as part of this study. The data from this research will provide valuable evidence of the ethical issues raise by the clinical development and use of stem cells in India and the problem with the existing framework of governance.

The interview would last no more than one hour. The interview and all correspondence will be treated as confidential and consistent with the best ethical research practice.

I very much hope that you will be able to participate in this research, as I would greatly value your contribution. Ideally, I would like to schedule a

meeting between...to...I will follow up in next weeks. Please do not hesitate to contact me, if you would like to discuss the project or require more information.

Thank you in advance for your time and assistance,

Yours sincerely,

Shashank S. Tiwari

Appendix II: Information sheet

The ethics and governance of stem cell clinical research in India

Shashank S. Tiwari

E-mail; lbxst1@nottingham.ac.uk

Introduction

India is rapidly becoming established as a major player in the development of stem cell therapies, with a significant numbers of research centres, private clinics and companies active in this area. The current stem cell therapy market in India is approximately US $540 million and it is expected to grow rapidly. The country is becoming an attractive destination for global stem cell companies and research institutes in the areas of clinical trials/clinical research, stem cell research and contract manufacturing. However, clinical research and the therapeutic application of stem cells are less regulated than in many developed countries, and this has led to a number of ethical controversies and concerns, including: the ready availability of different stem cell-based interventions offered by a range of individuals and institutions; and claims that these are successful in curing a number of diseases. There are calls for more formal oversight and statutory regulation of the emerging market for stem cell therapy, otherwise false claims and serious risks to patient safety could destroy the sector.

Project Aims and Research Questions

- To describe the current clinical development and use of stem cell therapies in India and the ethical issues this raises;
- To analyse the governance of research and clinical practice in relation to stem cell therapies, the responsibilities of the main institutions involved and problems with the existing system of governance;
- To explore the extent to which ethical principles are being translated into practice and how public policy might be developed to better ensure ethical conduct and public protection in this area.

Methods

The study will combine various qualitative methods, drawing on data from documentary and media analysis, and semi-structured interviews with scientists, clinicians, and policy makers.

Relevance to Policy and Practice

The study will provide valuable evidence of the ethical issues raise by the clinical development and use of stem cells in India, the ethical principles being introduced to address these problems, the extent to which these principles are being translated into practice and the main barriers facing the effective governance of the stem cell field. This will be of direct relevance to scientists, clinicians, companies, and policy makers in both India and other developing countries.

Appendix III: Interview guide

Basic Research

1. In which area of stem cell research you are involved? **(Scientists, Firms)**
2. What are the short term and long term potential applications of your research? **(Scientists, Firms)**

Clinical Research

3. In what kinds of stem cell clinical research you are involved? **(Clinicians, Firms)**
4. What are the potential applications of your clinical research? **(Clinicians, Firms)**

Clinical Services

5. What kinds of stem cell therapies/services you offer to your patients? **(Clinicians, Firms)**
6. What are the potential benefits of stem cell based treatments compared with other existing treatments? **(Scientists, Clinicians, Firms, Regulators)**
7. Are your patients only from India or abroad as well? **(Clinicians, Firms)**
8. Have these therapies gone through clinical trials? **(Clinicians, Firms)**

9. In your opinion, at what stage, it is appropriate to move from lab to clinic? **(Scientists, Clinicians, Firms, Regulators)**
10. What are your views regarding stem cell clinical development in India? **(Scientists, Clinicians, Firms, Regulators)**

Linkages

11. Do you have any kind of national/international collaboration? **(Scientists, Clinicians, Firms)**
12. Could you please let me know about the nature of collaboration? **(Scientists, Clinicians, Firms)**
13. Do you also discuss any ethical issues? **(Scientists, Clinicians, Firms)**

Ethics

14. What is the source of your research material? **(Scientists, Clinicians, Firms)**
15. Are there different ethical issues associated with different sources of embryos? **(Scientists, Clinicians, Firms)**
16. There is national/international criticism, of the way some clinicians/firms are practicing/offering stem cell therapies/services to the patients. What are your views regarding that? **(Scientists, Clinicians, Firms)**

17. Every clinical trial needs approval of Institutional Ethics Committee/Review Board. How do you see this whole process of approval mechanism? **(Clinicians, Firms, Regulators)**
18. How do you recruit your participants for clinical trials? **(Clinician, Firms)**
19. Are there any particular difficulties in obtaining informed consent? **(Clinicians, Firms)**
20. What are your views on the process of clinical trial registration? **(Clinicians, Firms, Regulators)**
21. How the ongoing clinical trials being monitored? **(Clinicians, Firms, Regulators)**
22. How do you ensure maximum benefits to trial participants? **(Clinicians, Firms, Regulators)**
23. India is emerging as a centre for stem cell based therapies which attracts Indian as well as foreign patients. Which patients are making more use of these therapies? **(Clinicians, Firms)**
24. Are there different ethical issues associated with different groups of patients? **(Clinicians, Firms)**
25. Are there any particular ethical issues associated with those patients, who comes India for stem cell based treatments? **(Clinicians, Firms)**
26. In India, the policy related to stem cell research and therapy is still developing. Are there anything in the existing guidelines which

addresses International audience? **(Scientists, Clinicians, Firms, Regulators)**

Governance

27. How the stem cell clinical trials are regulated in India? **(Scientists, Clinicians, Firms, Regulators)**
28. What are your views regarding current policy related to informed consent? **(Clinicians, Firms , Regulators)**
29. How these policies are relevant in Indian condition? **(Clinicians, Firms, Regulators)**
30. What is your opinion regarding stem cell research regulation in the country? **(Scientists, Clinicians, Firms, Regulators)**
31. What is your opinion about the current guidelines of the DCGI regarding stem cell marketable product? **(Scientists, Clinicians, Firms)**
32. Do all these regulations work in practice? **(Scientists, Clinicians, Firms, Regulators)**
33. What is the role of your organisation in the development and governance of stem cell science in India? **(Regulators)**
34. What is your opinion about recently established National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT)? **(Scientists, Clinicians, Firms, Regulators)**

35. How do you co-ordinate with other government bodies, who are also involved in the governance of stem cell science in India? **(Regulators)**
36. How do you see the effort of ICMR regarding stem cell public consultations? **(Scientists, Clinicians, Firms)**
37. What were the issues which initiated public consultations regarding stem cell research? **(Regulators)**
38. How do you ensure full representation of different stakeholders in public consultations? **(Regulators)**
39. As a regulatory agency what kind of challenges you are facing? **(Regulators)**
40. There are some reports related to safety and risk of the research participants during clinical trials in general? Is there any kind of issues related to stem cell clinical trial? **(Clinicians, Firms, Regulators)**